BSD MEDICAL CORP
Form 10-K
November 06, 2009

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

FORM 10-K
(Mark One)
[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended August 31, 2009

[ ] 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: 001-32526

BSD MEDICAL CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	75-1590407
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2188 West 2200 South, Salt Lake City, Utah	84119
(Address of principal executive office)	(Zip Code)

Registrant's telephone number, including area code: (801) 972-5555

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

Title of Each Class	Name of Each Exchange on which Registered
Common Stock, Par Value $0.001	The NASDAQ Stock Market LLC

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[X]

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[X]

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes [ ] No[ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information 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 definitions 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 [X]

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of February 29, 2009 was approximately $37,128,000.

As of November 6, 2009, the registrant had 22,014,970 shares of its common stock, par value $.001, outstanding.

Documents Incorporated by Reference: Portions of the definitive Proxy Statement to be delivered to shareholders in connection with the 2010 Annual Meeting of Shareholders, which is expected to be held February 3, 2010, are incorporated by reference into Part III hereof.

BSD MEDICAL CORPORATION
FORM 10-K

For the Year Ended August 31, 2009

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PART I

ITEM 1. BUSINESS

Overview

BSD Medical Corporation (the "Company") was originally incorporated under the laws of the State of Utah on March 17, 1978. On July 3, 1986, the Company was reincorporated in the State of Delaware.

We develop, manufacture, market and service medical systems that deliver precision-focused radio frequency (RF) or microwave energy into diseased sites of the body, heating them to specified temperatures as required by a variety of medical therapies. Our business objectives are to commercialize our products developed for the treatment of cancer and to further expand our systems to treat other diseases and medical conditions. Our product line for cancer therapy has been created to offer hospitals and clinics a complete solution for thermal treatment of cancer as provided through microwave/RF systems.

While our primary developments to date have been cancer treatment systems, we also pioneered the use of microwave thermal therapy for the treatment of symptoms associated with enlarged prostate, and we are responsible for technology that has contributed to a new medical industry addressing the needs of men's health. In accordance with our strategic plan, we subsequently sold our interest in TherMatrx, Inc., the company established to commercialize our technology to treat enlarged prostate symptoms, to provide substantial funding that we can utilize for commercializing our systems used in the treatment of cancer and in achieving other business objectives.

In spite of the advances in cancer treatment technology, nearly 40% of cancer patients continue to die from the disease in the United States. Our product line includes systems that have been strategically designed to offer a range of thermal treatment systems for the treatment of cancer, including both hyperthermia and ablation treatment systems. Studies have shown that both hyperthermia and ablation treatments kill cancer but they have different clinical applications.

Our hyperthermia cancer treatment systems are used to treat cancer with heat (hyperthermia) while boosting the effectiveness of radiation through a number of biological mechanisms. Hyperthermia is usually used to increase the effectiveness of other therapies; e.g., radiation therapy and chemotherapy for the treatment of locally advanced cancers. Hyperthermia usually refers to treatments delivered at temperatures of 40-49°C for one hour.

Our microwave ablation system is to be used to ablate (remove or vaporize) soft tissue with heat alone. Thermal ablation usually refers to heat treatments delivered at temperatures above 55°C for short periods of time. Thermal ablation is used to destroy local tumors using a short intense focus of heat on a specific area, which is usually small, similar to surgical removal of the tumor.

Commercialization of our systems that are used to treat cancer is our most immediate business objective. Current and future cancer treatment sites for our systems may include cancers of the prostate, breast, head, neck, bladder, cervix, colon/rectum, ovarian, esophagus, liver, kidney, brain, bone, stomach and lung. Our cancer treatment systems have been used to treat thousands of patients throughout the world and have received many awards, including the Frost & Sullivan "Technology Innovation of the Year Award" for cancer therapy devices awarded for the development of the BSD-2000.

Although we have not entered most of these markets, we also believe that our technology has application for a number of other medical purposes in addition to cancer.

On April 22, 2008 we changed the listing of our stock from the American Stock Exchange (AMEX) to the NASDAQ Stock Market (NASDAQ), and our stock now trades under the NASDAQ symbol “BSDM.”

The Sale of TherMatrx

One of our important contributions to the advancement of medical therapy has been our pioneering work in developing a new treatment for conditions associated with enlargement of the prostate that afflicts most men as they age. As the prostate enlarges it constricts urine flow. The condition is known medically as benign prostatic hyperplasia or BPH. We developed a technology that allows men to be treated for BPH through an outpatient procedure as an alternative to surgery or a lengthy regimen of medication.

We determined early in our planning that we would treat our development of BPH therapy as a spin-off business with the intent of providing funding for our primary business objectives. We established a new company, TherMatrx, Inc., and received capital from investors to conduct clinical trials, and, after obtaining U.S. Food and Drug Administration ("FDA") approval in July 2001, the funding to commercialize the development. We were compensated for providing manufacturing, regulatory and engineering support to assure the success of the new company.

On July 15, 2004, TherMatrx, Inc. was sold to American Medical Systems Holdings, Inc. (AMS). Our part of the total proceeds from this sale was approximately 25%. A portion of the payout from the sale was based on contingency payments. We received approximately $33.7 million from the TherMatrx sale, including an additional $202,223 in April 2007. We are not currently entitled to or expect any further payments or proceeds from the sale of TherMatrx.

Our Contributions to Cancer Therapy

Despite the massive attention given to cancer prevention and treatment, the American Cancer Society estimates that 1,500,000 new cancer cases will be diagnosed and that 562,340 Americans will die from cancer during 2009. In the United States the chance of developing cancer during a person's lifetime is one in two for men and one in three for women. Cancer develops when abnormal cells in a part of the body begin to grow out of control and spread to other parts of the body.

Our cancer treatment systems have been developed to both kill cancer directly with heat and to increase the effectiveness of the primary cancer treatment used in conjunction with the heat therapy. The primary cancer therapies currently used include:

- Radiation therapy, which is treatment with high-energy rays to kill or shrink cancer cells. The radiation may come from outside of the body (external radiation) or from radioactive materials placed directly in a tumor (internal or implant radiation, sometimes called brachytherapy).
- Chemotherapy, which is treatment with drugs to destroy cancer cells.
- Surgery, which is the resection, or removal, of a tumor or organ of the body.

Some cancers, such as certain cancers of the liver, prostate, kidney, bone metastases and lung cancer, are treated using heat alone to deliver thermal ablation. For these treatments we have developed the MicroThermX Microwave Ablation System that is used to ablate soft tissues at high temperatures as a stand-alone therapy. Over 40,000 solid tumor ablation procedures were performed in the U.S. last year and approximately 140,000 procedures were performed worldwide.

The treatment of many cancers is generally prescribed with one or more of the primary cancer therapies noted above. Because cancer remains a leading cause of death, these three cancer therapies are still inadequate, and there is an enormous need for better treatment. We have engineered systems designed to increase the effectiveness of these cancer treatments through the use of precision-focused RF/microwave energy to selectively heat cancer, creating "hyperthermia" in cancerous tumors. Hyperthermia is an emerging cancer therapy that both kills cancer cells directly and has been shown to be a potent additive treatment in making certain of the major existing cancer therapies more effective for some cancers.

Hyperthermia therapy has been shown to substantially improve the results from cancer treatments for a variety of tumors. Completed randomized clinical trials compared the effectiveness of radiation therapy combined with hyperthermia therapy against the results of radiation therapy alone in cancer treatment produced the following results: For melanoma, after two years, local control (local regression or disappearance of the tumor) was 28% for the control group of patients who received radiation therapy alone versus 46% local control for the patients who received both hyperthermia and radiation therapy. For recurrent breast cancer, the complete response rate (complete disappearance of the tumor) increased from 38% for those receiving radiation therapy alone to 60% for those patients who received both hyperthermia and radiation therapy. For glioblastoma (brain cancer), the two-year survival rate for patients who received radiation therapy alone was 15%, compared to 31% survival rate two years after treatment for those who received both hyperthermia and radiation therapy. For advanced cervical cancer, the complete response rate (disappearance of the tumor) rose from 57% for patients who received radiation treatments alone to 83% for patients receiving both hyperthermia and radiation therapy. The cervical cancer data was based on the condition of patients three years after treatment. For high risk soft-tissue sarcomas, patients were 30% more likely to be alive and cancer free almost three years after starting treatment if hyperthermia was added to their chemotherapy treatment. Almost three years after starting treatment, the sarcoma patients treated with hyperthermia and chemotherapy were 42% less likely to experience a recurrence of their cancer at the same site or to die than those who were getting chemotherapy alone.

Cancerous tumors are uncontrolled growths of mutated cells that require more energy to survive than do cells of normal tissue. As cancer cells grow rapidly, they tend to outstrip their blood supply, leaving them oxygen-starved, since there is not enough blood to carry sufficient oxygen to these cells. Oxygen-starved cancer cells are resistant to radiation therapy because the destructive power of radiation therapy depends heavily on tearing apart the oxygen molecules located in cancer cells. When oxygen molecules are torn apart, they form oxygen radicals that can attack cancer cell DNA. Blood depletion also makes cancer resistant to chemotherapy, where blood transport is required to deliver the drug into the tumor. Our hyperthermia therapy systems precisely deliver microwave energy to elevate the temperature of tumors, usually between 40°C and 45°C (104°F to 113°F). The elevated temperatures draw blood to the tumor as the body's natural response to the stimulus of heat. The increased blood supply to the tumor improves delivery of drugs to tumors in chemotherapy. It also delivers more oxygen to the tumor, increasing the effectiveness of radiation therapy.

While sensitizing tumors for more effective treatment from radiation and/or chemotherapy, hyperthermia also destroys cancer cells directly through damage to the plasma membrane, the cytoskeleton and the cell nucleus, and by disrupting the stability of cellular proteins. Tumors with poor blood supply systems lack the natural cooling capacity provided by efficient blood flow in normal tissues, making them selectively susceptible to the destructive effects of hyperthermia therapy.

Hyperthermia has other therapeutic uses. It can be used to shrink tumors prior to surgery, potentially making resection easier or even possible. Research has shown hyperthermia to be an activator for some gene therapies by speeding gene production (heat mediated gene therapy). Hyperthermia may play a role in the development of new anti-tumor vaccines that are based on the production of heat shock proteins. Research has shown hyperthermia to be an angiogenesis inhibitor, which means it helps prevent cancer from inducing growth of new blood vessels to expand

its blood supply. Hyperthermia could also become a follow-up therapy for other angiogenesis inhibitors, used in the final destruction of cancer cells depleted of blood by angiogenesis inhibitor therapy. Hyperthermia has been shown to improve a patient's quality of life. Even in situations where there is no hope for survival, hyperthermia may provide benefits through alleviation of some of the side effects of cancer, including bleeding, pain and infection.

Since the founding of the Company, we have been heavily involved in developing technological advances to expand the use of hyperthermia therapy for the treatment of cancer. Our efforts have included joint work with many notable cancer research centers in the United States and Europe. In past years, funding for our research efforts has been provided by such sources as the National Institutes of Health in the United States and major European government agencies. In recent years, we have focused our efforts in perfecting the technology required to precisely deliver deep, non-invasive hyperthermia therapy for the treatment of pelvic and other deep cancers and to demonstrate effective use of deep hyperthermia through clinical trials. We believe that our BSD-2000 system has emerged from this development effort as the world's most advanced system for hyperthermia therapy.

We have developed various technologies for heating cancerous tumors, depending on their location in the body. Through our developments, cancers such as melanomas or recurrent breast cancer located near the surface of the body can be treated with superficial cancer treatment applicators and systems. Cancers that can be accessed through natural body orifices, or that are accessible through catheters inserted into the tumor as part of invasive radiation techniques (which are used to treat prostate cancer or head and neck cancer) can be treated with small, inserted antennas that we have developed to deliver focused microwave energy into the cancerous tissue. We have also developed systems to non-invasively treat cancers located deep in the body by focusing electromagnetic energy on the cancer through a cylindrical applicator that surrounds the body. This cylindrical applicator contains an array of multiple antennae that focus radio frequency energy, and therefore heat, on the tumor. Temperature levels for treatments are monitored through small temperature sensors. Some of our systems can be interfaced with magnetic resonance imaging, or MRI, so that the treatment in progress can be observed, and temperatures can be monitored through images colorized to depict gradation of temperature levels (thermography).

Our BSD-500 is used to treat cancers located near the surface of the body, or areas that can be accessed using inserted antennae. The BSD-500 comes in several versions, depending on the customer requirements. The BSD-2000 is used to non-invasively treat deep cancers. This system also comes in several versions, including models with three dimensional, or 3D, steering of electromagnetic energy, as well as the ability to be integrated with MRI.

The BSD-500 has received FDA approval. In addition, the system has gone through an extensive revision, and we have obtained FDA approval of two major FDA supplements that were necessary for commercialization.

The BSD-2000 does not currently have FDA approval except as an investigational device. On May 18, 2009, we obtained Humanitarian Use Device (HUD) designation for the BSD-2000 Hyperthermia System for use in conjunction with radiation therapy for the treatment of cervical carcinoma patients who are ineligible for chemotherapy, and we subsequently filed a Humanitarian Device Exemption (HDE) submission with the FDA. Obtaining the HUD designation and approval of the HDE are the two steps required to obtain HDE marketing approval, which requires us to demonstrate the device's safety and probable benefit in treating a disease or condition that affects fewer than 4,000 individuals in the United States per year. The HDE is still under review by the FDA. We have certified the BSD-2000 for the CE Mark required for export into certain European and non-European countries. We sought and obtained regulatory approval for the sale of the BSD-2000 in the People's Republic of China during 2005.

Our MicroThermX-100 thermal ablation system received FDA marketing clearance in September 2008 for ablation of soft tissue, but following field evaluations of the original design, we elected to pursue a more advanced Phase II ablation system before entering the market. The Phase II, or our MicroThermX-180 Microwave Ablation System (the "MTX-180"), will provide a wider range of clinical application, improved ease of use and additional revenue streams. We believe the MTX-180 has the potential to be the market leader in microwave ablation.

Most of our sales of cancer therapy systems over recent past periods have been to cancer research institutions for use in conducting clinical trials with our equipment. As a company, we continue the marketing of our commercial version of the BSD-500 and plan to market the MTX-180 in 2010. We believe obtaining FDA approval for the BSD-2000 would greatly contribute to our sales efforts by providing the additional technology required for the treatment of solid tumors located virtually anywhere in the body.

Our Products and Services

We have developed technology and products for thermal ablation and hyperthermia cancer therapy through multiple techniques, which collectively allow cancer to be treated virtually anywhere in the body:

- Thermal ablation ablates (removes or vaporizes) soft tissues at high temperatures through focused microwave energy.

- Superficial hyperthermia non-invasively treats cancerous tumors located within a few centimeters of the surface of the body, such as melanoma and recurrent breast cancer.

- Internal or interstitial hyperthermia treats tumors in combination with internal radiation therapy by inserting tiny microwave antennae that deliver hyperthermic microwave energy to tumors through the same catheters used to deliver radioactive materials, or "seeds," to tumors for radiation therapy. This technique can be employed in treating prostate cancer, breast cancer, head and neck cancer and a variety of other cancer sites.

- Deep hyperthermia non-invasively treats tumors located deep within the body, including many problematic cancer sites located in the pelvis.

MTX-180. Our MTX-180 has been developed to employ precision-guided microwave energy to ablate soft tissue. The MTX-180 is a compact, mobile system that includes a state-of-the-art computer, a microwave generator, single-patient-use disposable applicators and a proprietary thermistor-based temperature monitoring system. The delivery of microwave energy is controlled by time and power parameters set by the operator utilizing an interactive touch-screen monitor that allows the operator to quickly and easily control the treatment. The MTX-180 provides minimally invasive access to the target tissue and can be used in open surgical as well as in percutaneous ablation procedures, which will allow the MTX-180 to be used by both surgeons and interventional radiologists. The MTX-180 was developed to provide treatments as a stand-alone therapy, rather than only in combination with other therapies.

The MTX-180 represents a major part of our business plan moving forward. It introduces into our product line a disposable applicator used in each treatment, which we believe represents the potential for a significant ongoing revenue stream after the sale of the system. Our sales force is experienced in marketing to interventional radiologists and surgeons, the users of thermal ablation systems. Internationally, we expect sales will be conducted through established and new distributors located primarily in Europe and Asia.

In September 2008, the FDA granted us a 510(k) clearance to market the Phase I MTX-100, which authorizes the commercial sale of the device in the United States. At the same time that we received the 510(k) clearance for the MTX-100 System, we had already started design of a more advanced Phase II ablation system that would provide a wider range of clinical applications and improved ease of use as well as additional revenue streams. Since receipt of FDA clearance to market the MTX-100, we have devoted significant efforts to optimizing the design of the system to improve its ease of use and its medical applications. Following clinical evaluations of Phase I, we decided to postpone market entry until completion of the optimized Phase II MTX-180 design. We believe this will allow us to enter this market with an optimized system that will have a wider range of clinical applications and increased revenue streams.

Additional time will be required to complete the market-ready Phase II design, apply for applicable regulatory approvals, and finalize the manufacturing processes for the MTX-180 and the applicators. Also, final marketing and sales strategies must be completed prior to market introduction. We currently are unable to predict when these efforts will be completed and when revenues from the sale of the MTX-180 and related applicators will begin. We do not believe, however, that these revenues will begin until at least the first or second quarter of calendar year 2010, and we cannot be sure that these revenues will be consistent with our expectations.

BSD-500. Our BSD-500 systems are used to deliver either superficial hyperthermia therapy, which is non-invasive and delivered externally using antennae placed over the tumor, or interstitial hyperthermia therapy, which is delivered using antennae that are inserted into the tumor, or both. These systems include a touch screen display monitor by which the operator controls the hyperthermia treatment, computer equipment and software that controls the delivery of microwave energy to the tumor, and a generator that creates the needed microwave energy for the treatment. Additionally, the systems include a variety of applicator (radiating antennae) configurations, depending on the system. Various configurations of non-invasive applicators (antennae) are used for superficial hyperthermia treatments. For interstitial hyperthermia treatments, the system may include up to 24 small microwave heat-delivering antennae that are inserted into catheters used for internal radiation therapy (called brachytherapy).

Our primary FDA approval (described as a pre-market approval, or PMA, which is the standard FDA approval required to market Class III medical devices in the United States) for the BSD-500 is for the use of hyperthermia and radiation therapy to treat certain tumors using the BSD-500 Hyperthermia System. There are some clinical studies that have been published that show the effectiveness and safety for the use of hyperthermia and certain chemotherapy drugs for the treatment of some cancers. We do not currently have FDA approval for the use of hyperthermia in conjunction with chemotherapy, but physicians are allowed to utilize medical devices that have been approved or cleared by the FDA, including the BSD-500 Hyperthermia System, for off label indications (indications for use that are not included in the FDA approval or clearance).

We have received FDA approval through FDA supplements for implementation of a new operating system and a new power generation system and other commercial upgrades for the BSD-500 configurations. We have also certified the BSD-500 systems for the CE Mark, which is required for export into some European and non-European countries.

BSD-2000. The BSD-2000 family of products includes the BSD-2000, the BSD-2000/3D and the BSD-2000/3D/MR. These systems non-invasively deliver localized therapeutic heating (hyperthermia) to solid tumors by applying radiofrequency (RF) energy to certain cancerous tumors, including those located deep within the body. These systems consist of four major subsystems: an RF power generator delivery subsystem; a proprietary, thermistor-based, thermometry subsystem; a computerized monitoring and control subsystem; and an applicator subsystem that includes an applicator and patient support system; as well as various accessories. The BSD-2000 delivers energy to a patient using a power source and an array of multiple antennae that surround the patient's body. The BSD-2000 systems create a central focusing of energy that can be adjusted to target the 3-dimensional shape, size, and location of the tumor, thus providing dynamic control of the heating delivered to the tumor

region. The basic BSD-2000 has eight microwave antennae enabling this electronic steering of energy within the patient's body. The BSD-2000/3D has 24 microwave antennae enabling additional electronic steering along the long axis of the body. The 3D steering is particularly useful when implemented with a magnetic resonance system that is capable of non-invasive 3D imaging showing the heated regions, thus permitting the 3D steering to more accurately target the energy to the tumor site.

The BSD-2000 system has not yet received PMA from the FDA for commercial marketing in the United States, but the BSD-2000 has obtained an investigational device exemption, or IDE, for placement in the United States for research purposes only. We have also certified the BSD-2000 family for the CE Mark required for export into certain European and non-European countries and have obtained regulatory approval for the sale of the BSD-2000 in the People's Republic of China.

We have been engaged over the past three years in the extensive process of supporting an FDA submission requesting PMA for the BSD-2000 that was filed on March 28, 2006. During the PMA review process, we continued to work closely with the FDA to determine an appropriate pathway to obtain a marketing approval for the BSD-2000 utilizing the clinical data that was available to us to support a marketing approval. During this process, we submitted multiple amendments and held multiple face-to-face meetings with the FDA. As a result of the process, the FDA suggested that the HDE marketing approval process might be the most expeditious pathway for us to obtain a marketing approval. Due to the length of time that the submission had already been under review by the FDA, the significant amount of additional time required to continue to pursue the PMA, and our desire to bring the BSD-2000 to market as quickly as possible, we followed the FDA's suggestion.

On May 18, 2009, the FDA granted HUD designation for our BSD-2000 for use in conjunction with radiation therapy for the treatment of cervical carcinoma patients who are ineligible for chemotherapy. This is the first of the two steps required to obtain HDE marketing approval. Subsequent to the FDA granting the HUD for the BSD-2000, which confirms that the intended use population is fewer than 4,000 patients per year, we filed an HDE submission with the FDA. The FDA generally has 75 days from the date of receipt of the HDE submission to grant or deny an HDE application. This period includes a 30-day filing period during which the FDA determines whether the HDE application is sufficiently complete to permit substantive review. During this review, the FDA may refine the indications for use which received HUD designation to finalize the indications for use for which HDE approval will be granted. This decision will be based on the data that is available to support the device's HDE application. We believe that the data previously submitted to the FDA and reviewed by the agency in our PMA application can be used to support the HDE approval. As of the date of filing this report, the FDA continues its review of our HDE marketing submission for the BSD-2000. Although we remain optimistic that HDE marketing approval will be granted, we are unable to predict when the review process will be completed and its ultimate outcome. If we are unable to receive HDE marketing approval, or if the FDA requires us to undergo extensive testing in order to grant HDE marketing approval, our business could be adversely affected.

The PMA was placed on hold until the HUD designation was granted by the FDA. Once the HUD designation was granted and the HDE was filed, per FDA regulations, we withdrew the PMA submission. We can decide to pursue PMA for the BSD-2000 at a future date.

The HDE approval of the BSD-2000 Hyperthermia System will authorize the commercial sale of the BSD-2000 in the United States. However, there are some differences between the HDE marketing approval and PMA approval, as well as some limitations on the HDE approved devices. The HDE approval demonstrates safety and probable benefit, is intended for use in the treatment of a disease that affects fewer than 4,000 individuals in the United States per year, is only granted when no comparable device has been approved to treat the same disease population, and requires approval from an Institutional Review Board before being used in a facility. In addition, we cannot charge an amount for an HDE approved device that exceeds the costs of research and development, fabrication, and distribution. A device can have both PMA and an HDE approval as long as the approvals are for different indications for use. In addition, a product can have multiple HDE approvals for different applications, and we may decide to pursue additional HDE approvals for the BSD-2000 in the future.

Development of the BSD-2000, the BSD-2000/3D and the BSD-2000/3D/MR has required substantial effort involving the cooperative work of such United States research institutions as Duke University, Northwestern University, University of Southern California, Stanford University, University of Utah and University of Washington St. Louis. Contributing European research institutions include Daniel den Hoed Cancer Center of the Academisch Ziekenhuis (Rotterdam, Netherlands), Haukeland University Hospital (Bergen, Norway), Dusseldorf University Medical School, Tübingen University Medical School, Essen University Hospital, Charité Medical School of Humboldt University (Berlin), Luebeck University Medical School, Munich University Medical School Grosshadern, Interne Klinik Argirov of the Munich Comprehensive Cancer Center, University of Erlangen (all of Germany), University of Verona Medical Center (Italy), Graz University Medical School (Austria) and Kantonsspital Aarau (Switzerland).

BSD-2000/3D. Through research funded by the National Cancer Institute in the United States and supportive efforts by other domestic and international research institutions, we enhanced the BSD-2000 to create the new BSD-2000/3D. The BSD-2000/3D adds three-dimensional steering of deep focused energy, as opposed to the two-dimensional steering of energy available in the BSD-2000, delivering even more precise heating of the tumor. As part of our international collaborative research efforts, sophisticated treatment planning software for the BSD-2000/3D has also been developed.

We have not yet submitted to the FDA a PMA application for the BSD-2000/3D. However, we have obtained the CE Mark necessary to export the BSD-2000/3D to certain European countries and other countries requiring CE Mark certification.

BSD-2000/3D/MR. As a further enhancement of the BSD-2000/3D, we have added to it the option of concurrent magnetic resonance imaging, or MRI, used for monitoring the delivery of deep hyperthermia therapy. Using sophisticated microwave filtering and imaging software, the BSD-2000/3D/MR allows an MRI system to be interfaced with and operate simultaneously with a BSD-2000/3D. The development of MRI treatment monitoring is a significant breakthrough in the development of hyperthermic oncology primarily because it allows non-invasive “on-line” review of hyperthermic treatment progress.

We installed and tested the first BSD-2000/3D/MR system at a leading German oncological research institution, the Clinic of Medical Oncology of the Klinikum Großhadern Medical School of Ludwigs-Maximilians-Universität München, in Munich, Germany. We have since installed BSD-2000/3D/MR systems at multiple other locations.

As is the case for the BSD-2000/3D, we have not yet submitted to the FDA a PMA application for the BSD-2000/3D/MR. We can, however, market the BSD-2000/3D/MR in Europe as we have CE Mark approval for the BSD-2000/3D/MR, provided we interface the system with an MRI system that also is approved in Europe.

Marketing and Distribution

Our target customers include clinics, hospitals and institutions in which cancer is treated, located either in the United States or international markets.

To support our sales and marketing efforts in the United States, we maintain a sales and marketing organization currently consisting of eight persons. Our vice president of international sales directs our international sales and marketing efforts, which consist of relationships with distributors and other agents as well as our own direct sales efforts.

We are currently concentrating on expanding our business into international markets, which we consider to represent our greatest business opportunities.

We entered into an agreement with Dalian Orientech Co. LTD, a privately owned company, to assist us in obtaining regulatory approval for the sale of the BSD-2000 in the People's Republic of China, and thereafter to act as our distributor for the sale of the BSD-2000 in that country. We subsequently obtained Chinese regulatory approval, allowing the distributor to begin to market and sell the BSD-2000 system to hospitals in China. We believe the prospects for increased sales of our systems in China represent one of our greatest business opportunities.

Historically, a significant portion of our revenues have been derived from sales to Medizin-Technik GmbH located in Munich, Germany, which is our exclusive distributor of hyperthermia systems in Germany, Austria and Switzerland, and to certain medical institutions in Belgium and the Netherlands. Medizin Technik is owned by Dr. Gerhard W. Sennewald, one of our directors and a significant stockholder. We have also sold systems in Poland and Italy, and have conducted our own direct sales and marketing efforts in other countries in Europe, India, and Asia. We recently announced the selection of a distributor in India, the world's second most populated country, and have appointed a sales manager for Latin America whose focus will be the medical markets in Mexico, Brazil, Argentina and Chile, as well as other Latin American countries.

Third-Party Reimbursement

We view obtaining adequate third-party reimbursement arrangements as essential to achieving commercial acceptance of our hyperthermia therapy products. Our products are purchased primarily by clinics, hospitals and other medical institutions that bill various third-party payors, such as Medicare, Medicaid, other government programs and private insurance plans, for the health care services provided to their patients using our products. Additionally, managed care organizations and insurance companies directly pay for services provided to their patients. The Center for Medicare and Medicaid Services, or CMS, has established 23 billing codes that allow for third-party reimbursement and can be used for or in combination with the delivery of hyperthermia therapy, depending on the circumstances of the treatment. Appropriate codes apply to billing for superficial and interstitial hyperthermia delivered using our BSD-500 systems when used in combination with radiation therapy. Codes also have been established for providing deep hyperthermia therapy. Billing codes are available for both institutions and physicians. Even though billing codes have been established, payments must also be approved by and authorized through the various third-party payors, and third-party payors can establish varying reimbursement plans and levels that can affect hyperthermia reimbursement levels.

In November 1995, HCFA, the predecessor agency to CMS, authorized Medicare reimbursement of costs for all investigational therapies and devices for which underlying questions of safety and effectiveness of that device type have been resolved, based on categorization by the FDA. Our BSD-2000 system, which has been given IDE status by the FDA, has been placed in this category by the FDA, and thus may be reimbursed by Medicare.

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Medical reimbursement rates are unpredictable, and we cannot project the extent to which our business may be affected by future legislative and regulatory developments. There can be no assurance that future health care legislation or regulation will not have a material adverse effect on BSD's business, financial condition and results of operations, or that reimbursement, existing or in the future, will be adequate for all customers.

Competition

Competition in the medical products industry is intense. We believe that established product lines and cancer therapies, FDA approvals, know-how and reputation in the industry are key competitive factors. Currently, only a few companies besides BSD have received FDA approval to manufacture and sell hyperthermia therapy systems within the United States, including U.S. Labthermics and Celsion Corporation. Celsion has been principally involved with clinical trials related to thermotherapy, hyperthermia and related fields, however Celsion has announced the transformation of its company from a medical device company to a biopharmaceutical, solely focused on the development of drugs for the treatment of cancer. Labthermics produces ultrasound-based systems, which compete with our microwave hyperthermia systems; however Labthermics is not currently active in the sale of products in our industry. Several other companies have received IDEs in the United States or other international clearance for certain experimental hyperthermia systems designed to treat both malignant and benign diseases. Additionally, other companies, particularly established companies that currently manufacture and sell other cancer therapy systems, could potentially become competitors (in that they are also engaged in cancer treatment businesses), and they have significantly greater resources than we do.

Competitors in the thermal ablation market include RadioTherapeutics, a division of Boston Scientific Corporation, Covidien Ltd., Angiodynamics, Inc. and Microsulis Medical Ltd.

Product Service

We generally provide a 12-month warranty and record a liability for the warranty following installation on all cancer treatment systems and a 90-day limited warranty on individual components. We install and service the hyperthermia systems we sell to domestic customers. In addition, we or our consultants provide technical and clinical training to our customers. Subsequent to the applicable warranty period, we offer our domestic customers full or limited service contracts.

Generally, our distributors install and service systems sold to foreign customers and are responsible for managing their own warranty programs for their customers, including labor and travel expenses. We provide warranties for the replacement and/or repair of parts for 12 months for systems sold internationally through distribu