

BSD MEDICAL CORP  
Form 10-K  
November 14, 2011

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended August 31, 2011

☐ 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

(State or other jurisdiction of incorporation or organization)

75-1590407

(I.R.S. Employer Identification No.)

2188 West 2200 South, Salt Lake City, Utah  
(Address of principal executive office)

84119  
(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

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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 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 Smaller reporting company ☐  
a smaller reporting company)

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of February 28, 2011 was approximately \$99,532,000.

As of November 14, 2011, the registrant had 29,661,823 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 2012 Annual Meeting of Shareholders, which is expected to be held February 2, 2012, are incorporated by reference into Part III hereof.

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BSD MEDICAL CORPORATION  
FORM 10-K

For the Year Ended August 31, 2011

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## PART I

### ITEM 1. BUSINESS

#### Overview

BSD Medical Corporation (the “Company” or “BSD”) 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 systems to treat cancer and benign diseases using heat therapy delivered using focused radiofrequency (RF) and microwave energy. Our business objectives are to commercialize our products for the treatment of cancer and to further expand our products 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 using 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. We utilized that funding to commercialize our systems used in the treatment of cancer and to achieve 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 ablation and hyperthermia treatment systems. Studies have shown that both ablation and hyperthermia treatments kill cancer, but they have different clinical applications.

Our microwave ablation system is used to ablate (destroy) 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.

Our hyperthermia cancer treatment systems are used to treat cancer with heat (hyperthermia) while boosting the effectiveness of radiation for certain tumors 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.

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, ovaries, 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, which was awarded in 2005 for the development of the BSD-2000 Hyperthermia System.

Although we have not yet taken advantage of many of these market opportunities, we believe that our technology has application for a number of other medical purposes in addition to cancer.



Through August 31, 2011, most of our operating revenues have been from the sale of our hyperthermia cancer systems and related revenues. In addition to revenues from the sale of ablation and hyperthermia treatment systems, we recognize revenue from the sale of parts and accessories related to our systems, the sale of consumable devices used with certain of our systems, training, service contracts, and other miscellaneous revenues. System and product sales totaled \$2,581,275, \$1,261,490 and \$3,293,116 for the years ended August 31, 2011, 2010 and 2009, respectively. Equipment rental income was \$110,207 for the year ended August 31, 2011. Sales of consumable devices, service and other revenues totaled \$345,993, \$320,786 and \$243,371 for the years ended August 31, 2011, 2010 and 2009, respectively.

Our common stock trades on the NASDAQ Stock Market (NASDAQ) under the symbol “BSDM.”

### Our Contributions to Cancer Therapy

Despite the massive attention given to cancer prevention and treatment, the American Cancer Society estimates that during 2011 approximately 1,597,000 new cancer cases will be diagnosed and that approximately 572,000 Americans will die from cancer. 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 treatments used in conjunction with the heat therapy. Therapies currently used to treat cancer include:

- Radiation therapy, which is treatment with high-energy ionizing rays. The radiation may come from outside of the body (external radiation) or from radioactive materials placed directly in a tumor (internal or implanted radiation sources, sometimes called brachytherapy).
- Chemotherapy, which is treatment with drugs.
- Surgery, which is the resection, or removal, of a tumor or organ of the body.
- Ablation, which is the use of precision-guided energy to ablate (destroy) soft tissue. Some cancers, such as certain cancers of the liver, prostate, kidney, bone metastases and lung are treated using ablation as an alternative to surgery.

Because cancer remains a leading cause of death, the current primary cancer therapies are still inadequate, and there is a need for better treatments. 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 a 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 has been shown to be a significant potentiator of other therapies. Clinical studies have demonstrated that hyperthermia can more than double the efficacy of radiation therapy in select tumors, without an increase in toxicity, and can enhance the efficacy of a number of chemotherapeutic agents, providing a safe and efficacious treatment for many types of solid tumors. Published data from 18 randomized trials on hyperthermia demonstrated significantly better results from hyperthermia combined with radiotherapy (n=13), chemotherapy (n=3), and radiotherapy plus chemotherapy (n=2), compared to the same treatment without hyperthermia.



A meta-analysis was published that included all published, randomized studies that compared hyperthermia and radiation therapy to radiation therapy alone. The analysis involved 23 studies of 1,861 patients. Results of this meta-analysis showed a significant improvement in outcome from the addition of hyperthermia to radiotherapy for a number of tumor sites; i.e., chest wall, cervix, rectum, bladder, melanoma, and head and neck, to a high degree of statistical significance. 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. High risk soft-tissue sarcoma 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. Median disease-free survival was 32 months in the hyperthermia and chemotherapy group vs. 17 months in the chemotherapy only group. 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 (hypoxic), 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 deliver microwave energy to elevate the temperature of tumors, usually between 40°C and 45°C (104°F to 113°F). Hyperthermia kills cells in solid tumors, without damaging normal tissues, because higher temperatures selectively destroy cells that are hypoxic and have low pH, a condition of tumor cells and not a condition of normal cells. 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. The basis for the supra-additive effect of hyperthermia on radiotherapy comes from the ability of hyperthermia to kill cells that are hypoxic, have a low pH, and are in the S-phase of division, which are all conditions that make cells radioresistant. The elevated temperatures draw blood to the tumor as the body's natural response to the stimulus of heat, leading to higher oxygen concentration. These effects on blood flow and tumor oxygenation make the cancer cells more susceptible to other anti-cancer therapies. The increased blood supply to the tumor improves delivery of drugs to tumors in 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.

Hyperthermia can have other therapeutic uses. Clinical studies have shown that hyperthermia can be used to shrink tumors prior to surgery, potentially making resection easier or even possible. Research has shown hyperthermia can 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 may be an angiogenesis inhibitor, which means it helps prevent cancer from inducing growth of new blood vessels to expand its blood supply. Hyperthermia may 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.

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 a world leader 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 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 directly 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 target 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 Hyperthermia System ("BSD-500") is used to treat certain 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 Hyperthermia System ("BSD-2000") is used to non-invasively treat certain 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 magnetic resonance imaging, or MRI.

The BSD-500 has received U.S. Food and Drug Administration ("FDA") approval for the treatment of certain tumors. In addition, the system has gone through an extensive revision, and we have obtained FDA approval of two major supplements that were necessary for commercialization. We have certified the BSD-500 for the CE (Conformite Europeenne) Mark required for export into certain European and non-European countries.

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 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 Phase I MicroThermX® Microwave Ablation System (“MicroThermX®”) thermal ablation system received FDA marketing clearance in September 2008 for ablation of soft tissue. Following field evaluations of the original design, we elected to pursue a more advanced Phase II ablation system before entering the market. The more advanced Phase II design of our MicroThermX® provides superior performance, improved ease of use and, we expect, additional revenue streams. The MicroThermX® was designed to provide a higher power, optimized system targeted to the growing therapeutic interventional and surgical oncology market. We believe the MicroThermX® has the potential to be a market leader in microwave ablation. Our Phase II MicroThermX® received FDA marketing clearance in August 2010 for ablation of soft tissue. We have certified the MicroThermX® for the CE Mark required for export into certain European and non-European countries.

#### Our Products and Services

We have developed technology and products for thermal ablation and hyperthermia cancer therapy through multiple techniques:

- Thermal ablation ablates (destroys) 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 as well as other cancer sites.
- Deep hyperthermia non-invasively treats tumors located deep within the body.

**MicroThermX® Microwave Ablation System.** Our MicroThermX® is a compact, mobile, state-of-the-art, proprietary system that includes a microwave generator, single-patient-use disposable antennas, and a thermistor-based temperature monitoring system. The innovative design of the MicroThermX® is the first of its kind that allows delivery of higher power levels using a single generator. The MicroThermX® utilizes innovative synchronous phased array technology that was developed and patented by us to provide larger and more uniform zones of ablation during a single procedure. The MicroThermX® introduces into our product line an innovative disposable antenna that is used in each ablation treatment, which we believe will provide a significant ongoing revenue stream after the sale of the system. The soft tissue ablation world market potential is estimated to exceed \$2.3 billion.

In August 2010, the FDA granted us a 510(k) clearance to market the MicroThermX® for ablation of soft tissue. Clearance from the FDA of the 510(k) Premarket Notification submission authorizes the commercial sale of the MicroThermX® in the United States. We have also received CE Marking for the MicroThermX®, which allows us to market the MicroThermX® in the thirty countries that comprise the European Union (“EU”) and the European Free Trade Association (“EFTA”). CE Marking is also recognized in many countries outside of the EU, providing us the ability to market the MicroThermX® to a number of international markets.

After increasing production capacity, completing placement of systems in key hospitals, and witnessing early clinical successes, we have signed geographically exclusive distribution agreements for the MicroThermX® product line with four domestic specialty distribution firms. This accomplishes our early market launch objectives and strategic initiative to capitalize on the large ablation market by establishing an exclusive, specialty distribution network that will provide nationwide sales coverage for the MicroThermX® line of products. Distributors have been selected based on their sales record, their synergistic product mix, and their focus in the field of interventional

oncology/radiology, the target market for our ablation product line.

To support the global distribution network for the MicroThermX® product line, we have increased our marketing and sales staff, including additional Regional Sales Management and an International Sales Director. We believe that increasing MicroThermX® marketing and sales resources to support our existing management team is key to making the strategic decision to utilize specialty distribution firms a success. Additional marketing and sales resources will provide hands-on field training and management of the distribution network. We further believe the sales and distribution network that is now in place will ensure that trained sales representatives are presenting the advantages of the MicroThermX® to interventional oncologists throughout the United States.

The increased sales activity has resulted in a full schedule of clinical evaluations. These evaluations represent an important milestone in the MicroThermX® sales cycle, with hospital capital budgeting, committee review and other approvals required to complete the sales cycle. The evaluations have led to an increase in the number of sites that may decide to purchase equipment following clinical evaluations.

We have met with over forty international distribution firms and have started contract negotiations with select European based firms. We are currently visiting the headquarters of these specialty distribution firms to finalize contract negotiations and begin training of international distributor sales representatives. In January 2011, we announced the sale and shipment of the first MicroThermX® to one of the largest interventional radiology/oncology distributors in Italy, and we anticipate additional international shipments of the MicroThermX® and supplies of disposable antennas early in calendar year 2012.

The medical facilities where we initially placed MicroThermX® systems continue to reorder disposable microwave antennas, providing early validation of the potential ongoing revenue stream we anticipate. In addition, existing users of the MicroThermX® are reporting positive clinical results in the treatment of tumors.

Our Italian distributor continues to report more cases performed with the MicroThermX®, with equally good clinical results. The distributor is co-sponsoring with us clinical trials that are anticipated to start in the first quarter of 2012.

**BSD-500.** Our BSD-500 Hyperthermia System, or the BSD-500, is 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. 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. However, we do not currently have FDA approval for the use of hyperthermia in conjunction with chemotherapy. Physicians are allowed to utilize medical devices that have been approved or cleared by the FDA, including the BSD-500, for off label indications (indications for use that are not included in the FDA approval or clearance), but a manufacturer cannot promote for an off label use in the United States, as the FDA considers this to be an unproven clinical application.



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 Hyperthermia System, or 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 clinician to view the heating pattern in the tumor and steer the energy to the tumor site.

The BSD-2000 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.

In March 2006, we filed an FDA submission requesting PMA for the BSD-2000. During the PMA review process, we worked 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 marketing approval. During this process, the FDA suggested that the HDE marketing approval process might be the most expeditious pathway for us to obtain marketing approval.

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. As of the date of filing this report, the FDA continues its review of our HDE marketing submission for the BSD-2000. 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 might 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 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 BSD-2000/3D. The BSD-2000/3D adds three-dimensional steering of deep focused energy, enabling additional electronic steering along the long axis of the body. 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 marketing 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 marketing 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.

**Hyperthermia Systems.** To support our direct sales and marketing efforts for our hyperthermia systems and products in the United States, we currently utilize independent sales representatives supported by senior management of the Company.

Historically, a significant portion of our revenues have been derived from sales to Dr. Sennewald Medizintechnik 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. This company 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.

In 2005, we entered into an agreement with Dalian Orientech Co. LTD (“Orientech”), 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 currently are negotiating a new distribution agreement with Orientech and Orientech is leading efforts to renew our Chinese regulatory approval.

**MicroThermX® Microwave Ablation System.** As previously discussed, we have signed geographically exclusive distribution agreements for the MicroThermX® product line with four domestic specialty distribution firms. Along with our Regional Sales Managers, who conduct direct sales efforts in certain defined geographical areas, we expect this exclusive, specialty distribution network to provide nationwide sales coverage for the MicroThermX® line of products.

We have one distributor in Italy, and have met with several international distribution firms. We have started contract negotiations with select European based firms, and have recently hired an International Sales Director.

## Third-Party Reimbursement

We view obtaining adequate third-party reimbursement arrangements as essential to achieving commercial acceptance of our hyperthermia and ablation 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 (CMS), has established billing codes that allow for third-party reimbursement and can be used for or in combination with the delivery of hyperthermia and ablation therapies, 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. Appropriate codes apply to billing for certain ablation procedures. 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 and ablation 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.

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

We have presented what we believe are our competitive advantages in the discussion of our products above.

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 clearances 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., NeuWave Medical, MedWaves Incorporated, and Microsulis Medical Ltd. Many of these companies have been in the thermal ablation business for several years, are significantly larger organizations, and have more financial resources than the Company.

### Product Service

We generally provide a 12-month warranty and record a liability for the warranty following installation on all hyperthermia 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 hyperthermia 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 distributors and for 90 days for individual components. Spare parts are generally purchased by the distributors and stored at the distributors' maintenance facilities to allow prompt repair. Distributor service personnel are usually trained at customer sites and at our facilities in Salt Lake City, Utah.



## Production

We manufacture and test our systems and products at our facilities in Salt Lake City, Utah. Our manufacturing facility is ISO 13485:2003 certified and follows FDA quality systems regulations. Some equipment components we purchase from suppliers are customized to our specifications. Key factors in our manufacturing process are assembly and testing. We purchase component parts and other materials from a variety of suppliers. We do not depend on a single supplier for any item, and believe we can acquire materials and parts from multiple sources on a timely basis.

## Product Liability Exposure

The manufacturing and marketing of medical devices involves an inherent risk of product liability. We presently carry product liability insurance with coverage limits of \$5 million. However, we cannot assure that our product liability insurance will provide adequate coverage against potential claims that might be made against us. No product liability claims are presently pending against us; however, we cannot assume that product liability claims will not be filed in the future or that such claims will not exceed our coverage limits.

## Government Regulation

The medical devices that we have developed and are developing are subject to extensive and rigorous regulation by numerous governmental authorities, principally by the FDA, and comparable foreign agencies. Pursuant to the Federal Food, Drug and Cosmetic Act, as amended, the FDA regulates and must approve the clinical testing, manufacture, labeling, distribution, and promotion of medical devices in the United States.

Although our MicroThermX® has received FDA marketing clearance as a 510(k) submission, most of our hyperthermia treatment systems, including the BSD-500 and the BSD-2000 and related products, have required or require PMA or an HDE marketing approval from the FDA instead of the simpler 510(k) clearance. PMA or HDE approval requires that we demonstrate that the medical device is safe and effective or safe with a probable benefit. To do this, we conduct either laboratory and/or clinical testing. FDA approval must be obtained before commercial distribution of the product. We intend to continue to make improvements in and to our existing products. Significant product changes for PMA or HDE approved devices must be submitted to the FDA under investigational device exemptions, or IDEs, or under PMA or HDE supplements. As described in the above section entitled "Our Products and Services", we have obtained a PMA for our BSD-500 system and IDE status for our BSD-2000 system. Significant changes to the MicroThermX® may require a new 510(k). A PMA submission was made to the FDA for the BSD-2000 in March 2006. Due to the lengthy nature of the PMA review process and the length of time that the submission was under review by the FDA, we worked closely with the FDA to seek the most expeditious pathway that could lead to marketing approval for the BSD-2000. The FDA recommended that BSD pursue HDE marketing approval rather than continue to pursue the PMA approval and BSD followed the FDA's recommendation.

On May 18, 2009, the FDA granted HUD designation for the 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, 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. We subsequently filed an HDE submission with the FDA, which is the final step required to obtain HDE marketing approval. The HDE is still under review by the FDA. The HDE approval of the BSD-2000 would authorize the commercial sale of the BSD-2000 in the United States.

Foreign countries, in which our products are or may be sold, have regulatory requirements that can vary widely from country to country. Sales into the European Union, or EU, require compliance with the Medical Devices Directive, or MDD, and require us to obtain the necessary certifications to have a CE Mark affixed to our products. We have obtained necessary ISO certification of our quality, development, and manufacturing processes, and we have successfully completed the CE Mark testing and Annex II audit. However, we must maintain compliance with all current and future directives and requirements to maintain ISO certification and to continue to affix the CE Mark, and there can be no assurance that we will continue to maintain compliance with regulatory requirements imposed on us.

After we receive FDA approval to market a medical device, we continue to have ongoing responsibilities under the Federal Food, Drug, and Cosmetic Act and FDA regulations. The FDA reviews design and manufacturing practices, labeling, record-keeping, and required reporting of adverse experiences. All medical devices must be manufactured in accordance with regulations specified in the FDA Quality System Regulations, or QSR, and in compliance with the ISO and other applicable standards. In complying with these regulations, we must continue to expend time, money and effort in the areas of design control, production, and quality control to ensure full compliance. The FDA's mandatory Medical Device Reporting regulation requires us to provide information to the FDA on death or serious injuries alleged to have been associated with the use of our products, as well as information on product malfunctions that would likely cause or contribute to a death or serious injury if the malfunctions were to recur. In Europe, the MDD vigilance system regulations require that we, through a representative in Europe, provide information to authorities on death or serious injuries alleged to have been associated with the use of our products, as well as information on product malfunctions that would likely cause or contribute to a death or serious injury if the malfunctions were to recur. If the FDA were to assert that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable risk to patient health, the FDA could seize our medical devices, ban such medical devices, or order a recall, repair, replacement or refund of such devices, and require us to notify health care professionals and others that the devices present unreasonable risk of substantial harm to the public. The FDA may also impose operating restrictions and assess civil or criminal penalties against us. The FDA can also recommend prosecution to the Department of Justice. Certain regulations are subject to administrative interpretation and we cannot assure that future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us.

International sales of medical devices are subject to FDA export requirements. We have obtained export approvals for all countries into which we have delivered products. This includes countries in Western Europe and much of Eastern Europe and many Asian countries.

International sales are subject to the regulatory and safety requirements of the country into which the sale occurs. There can be no assurance that all of the necessary approvals will be granted on a timely basis or at all. Delays in receipt of or failure to receive such approvals would have a material adverse effect on our financial condition and results of operations.

In addition to FDA regulations, certain U.S. health care laws apply when a claim for reimbursement for one of our medical devices is submitted to Medicare, Medicaid, or other federal health care programs. For instance, federal law prohibits the filing of false or improper claims for federal payments. In addition, federal law prohibits the payment of anything of value for the purpose of inducing referrals of business reimbursable under a federal health care program. Other federal laws prohibit physicians from making referrals for certain services and items payable under certain federal programs if the physician has a financial relationship with the entity providing the service or item.

All of these laws are subject to evolving interpretations. If the federal government were to conclude that we are not in compliance with any of these health care laws, we could be subject to substantial criminal and civil penalties, and could be excluded from participation as a supplier to beneficiaries in federal health care programs.

The Federal Communications Commission, or FCC, regulates the frequencies of microwave and radio frequency emissions from medical and other types of equipment to prevent interference with commercial and governmental communications networks. The BSD-500 fixed frequency systems and applicators and the MicroThermX® ablation system and applicators emit 915 MHz, which is approved by the FCC for medical applications. Accordingly, these systems do not require shielding to prevent interference with communications. Our BSD-2000 deep hyperthermia variable-frequency generators and applicators require electromagnetic shielding.

#### Patents, Licenses, and Other Rights

Because of the substantial length of time and expense associated with bringing new products through development and regulatory approval to the marketplace, the medical device industry places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our policy is to file patent applications to protect significant technology, inventions and product improvements. We currently own three patents in the United States related to certain components or technology of our hyperthermia systems. We currently have one patent license from Duke University. Eleven new U.S. patent applications are pending and have been published in the United States, and one foreign patent is issued and others are pending. A total of 23 U.S. patents have been issued to BSD. We believe that our patents represent the early pioneering and dominant patents in this field.

In July 1979, we entered into an exclusive worldwide license for a unique temperature probe (sensor) called the Bowman Probe. The Bowman Probe is considered to be the “gold standard” in temperature monitoring devices for hyperthermia. The license will remain in effect as long as the technology does not become publicly known as a result of actions taken by the licensor. We pay royalties based upon our sales of the Bowman Probe. The license agreement was amended and renewed in August 2000 and is currently in effect.

On July 31, 2007, BSD obtained an exclusive sub-license to a patent owned by Duke University using phased array technology for the treatment of primary breast cancer on terms that included hyperthermia equipment upgrades and payment of some prior patent costs. This technology and patent is expected to enhance future developments with the current BSD phased array hyperthermia systems.

On July 1, 2001, we acquired the rights to all FDA approvals and the rights to manufacture all cancer products formerly owned by Clini-Therm Corp. These products are related to the hyperthermia therapy delivered by our BSD-500 systems and our enhancements to such systems involve incorporating some of the Clini-Therm rights we acquired into such systems. This involved only a one-time cash payment with no continuing costs.

We cannot assure that the patents presently issued to us will be of significant value to us in the future or will be held valid upon judicial review. Successful litigation against these patents by a competitor would have a material adverse effect upon our business, financial condition and results of operations. We believe that we possess significant proprietary know-how in our hardware and software capabilities. However, we cannot assure that others will not develop, acquire or patent technologies similar to ours or that such secrecy will not be breached.



## Research and Development

Research and development expenses for fiscal years 2011, 2010 and 2009 were \$1,483,659, \$2,429, 215 and \$2,043,268, respectively. Our research and development expenses for the year ended August 31, 2011 have been partially offset by the \$488,958 proceeds from two separate U.S. government grants under the Qualifying Therapeutic Discovery Project (“QTDP”) Program received in our first fiscal quarter ended November 30, 2010. In addition to the offset of the QTDP grants, research and development expenses decreased in the current fiscal year primarily from the shift from product development activities to sales and marketing efforts for the MicroThermX® product line, and due to our operating expense reduction measures.

We submitted QTDP grant applications for our BSD-2000 Hyperthermia System and our MicroThermX® Microwave Ablation System and both applications were approved for the maximum award for a single program of \$244,479, or a total of \$488,958. In order to qualify for the QTDP grants, the project must have the potential to develop new treatments that address “unmet medical needs” or chronic and acute diseases; reduce long-term health care costs; represent a significant advance in finding a cure for cancer; advance U.S. competitiveness in the fields of life, biological, and medical sciences; or create or sustain well-paying jobs, either directly or indirectly. The QTDP was created by Congress in March 2010 as part of the Patient Protection and Affordable Care Act and provides a tax credit or a grant equal to 50% of eligible costs and expenses for tax years 2009 and 2010.

We continue our efforts to enhance our current hyperthermia and ablation products and to develop new products related to the following:

- development of various commercial configurations of the BSD-2000/3D/MR to adapt to both Siemens and GE MR configurations;
- updating our BSD-500 and BSD-2000 system designs for both reduced cost and improved manufacturability;
  - making enhancements to the BSD-500 and 2000 systems;
  - incorporating new requirements into the design and manufacturing processes;
  - finalizing design and testing of the MicroThermX® Microwave Ablation System;
  - establishing and validating commercial manufacturing of the MicroThermX®;
- supporting BSD-2000, BSD-2000/3D and BSD-2000/3D/MR CE Marking approval efforts
  - supporting MicroThermX® CE marking approval efforts;
  - supporting product approvals for non-US governments;
- designing and testing of new advanced cooled disposable microwave ablation applicators;
  - supporting BSD-2000 FDA approval efforts;
  - R&D projects not publically disclosed.

Technological changes play an important part in the advancement of our industry. We intend to continue to devote substantial sums to research and development. Research and development efforts inherently involve costs, risks and

uncertainties that could adversely affect our projections, outlook and operating results.

### Seasonality

Our operations are generally not subject to seasonal fluctuations.

### Segment Information and Sales Concentrations

We consider our operations to comprise one business segment. All of our operating assets are located in the United States.

A significant portion of our revenues are derived from sales to Dr. Sennewald Medizintechnik GmbH located in Munich, Germany, which is a significant distributor of our products in Europe and which is owned by Dr. Gerhard W. Sennewald, one of our directors and a significant stockholder. For fiscal year 2011 we had sales of \$1,063,495, or 35% of our total sales, from the sale of hyperthermia systems and various component parts sold to Medizintechnik, as compared to sales of \$309,259, or 20% of our total sales, in fiscal 2010. Management believes the terms of the transactions with Medizintechnik were arms length and fair to the Company.

A significant portion of our revenues are derived from sales to foreign customers. During the years ended August 31, 2011, 2010 and 2009, export sales totaled \$1,135,372, \$678,893 and \$1,668,547, or 37%, 43% and 47% of total sales, respectively. During fiscal year 2011, export sales to Germany were approximately 35% of total sales. During fiscal year 2010, export sales to China and Germany were approximately 23% and 12% of total sales, respectively. During fiscal year 2009, export sales to China, Switzerland and Poland were approximately 16%, 13% and 14% of total sales, respectively.

During the years ended August 31, 2011, 2010 and 2009, domestic sales totaled \$1,902,103, \$903,383 and \$1,867,940, or 63%, 57% and 53%, respectively.

In addition, because of the small number of hyperthermia systems sold each year, each customer may be considered significant.

### Backlog

As of August 31, 2011, we had no sales backlog. However, subsequent to August 31, 2011 through November 14, 2011, we have received purchase orders for hyperthermia systems totaling approximately \$520,000. The timing of reporting the sales for purchase orders will depend on the delivery of the systems to the customers and other revenue recognition criteria.

### Employees

As of August 31, 2011, we had 41 employees; 39 of whom were full-time employees. None of our employees are covered by a collective bargaining agreement. We consider our relations with our employees to be satisfactory. We depend upon a limited number of key management, manufacturing, and technical personnel. Our future success will depend in part on our ability to retain these highly qualified employees.

## Available Information

We file annual, quarterly and current reports, and other reports and documents with the Securities and Exchange Commission (the "SEC"). The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is <http://www.sec.gov>.

The Company's Internet address is <http://www.bsdmedical.com>. We make available on or through our investor link on our website, free of charge, our Annual Reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports as soon as reasonably practicable after this material is electronically filed or furnished to the SEC.

## ITEM 1A. RISK FACTORS

Our future operating results are highly uncertain. Before deciding to invest in BSD or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this annual report on Form 10-K. If any of these risks actually occur, our business, financial condition or results of operations could be seriously harmed. In that event, the market price for our common stock could decline and you may lose all or part of your investment. Although the Company has attempted to list the factors of which it is currently aware that may have an impact on its operations, there may be other factors of which the Company is currently unaware or to which it does not assign sufficient significance, and the following list should not be considered comprehensive.

We have a history of significant operating losses and such losses may continue in the future.

Since our inception in 1978, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of \$29,416,587 at August 31, 2011. We reported net losses of \$5,285,517, \$7,456,948 and \$11,384,870 in fiscal years 2011, 2010 and 2009, respectively.

We may continue to incur operating losses in the future as we continue to incur costs to develop our products, protect our intellectual property and expand our sales and marketing activities. To become profitable we will need to increase significantly the revenues we receive from sales of our hyperthermia systems and to successfully commercialize our MicroThermX® to improve our profitability on a quarterly or annual basis. We have been unable to do this in the past and we may be unable to do so in the future, and therefore may never achieve profitability.

Adverse worldwide economic conditions have made it difficult for our customers to obtain approval for the purchase of and funding for our hyperthermia systems.

Our hyperthermia cancer treatment systems represent capital equipment purchases for our customers. Adverse worldwide economic conditions have made it difficult for our customers to obtain approval for the purchase of and funding for our hyperthermia systems. This has contributed to a lack of growth in the worldwide sales of our systems. To the extent that adverse economic conditions continue, we believe our sales of hyperthermia systems will continue to be negatively impacted.



Our revenues can fluctuate significantly from period to period because our sales to date have been based upon a relatively small number of systems, the sales price of each being substantial enough to greatly impact revenue levels in the periods in which they occur.

Our revenues can fluctuate significantly from period to period because our sales, to date, have been based upon a relatively small number of hyperthermia systems, the sales price of each being substantial enough to greatly impact revenue levels in the periods in which they occur. Sales of a few systems, particularly BSD-2000/3D/MR systems, can cause a large change in our revenues from period to period and the sales cycle for our systems generally extends over multiple financial reporting periods. In addition, differences in the configuration of the systems sold, pricing, and other factors can result in significant differences in the sales price per system and in the total revenues reported in a given period. As a result, there may be quarterly financial reporting periods where we may report no or minimal revenues from the sale of hyperthermia systems.

A significant portion of our revenues have been from related parties, and we have had significant concentrations of revenues in foreign countries.

During the years ended August 31, 2011, 2010, and 2009, we had sales of \$1,063,495, \$309,259 and \$603,000, respectively, to entities controlled by a significant stockholder and member of our Board of Directors. These related party transactions represent approximately 35%, 20% and 17% of total sales for each respective year.

A significant portion of our revenues are derived from sales to foreign customers. During fiscal year 2011, export sales to Germany were approximately 35% total sales. During fiscal year 2010, export sales to China and Germany were approximately 23% and 12% of total sales, respectively. During fiscal year 2009, export sales to China, Switzerland and Poland were approximately 16%, 13% and 14% of total sales, respectively.

To the extent that we are unable to maintain or increase the level of our revenues derived from related parties or foreign customers, the results of our operations could be negatively impacted.

We have obtained FDA clearance to market our MicroThermX® Microwave Ablation System, and recently completed nationwide sales coverage for the MicroThermX® family of products. We cannot be assured that our efforts to commercialize the MicroThermX® will be successful.

In August 2010, the FDA granted us a 510(k) clearance to market our MicroThermX® Microwave Ablation System for ablation of soft tissue, authorizing the commercial sale of the MicroThermX® in the United States. Our MicroThermX® represents a major part of our business plan moving forward and introduces into our product line an innovative, high-end disposable that is used in each ablation treatment and which we believe will provide a significant ongoing revenue stream.

In June 2011, we completed nationwide sales coverage for the MicroThermX® line of products through signing exclusive agreements with four leading specialty distributors and hiring additional regional sales management. In addition, we have placed a select number of MicroThermX® systems with pivotal, high-profile, interventional oncology key opinion leaders. This increased sales activity has resulted in a full schedule of clinical evaluations and an increase in the number of sites that may decide to purchase equipment following clinical evaluations. However, we believe the sales cycle for the MicroThermX® may extend up to six months, and we currently are unable to predict when significant revenues from the sale of the MicroThermX® and related antennas will begin. We cannot be assured that our efforts to commercialize the MicroThermX® will be successful. If our efforts to commercialize the MicroThermX® are not successful, our business will be adversely affected.



International sales of our MicroThermX® family of products depend on our ability to successfully establish our international sales distribution channels.

With our United States sales and distribution network in place for our MicroThermX® family of products, we are placing significant emphasis on Europe and other international markets. We recently hired an International Sales Manager, have met with several international distribution firms and have started contract negotiations with select European based firms. International sales of our MicroThermX® family of products will depend on our ability to successfully establish sales distribution channels in Europe and other international markets. If these efforts are not successful, our business will be adversely affected.

Our hyperthermia therapy products may not achieve market acceptance, which could limit our future revenue and ability to achieve profitability.

To date, hyperthermia therapy has not gained wide acceptance by cancer-treating physicians. We believe this is due in part to the lingering impression created by the inability of early hyperthermia therapy technologies to focus and control heat directed at specific tissue locations as well as inaccurate conclusions drawn in early scientific studies that hyperthermia was only marginally effective. Additionally, market acceptance depends upon physicians and hospitals obtaining adequate reimbursement rates from third-party payors to make our products commercially viable, and we believe that reimbursement rates have not been adequate to stimulate strong interest in adopting hyperthermia as a new cancer therapy. If our sales and marketing efforts to promote hyperthermia therapy acceptance in the medical community fail, or our efforts to improve third-party reimbursement rates for hyperthermia therapy are not successful, then our future revenue from sales of our products may be limited, and we may never be able to obtain profitable recurring operations.

Sales of our products could be significantly reduced if government, private health insurers and other third-party payors do not provide sufficient coverage or reimbursement.

Our success in selling our products will depend in large part on the extent to which reimbursement for the costs of our products and related treatments are available from government health agencies, private health insurers and other third-party payors. Despite the existence of general reimbursement policies, local medical review policies may differ for public and private insurance payers, which may cause payment to be refused for some hyperthermia treatments. Private payers also may refuse to pay for hyperthermia treatments.

Medical reimbursement rates are unpredictable and we cannot predict the extent to which our business may be affected by future legislative and regulatory developments. Future health care legislation or regulation may limit our business or impose additional delays and costs on our business and third-party reimbursement may not be adequate to cover our costs associated with producing and selling our products.

Cancer therapy is subject to rapid technological change and therapies that are more effective than ours could render our technology obsolete.

The treatment of cancer is currently subject to extensive research and development. Many cancer therapies are being researched and our products may be rendered obsolete by existing therapies and as a result of therapy innovations by others. If our products are rendered obsolete, our revenue will decline, we may never achieve profitability, and we may not be able to continue in business.

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 the cancer treatment business), and they have significantly greater resources than we do.





Increasing sales of our hyperthermia systems depends on our ability to successfully expand our sales distribution channels; however, we have had failures with the productivity of new channels of distribution in the past. Expanding our channels of distribution will also significantly increase our sales expenses, which could negatively impact our financial performance.

We believe that the success of our efforts to increase sales of our hyperthermia systems in the future depends on our ability to successfully expand our sales distribution channels. Historically, we have sometimes failed in establishing successful new sales channels.

We anticipate that the success of our multi-year plan for selling hyperthermia systems will require expanding our sales and marketing organization through a combination of direct sales people, distributors and internal and external marketing expertise. However, as we pursue our marketing plan, there can be no assurance that we will be successful in securing reliable channels of distribution to meet our plan through expanded sales. Recruiting and training new distribution channels can take time and considerable expense. We project that sales and marketing expenses will increase substantially in the future as compared to past years. This added expense could have an adverse effect on our future financial performance that is greater than any potential increases in sales.

In addition, there can be no assurance that our channels of distribution that have been successful in the past will be successful in the future. We have derived a significant portion of our revenue from sales in Europe and in China. Sales in Europe were made through our distributor Dr. Sennewald Medizintechnik GmbH, which also purchases equipment components and parts from us. Medizintechnik is controlled by Dr. Sennewald, one of our directors. The loss or ineffectiveness of either Medizintechnik or our Chinese distributor as a distributor and significant customer could result in lower revenue.

We may face significant uncertainty in the industry due to government healthcare reform.

Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. We anticipate that the current administration, Congress and certain state legislatures will continue to review and assess alternative healthcare delivery systems and payment methods with an objective of ultimately reducing healthcare costs and expanding access. Public debate of these issues will likely continue in the future. The uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation may have an adverse effect on our customers' purchasing decisions regarding our products and services. At this time, we cannot predict which, if any, healthcare reform proposals will be adopted, when they may be adopted or what impact they may have on our business.

We are subject to government regulations that can delay our ability to sell our products and cause us to incur substantial expenses.

Our research and development efforts, pre-clinical tests and clinical trials, and the manufacturing, marketing, distribution and labeling of our products are subject to extensive regulation by the FDA and comparable international agencies. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive and our financial resources are limited. The FDA is currently considering a number of reforms in its regulatory processes, which may make the FDA review process longer and more cumbersome for medical devices.

Obtaining pre-market approval or marketing clearance as a 510(k) submission from the FDA is necessary for us to commercially market our systems in the United States. Obtaining approvals is a lengthy and expensive process. We may not be able to obtain these approvals on a timely basis, if at all, and such failure could harm our business prospects substantially. Further, even if we are able to obtain the approvals we seek from the FDA, the approvals granted might include significant limitations on the indicated uses for which the products may be marketed, which

restrictions could negatively impact our business. As described above in “Business—Our Products and Services”, the FDA is currently reviewing our HDE marketing submission for the BSD-2000. 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.

After a product is approved for commercial distribution by the FDA, we have ongoing responsibilities under the Federal Food, Drug, and Cosmetic Act and FDA regulations, including regulation of our manufacturing facilities and processes, labeling and record-keeping, and reporting of adverse experiences and other information. Failure to comply with these ongoing requirements could result in the FDA imposing operating restrictions on us, enjoining or restraining certain violations, or imposing civil or criminal penalties on us.

All of these laws are subject to evolving interpretations. If the federal government were to conclude that we are not in compliance with any of these health care laws, we could be subject to substantial criminal and civil penalties, and could be excluded from participation as a supplier to beneficiaries in federal health care programs.

We depend on adequate protection of our patent and other intellectual property rights to stay competitive.

We rely on patents, trade secrets, trademarks, copyrights, know-how, license agreements and contractual provisions to establish and protect our intellectual property rights. Our success will substantially depend on our ability to protect our intellectual property rights and maintain rights granted to us through license agreements. Our intellectual property rights may only afford us limited protection and may not adequately protect our rights or remedies to gain or keep any advantages we may have over our competitors, which could reduce our ability to be competitive and generate sales and profitability.

In the past, we have participated in substantial litigation regarding our patent and other intellectual property rights in the medical device industry. We have previously filed lawsuits for patent infringement against three of our competitors and subsequently settled all three of those lawsuits. Additional litigation against other parties may be necessary in the future to enforce our intellectual property rights, to protect our patents and trade secrets, and to determine the validity and scope of our proprietary rights. This litigation may require more financial resources than are available to us. We cannot guarantee that we will be able to successfully protect our rights in litigation. Failure to successfully protect our rights in litigation could reduce our ability to be competitive and generate sales and profitability.

A product liability settlement could exceed our ability to pay.

The manufacturing and marketing of medical devices involves an inherent risk of product liability. We presently carry product liability insurance with coverage limits of \$5 million. Our product liability insurance does not cover intended injury, injury or damage resulting from the intoxication of any person, payment of workers' compensation benefits, injury of our own employee, injury or damage due to war, damage to property that we own, damage to our work, loss of use of property, patent infringements, pollution claims, interest payments, depreciation of property, or injury or damage resulting from asbestos inhalation. We are responsible to pay the first \$10,000 resulting from any claim up to a maximum of \$50,000 in one year. We cannot assure that our product liability insurance will provide adequate coverage against potential claims that might be made against us. If we were to be subject to a claim in excess of our coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our limited resources, which would reduce our limited capital resources and liquidity and reduce capital we could otherwise use to obtain approvals for and market our products. In addition, liability or alleged liability could harm our business by diverting the attention and resources of our management and by damaging our reputation.

We are dependent upon key personnel, some of whom would be difficult to replace.

Our success will be largely dependent upon the efforts of Harold R. Wolcott, our President, Steven M. Smith, our Vice President of Sales, Marketing and Business Development, Dixie Toolson Sells, our Vice President of Regulatory Affairs, Dennis P. Gauger, our Chief Financial Officer, and other key employees. We do not maintain key-person insurance on any of these employees. Our future success also will depend in large part upon our ability to identify, attract and retain other highly qualified managerial, technical and sales and marketing personnel. Competition for these individuals is intense. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel could make it more difficult for us to manage our business and meet key objectives such as the sale of our products and the introduction of new products.

The market for our stock is limited and our stock price may be volatile.

The market for our common stock has been limited due to low trading volume and the small number of brokerage firms acting as market makers. Because of the limitations of our market and volatility of the market price of our stock, investors may face difficulties in selling shares at attractive prices when they want to. The average daily trading volume for our stock has varied significantly from week to week and from month to month, and the trading volume often varies widely from day to day. The following factors could impact the market for our stock and cause further volatility in our stock price:

- announcements of new technological innovations;
- FDA and other regulatory developments and changes;
- changes in third-party reimbursements;
- developments concerning proprietary rights;
- third parties receiving FDA approval for competing products; and
- market conditions generally for medical and technology stocks.

Our directors and executive officers own a substantial number of shares of our capital stock, which could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Our directors and executive officers own approximately 23% of our outstanding voting power. Accordingly, these stockholders, individually and as a group, may be able to influence the outcome of stockholder votes involving the election of directors, the adoption or amendment of provisions in our certificate of incorporation and bylaws and the approval of certain mergers or other similar transactions, such as a sale of substantially all of our assets. Such control by existing stockholders could have the effect of delaying, deferring or preventing a change in control of our company.

Future sales of shares of our securities pursuant to our universal shelf registration statement may negatively affect our stock price.

We currently have the ability to offer and sell up to \$50.0 million of common stock, preferred stock, warrants, senior debt, subordinated debt or units under a currently effective universal shelf registration statement. We have previously completed four offerings utilizing our universal shelf registration statement. Each of these offerings was completed during calendar year 2010. Sales of substantial amounts of shares of our common stock or other securities under our universal shelf registration statement could lower the market price of our common stock and impair our ability to raise capital.

Anti-takeover provisions in our certificate of incorporation may have a possible negative effect on our stock price.

Certain provisions of our certificate of incorporation and bylaws may make it more difficult for a third party to acquire, or discourage a third party from attempting to acquire, control of us. We have in place several anti-takeover measures that could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders. The increased difficulties faced by a third party who wishes to acquire us could adversely affect our stock price.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### ITEM 2. PROPERTIES

We own our office, production and research facilities located in Salt Lake City, Utah. The complete headquarters and production facility occupies approximately 20,000 square feet. The building is currently in good condition, is adequate for our needs, and is suitable for all company functions. We believe that we carry adequate insurance on the property.

#### ITEM 3. LEGAL PROCEEDINGS

There are no material legal proceedings, to our knowledge, pending against or being taken by us.

#### ITEM 4. REMOVED AND RESERVED

## PART II

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

Our common shares trade on the Nasdaq Stock Market under the symbol "BSDM". The following table sets forth the high and low sales prices, as provided by NASDAQ for the quarters in fiscal years 2010 and 2011. The amounts reflect inter-dealer prices, without retail mark-up, markdown or commission, and may not represent actual transactions.

Quarter Ended:	High	Low
November 30, 2009	4.77	1.84
February 28, 2010	2.75	1.60
May 31, 2010	2.10	1.27
August 31, 2010	3.58	0.86
November 30, 2010	7.40	2.13
February 28, 2011	5.57	3.62
May 31, 2011	4.79	3.40
August 31, 2011	4.50	2.30

As of August 31, 2011, there were 479 holders of record of our common stock. We have not paid any cash dividends on our common stock since our inception, and we currently plan to retain our future earnings, if any, to fund the growth of our business.

On November 8, 2011, the last reported sales price of our common stock on the Nasdaq Stock Market was \$2.60 per share.

## Repurchases of Equity Securities

None.

## Recent Sales of Unregistered Securities

None.

### Performance Graph

The following graph shows a comparison of the five-year cumulative total return for the Company's common stock, the S&P 500 Index, and the S&P Health Care Equipment Index, assuming an investment of \$100 on August 31, 2006. The cumulative return of the Company was computed by dividing the difference between the price of the Company's common stock at the end and the beginning of the measurement period (August 31, 2006 to August 31, 2011) by the price of the Company's common stock at the beginning of the measurement period.



## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data as of and for each of the fiscal years in the five year period ended August 31, 2011 were derived from the Company's financial statements audited by Tanner LLC, independent registered public accountants. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 of this Form 10-K and the financial statements and notes thereto included in Item 8 of this Form 10-K.

	Years Ended August 31,				
	2011	2010	2009	2008	2007
<b>Results of Operations Data:</b>					
Revenues	\$3,037,475	\$1,582,276	\$3,536,487	\$5,143,140	\$2,834,386
Loss from operations	(5,348,671 )	(7,477,966 )	(6,526,493 )	(4,252,344 )	(6,384,540 )
Net income (loss)	(5,285,517 )	(7,456,948 )	(11,384,870 )	(2,439,099 )	(3,348,195 )
<b>Income (loss) per common share - diluted</b>					
	\$(0.18 )	\$(0.32 )	\$(0.52 )	\$(0.11 )	\$(0.16 )
<b>Dividends per common share</b>					
	\$-	\$-	\$-	\$-	\$-
<b>Balance Sheet Data:</b>					
Total Assets	\$21,939,906	\$12,702,169	\$12,857,358	\$21,486,898	\$24,341,640
Long-term debt	-	-	-	-	-
Stockholders' equity	21,071,594	12,118,225	11,940,989	20,155,860	23,183,788

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

## Overview

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this annual report on Form 10-K contain forward-looking statements that involve risks and uncertainties. Forward-looking statements can also be identified by words such as "anticipates," "expects," "believes," "plans," "predicts," and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in the subsection entitled "Forward-Looking Statements" below and the Item 1A "Risk Factors" above. The following discussion should be read in conjunction with our financial statements and notes thereto included in this annual report on Form 10-K. All information presented herein is based on our fiscal year ended August 31, 2011. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

We develop, manufacture, market, and service systems to treat cancer and benign diseases using heat therapy delivered using focused microwave and radiofrequency (RF) energy. Our product lines include both ablation and hyperthermia treatment systems. Our microwave ablation system has been developed as a stand-alone therapy to ablate (destroy) soft tissue. Our hyperthermia cancer treatment systems, which have been in use for several years in the United States, Europe and Asia, are used to treat certain tumors with heat (hyperthermia) while increasing the

effectiveness of other therapies such as radiation therapy. We have developed extensive intellectual property, multiple products in the market and well established distribution in the United States, Europe and Asia. Certain of our products have received regulatory approvals and clearances in the United States, Europe and China.

On August 18, 2010 we announced that the FDA granted the Company a 510(k) clearance to market our MicroThermX® for ablation of soft tissue. Clearance from the FDA of BSD's 510(k) Premarket Notification submission authorizes the commercial sale of the MicroThermX® in the United States. The MicroThermX® was designed to provide a higher power, optimized system targeted to the growing therapeutic interventional and surgical oncology market. The MicroThermX® represents a major part of our business plan moving forward. It introduces into our product line an innovative disposable that is used in each treatment, which we believe will provide a significant ongoing revenue stream.

In June 2011, we completed nationwide sales coverage for the MicroThermX® line of products through signing exclusive agreements with four leading specialty distributors and hiring additional regional sales management. In addition, we have placed a select number of MicroThermX® systems with pivotal, high-profile, interventional oncology key opinion leaders. This increased sales activity has resulted in a full schedule of clinical evaluations and an increase in the number of sites that may decide to purchase equipment following clinical evaluations. However, we believe the sales cycle for the MicroThermX® may extend up to six months, and we currently are unable to predict when significant revenues from the sale of the MicroThermX® and related disposables will begin.

With our United States sales and distribution network in place for our MicroThermX® family of products, we are placing significant emphasis on Europe and other international markets. We recently hired an International Sales Manager, have met with several international distribution firms and have started contract negotiations with select European based firms. International sales of our MicroThermX® family of products will depend on our ability to successfully establish sales distribution channels in Europe and other international markets.

Through August 31, 2011, most of our operating revenues have been from the sale of our hyperthermia cancer systems and related revenues. In addition to revenues from the sale of ablation and hyperthermia treatment systems, we recognize revenue from the sale of parts and accessories related to our systems, the sale of consumable devices used with certain of our systems, training, service support contracts, and other miscellaneous revenues. System and product sales totaled \$2,581,275, \$1,261,490 and \$3,293,116 for the years ended August 31, 2011, 2010 and 2009, respectively. Equipment rental income was \$110,207 for the year ended August 31, 2011. Sales of consumable devices, service and other revenues totaled \$345,993, \$320,786 and \$243,371 for the years ended August 31, 2011, 2010 and 2009, respectively.

As of August 31, 2011, we had no sales backlog. However, subsequent to August 31, 2011 through November 14, 2011, we have received purchase orders for hyperthermia systems totaling approximately \$520,000. The timing of reporting the sales for purchase orders will depend on the delivery of the systems to the customers and other revenue recognition criteria.

## Results of Operations

### Fluctuation in Operating Results

Our results of operations have fluctuated in the past and may fluctuate in the future from year to year as well as from quarter to quarter. Revenue may fluctuate as a result of factors relating to the demand and market acceptance for our ablation and hyperthermia systems and related component parts and services, world-wide economic conditions, availability of financing for our customers, changes in the medical capital equipment market, changes in order mix and product order configurations, competition, regulatory developments, insurance reimbursement and other matters. Operating expenses may fluctuate as a result of the timing of sales and marketing activities, research and development, and general and administrative expenses associated with our potential growth. For these and other reasons described elsewhere, our results of operations for a particular period may not be indicative of operating results for any other period.



## Revenues

We recognize revenue from the sale of our ablation and hyperthermia cancer treatment systems and related parts and accessories (collectively, product sales), the sale of consumable devices used with certain of our systems, training, service support contracts and other miscellaneous revenues. During the year ended August 31, 2011, we also recognized revenues from equipment rental. Our revenues can fluctuate significantly from period to period because our sales, to date, have been based upon a relatively small number of hyperthermia systems, the sales price of each being substantial enough to greatly impact revenue levels in the periods in which they occur. Sales of a few hyperthermia systems, particularly BSD-2000/3D/MR systems, can cause a large change in our revenues from period to period and the sales cycle for our systems generally extends over multiple financial reporting periods. In addition, differences in the configuration of the hyperthermia systems sold, pricing, and other factors can result in significant differences in the sales price per system and in the total revenues reported in a given period. As a result, there may be quarterly financial reporting periods where we may report no or minimal revenues from the sale of hyperthermia systems. Through August 31, 2011, we had minimal revenues from our MicroThermX® family of products.

To date, hyperthermia therapy has not gained wide acceptance by cancer-treating physicians. We believe this is due in part to the lingering impression created by the inability of early hyperthermia therapy technologies to focus and control heat directed at specific tissue locations and inaccurate conclusions drawn in early scientific studies that hyperthermia was only marginally effective. Additionally, we do not believe that reimbursement rates from third-party payers have been adequate to promote hyperthermia therapy acceptance in the medical community.

We also believe the continuing worldwide economic downturn has made it difficult for many of our customers to obtain approval for the purchase of our hyperthermia systems and to arrange related financing.

Political, economic and regulatory influences are subjecting the U.S. healthcare industry to fundamental changes. We may continue to face significant uncertainty in the industry due to recent governmental healthcare reform. We believe the uncertainties regarding the ultimate features of reform initiatives and their enactment and implementation may also have an adverse effect on our customers' purchasing decisions regarding our products and services.

As a result of these negative factors, we have been unable to sustain a significant increase in the number of hyperthermia systems sold, and we believe these difficulties may continue to negatively impact the sales of our hyperthermia systems, the market introduction of our MicroThermX®, and our operating results.

The following table summarizes the number of our hyperthermia systems sold for the years ended August 31, 2011, 2010 and 2009:

	2011	2010	2009
MicroThermX®	1	-	-
Hyperthermia Systems:			
BSD-500	4	3	7
BSD-2000	2	2	4
BSD-2000/3D	-	-	1
BSD-2000/3D/MR	1	-	-
Total	7	5	12

We have historically derived a significant portion of our revenues from sales to related parties. All of the related party revenue was for the sale of hyperthermia systems and related component parts and services sold to Dr. Sennewald Medizintechnik GmbH. Dr. Sennewald, one of our directors and significant stockholders, is a stockholder, executive officer and a director of Medizintechnik. We derived \$1,063,495, or approximately 35%, of our total revenue in the year ended August 31, 2011 from sales to related parties, compared to \$309,259 or approximately 20%, in the year ended August 31, 2010, and \$603,000 or approximately 17% in the year ended August 31, 2009.

In the year ended August 31, 2011, we derived \$1,973,980, or approximately 65%, of our total revenue from non-related parties, as compared to \$1,273,017, or 80%, in the year ended August 31, 2010, and \$2,933,487, or 83%, in the year ended August 31, 2009.

The following tables summarize the sources of our revenues for the years ended August 31, 2011, 2010 and 2009:

Non-Related Parties	2011	2010	2009
Product sales	\$ 1,569,688	\$ 1,095,440	\$ 2,784,777
Consumable devices	116,724	12,300	4,802
Service contracts	141,224	131,826	78,763
Other	36,137	33,451	65,145
	1,863,773	1,273,017	2,933,487
Equipment rental	110,207	-	-
Total	\$ 1,973,980	\$ 1,273,017	\$ 2,933,487
Related Parties	2011	2010	2009
Product sales	\$ 1,011,587	\$ 166,050	\$ 508,339
Consumable devices	38,700	33,000	54,200
Other	13,208	110,209	40,461
Total	\$ 1,063,495	\$ 309,259	\$ 603,000

Total revenues for the year ended August 31, 2011 were \$3,037,475 compared to \$1,582,276 for the year ended August 31, 2010, an increase of \$1,455,199, or approximately 92%. The overall increase in revenues in the current fiscal year is due to more sales of hyperthermia systems in the current fiscal year, including the sale of one higher priced BSD-2000/3D/MR to a related party. We sold seven hyperthermia systems in fiscal year 2011 compared to five hyperthermia systems in fiscal year 2010. In addition, we recorded revenues in fiscal year 2011 of \$110,207 from equipment rental and \$189,257 from our MicroThermX® family of products. We had no revenues in the prior two fiscal years from these sources.

Total revenues for the year ended August 31, 2010 were \$1,582,276 compared to \$3,536,487 for the year ended August 31, 2009, a decrease of \$1,954,211, or approximately 55%. The overall decrease in revenues in fiscal year 2010 was due primarily to fewer sales of hyperthermia systems. We sold five hyperthermia systems in fiscal year 2010 compared to twelve hyperthermia systems in fiscal year 2009. In addition, we did not sell any higher priced BSD-2000/3D/MR or BSD-2000/3D systems to related parties in fiscal year 2010.

#### Gross Margin

Our gross margin and gross margin percentage will fluctuate from period to period depending on the mix of revenues reported for the period and the type and configuration of the hyperthermia systems sold during the period. Our total gross margin was \$1,324,549, or 44% of total sales, for fiscal year 2011, \$81,266, or 5% of total sales, for fiscal year 2010, and \$1,614,269, or 46%, for fiscal year 2009. The decrease in gross margin and gross margin percentage in fiscal year 2010 resulted primarily from the decrease in product sales, for which our gross margin is higher than our other sources of revenue. In addition, as sales volume increases, we believe we will more fully absorb certain fixed operating costs that are included in cost of sales, thus increasing our gross profit percentage.

#### Operating Costs and Expenses: Comparison of Fiscal Years ended August 31, 2011 and 2010

**Cost of Sales** – Cost of sales include raw material, labor and allocated overhead costs. We calculate and report separately cost of sales for both non-related and related party sales, which are sales to Medizintechnik. Cost of sales as a percentage of sales will fluctuate from period to period depending on the mix of sales for the period and the type and configuration of the hyperthermia systems sold during the period. Total cost of sales for fiscal 2011 was \$1,712,926 compared to \$1,501,010 for fiscal 2010, an increase of \$211,916, or approximately 14%. This increase resulted primarily from the sale of more hyperthermia systems in the current fiscal year compared to the last fiscal year, as further discussed above.

**Research and Development Expenses** – Research and development expenses include expenditures for new product development and development of enhancements to existing products. Our research and development expenses for the year ended August 31, 2011 have been partially offset by the \$488,958 proceeds from two separate U.S. government grants under the QTDP Program received in our first fiscal quarter ended November 30, 2010. Research and development expenses were \$1,483,659 for fiscal 2011 compared to \$2,429,215, for fiscal 2010, a decrease of \$945,556, or approximately 39%. In addition to the offset of the QTDP grants, research and development expenses decreased in the current fiscal year primarily from the shift from product development activities to sales and marketing efforts for the MicroThermX® product line, and due to our operating expense reduction measures.

**Selling, General and Administrative Expenses** – Selling, general and administrative expenses were \$5,189,561 for fiscal 2011 compared to \$5,130,017 in fiscal 2010, an increase of \$59,544, or approximately 1%. We implemented headcount reductions and other operating expense reduction measures in the latter part of fiscal year 2010. However, as we continue the roll out of the MicroThermX® product line and the support of its global distribution network, we have increased our marketing and sales staff, including three regional sales managers, an international sales manager, a director of marketing and a customer service manager, and incurred additional marketing, sales and related operating expenses. As a result, we incurred an increase in our selling, general and administrative expenses for the year ended August 31, 2011. We believe that the level of our selling, general and administrative expenses will continue to increase over the levels reported for the year ended August 31, 2011, and the increase may be significant.



Operating Costs and Expenses: Comparison of Fiscal Years ended August 31, 2010 and 2009

Cost of Sales – Cost of sales include raw material, labor and allocated overhead costs. We calculate and report separately cost of sales for both non-related and related party sales, which are sales to Medizintechnik. Cost of sales as a percentage of sales will fluctuate from period to period depending on the mix of sales for the period and the type and configuration of the hyperthermia systems sold during the period. Total cost of sales for fiscal 2010 was \$1,501,010 compared to \$1,922,218 for fiscal 2009, a decrease of \$421,208, or approximately 22%. This decrease resulted primarily from the sale of fewer hyperthermia systems in fiscal year 2010 compared to fiscal year 2009, as further discussed above.

Research and Development Expenses – Research and development expenses include expenditures for new product development and development of enhancements to existing products. Research and development expenses were \$2,429,215 for fiscal 2010 compared to \$2,043,268, for fiscal 2009, an increase of \$385,947, or approximately 19%. The increase in research and development expenses in fiscal year 2010 was due primarily to the continued development of our MicroThermX®, the filing of our 510(k) submission with the FDA for premarket clearance of the device and CE Marking for approval in EU countries. We also continued our efforts to enhance our current hyperthermia products and to develop new products.

Selling, General and Administrative Expenses – Selling, general and administrative expenses were \$5,130,017 for fiscal 2010 compared to \$6,097,494 in fiscal 2009, a decrease of \$967,477, or approximately 16%. The decrease in selling, general and administrative expenses in fiscal year 2010 was due to the headcount reductions and other operating expense reduction measures implemented in May 2010. In addition, our selling, general and administrative expenses for fiscal 2009 were higher due to severance payments made to our former president, higher non-cash stock option expense, and higher professional fees.

Other Income (Expense)

Interest and Investment Income: Interest and investment income was \$67,233, \$11,042, and \$584,523 for the years ended August 31, 2011, 2010 and 2009, respectively. The increase in interest and investment income in fiscal year 2011 compared to fiscal year 2010 resulted from higher balances of cash and cash equivalents during fiscal year 2011 resulting from our stock offerings. The decrease in interest and investment income in fiscal year 2010 compared to fiscal year 2009 resulted primarily from lower levels of investments compared to prior fiscal years. The proceeds from the sale of our mutual funds in March and May 2009 were deposited in money market funds and savings accounts. Subsequently, the interest and investment income earned was substantially less than previously earned on our mutual funds, but we believe we have significantly reduced the exposure to our funds of market fluctuations.

Realized Loss on Investments: We sold 100% of our investments in mutual funds in March and May 2009. The investments had a total cost basis of \$16,652,543 and we received total proceeds of \$10,150,957, resulting in a realized loss of \$6,501,586. We had no realized loss on investments in fiscal years 2011 or 2010. As a result of the sale of investments, at August 31, 2011 and 2010, we had no investments, but cash and equivalents comprised primarily of money market funds.

### Income Tax (Provision) Benefit

During the fiscal years ended August 31, 2011 and 2010, we recorded an immaterial income tax provision of \$800 and income tax benefit of \$6,571, respectively, primarily related to state income taxes.

The income tax benefit for the fiscal year ended August 31, 2009 represents an increase in our income tax receivable resulting from our ability to carry back our taxable loss in that year to offset income taxes previously paid, partially offset by a deferred tax provision. As a result of the enactment of the American Recovery and Reinvestment Act of 2009 in February 2009, we are able to carry back our fiscal 2009 operating losses and realized losses on investments to the extent of the remaining taxable income for our fiscal year 2005.

The deferred income tax provision of \$229,000 in the fiscal year ended August 31, 2009 resulted from our recording a valuation allowance against our deferred tax assets. In recording the valuation allowance, we were unable to conclude that it is more likely than not that our deferred tax assets, including our taxable loss and tax credit carry forwards, will be realized. In reaching this determination, we evaluated factors such as prior earnings history, expected future earnings and our ability to carry back reversing items to offset income taxes paid. As a result, we do not anticipate that we will record material income tax benefits from taxable losses and tax credits as a result of recording a 100% valuation allowance against the related deferred tax assets.

### Liquidity and Capital Resources

Since inception through August 31, 2011, we have generated an accumulated deficit of \$29,416,587 where generally our operating revenues have been insufficient to cover our operating expenses. We have financed our operations primarily through the sale of our common stock, the exercise of stock options and warrants, and from the sale of an investment in a spinoff operation. As of August 31, 2011, we had cash and cash equivalents of \$17,135,968, comprised primarily of money market funds and savings accounts.

As of August 31, 2011, we had current liabilities totaling \$676,154, comprised of accounts payable, accrued liabilities and deferred revenue incurred in the normal course of our business. Our long-term liabilities consisted of deferred revenue of \$192,158.

### Stock Offerings

On October 1, 2009, our universal shelf registration statement was declared effective by the SEC for the issuance of common stock, preferred stock, warrants, senior debt, subordinated debt and units up to an aggregate amount of \$50.0 million. We may periodically offer one or more of these securities in amounts, prices and on terms to be announced when and if the securities are offered. At the time any of the securities covered by the registration statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering. We have previously completed four offerings utilizing our universal shelf registration statement. Each of these offerings was completed during calendar year 2010.

On each of February 11, 2010, May 3, 2010, August 19, 2010, and November 15, 2010, we entered into a placement agency agreement (collectively, the "Agency Agreements") with Roth Capital Partners, LLC (the "Placement Agent"), pursuant to which the Placement Agent agreed to use its reasonable efforts to arrange for the sale of shares of our common stock and warrants in registered direct public offerings. These offerings are referred to herein as the "February Offering," "May Offering," "August Offering" and "November Offering" (each, an "Offering" and collectively the "2010 Offerings"). In connection with each of the Offerings, we and certain institutional investors also entered into securities purchase agreements (collectively, the "Purchase Agreements") pursuant to which we agreed to sell shares of our common stock and warrants to purchase additional shares of our common stock to the investors. The common

stock and warrants were sold in fixed combinations, with each combination consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock (0.50 shares in the case of the November Offering). The warrants became exercisable six months and one day following the closing date of the Offering and will remain exercisable for five years thereafter. The exercise price of the warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

The number of shares of our common stock and number of shares of our common stock issuable upon exercise of the warrants as well as the purchase price per fixed combination and the exercise price associated with each warrant which were sold the 2010 Offerings are shown below:

2010 Offerings	Shares of Common Stock	Warrants – Shares of Common Stock Issuable upon Exercise of the Warrants	Purchase Price per Fixed Combination	Warrant Exercise Price (Per Share)
February Offering	1,176,471	882,354	\$ 1.70	\$ 2.04
May Offering	1,644,737	1,233,553	\$ 1.52	\$ 1.94
August Offering	1,225,000	918,750	\$ 2.25	\$ 3.27
November Offering	1,750,000	875,000	\$ 5.97	\$ 7.73

The Placement Agent was entitled to a cash fee of 6.5% of the gross proceeds paid to us for the securities we would sell in each of the Offerings. We would also reimburse the Placement Agent for all reasonable and documented out-of-pocket expenses that would be incurred by the Placement Agent in connection with each of the Offerings, which could not exceed in the case of each of the Offerings the lesser of (i) \$75,000 (\$30,000 in the case of the November Offering and in the case of the February Offering, \$75,000 less a \$25,000 cash advance for expenses), or (ii) 8% of the gross proceeds of the Offering, less the Placement Agent’s placement fee (and in the case of the February Offering, also less the \$25,000 cash advance for expenses). Each of the Agency Agreements contains customary representations, warranties and covenants by us. They also provide for customary indemnification by us and the Placement Agent for losses or damages arising out of or in connection with the sale of the securities being offered. We also agreed to indemnify the Placement Agent against liabilities under the Securities Act of 1933, as amended. We also agreed to contribute to payments the Placement Agent may be required to make in respect of such liabilities.

The exercisability of the warrants sold in the 2010 Offerings may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.9% of our common stock.

We agreed with each of the purchasers that while the warrants are outstanding, we will not affect or enter into an agreement to affect a “Variable Rate Transaction,” which means a transaction in which we:

- issue or sell any convertible securities either (A) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of our common stock at any time after the initial issuance of such convertible securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for our common stock, other than pursuant to a customary “weighted average” anti-dilution provision; or

- enter into any agreement (including, without limitation, an equity line of credit) whereby we may sell securities at a future determined price (other than standard and customary “preemptive” or “participation” rights).

We agreed with each of the purchasers if we issue securities within the 12 months following the closing of an Offering, the purchasers shall have the right to purchase all of the securities on the same terms, conditions and price provided for in the proposed issuance of securities.

We also agreed to indemnify each of the purchasers against certain losses resulting from our breach of any of our representations, warranties, or covenants under agreements with each of the purchasers, as well as under certain other circumstances described in the Purchase Agreements.

We closed the February Offering on February 17, 2010. The aggregate gross proceeds to us from the February Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$2 million. The net proceeds to us from the February Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$1.7 million.

We closed the May Offering on May 6, 2010. The aggregate gross proceeds to us from the May Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$2.5 million. The net proceeds to us from the May Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$2.3 million.

We closed the August Offering on August 24, 2010. The aggregate gross proceeds to us from the August Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$2.75 million. The net proceeds to us from the August Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$2.5 million.

We closed the November Offering on November 18, 2010. The aggregate gross proceeds to us from the November Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$10.45 million. The net proceeds to us from the November Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$9.7 million.

#### Warrant Exercises

During our fiscal year ended August 31, 2011, investors exercised warrants to purchase a total of 1,501,134 common shares, with net proceeds to the Company of approximately \$3.0 million. As of November 14, 2011, we have issued 772,060 shares of our common stock as a result of the exercise of warrants issued in the February Offering, and 729,074 shares of our common stock as a result of the exercise of warrants issued in the May Offering.

#### Cash Flows from Operating, Investing and Financing Activities

During the year ended August 31, 2011, we used net cash of \$4,157,225 in operating activities, primarily as a result of our net loss of \$5,285,517, decreased by non-cash expenses totaling \$1,362,205, including depreciation and amortization, stock-based compensation and stock issued for services. Net cash used in operating activities also included increases in receivables of \$414,223 and inventories of \$167,960, partially offset by decreases in income tax receivable of \$50,000 and other current assets of \$13,902, and increases in accounts payable of \$104,854, accrued liabilities of \$108,084 and deferred revenue of \$71,430.



During the year ended August 31, 2010, we used net cash of \$5,679,575 in operating activities, primarily as a result of our net loss of \$7,456,948, decreased by non-cash expenses totaling \$1,289,063, including depreciation and amortization, stock-based compensation and stock issued for services. Net cash used in operating activities also included increases in receivables of \$60,731, inventories of \$443,778 and other current assets of \$40,514 and decreases in accounts payable of \$29,823 and accrued liabilities of \$324,159, partially offset by a decrease in income tax receivable of \$1,365,758 and an increase in deferred revenue of \$21,557.

Net cash used in investing activities, resulting from the purchase of property and equipment, was \$214,554 and \$122,521 for the years ended August 31, 2011 and 2010, respectively.

Net cash provided by financing activities for the year ended August 31, 2011 was \$13,024,182, comprised of net proceeds from the sale of common stock of \$9,702,656, proceeds from the exercise of warrants of \$2,989,406 and proceeds from the exercise of stock options of \$332,120. Net cash provided by financing activities for the year ended August 31, 2010 was \$6,493,723, comprised of net proceeds from the sale of common stock.

We believe that our current cash and cash equivalents will be sufficient to fund our operations for the next twelve months.

If we cannot cover any future cash shortfalls with cost cutting or available cash, or our sales are less than projected, we would need to obtain additional financing. Due to adverse conditions in the global financial markets, we cannot be certain that any financing will be available when needed or will be available on terms acceptable to us. If we raise equity capital, our stockholders will be diluted. Insufficient funds may require us to delay, scale back or eliminate some or all of our programs designed to facilitate the commercial introduction of our systems or entry into new markets.

As of August 31, 2011, we had no significant commitments for the purchase of property and equipment.

We had no material off balance sheet arrangements as of August 31, 2011.

#### Other Cash Receipts

In November 2010, we were awarded two separate U.S. government grants under the QTDP Program. We submitted grant applications for our BSD-2000 and our MicroThermX® and both applications were approved for the maximum award for a single program of \$244,479, or a total of \$488,958. In order to qualify for the QTDP grants, the project must have the potential to develop new treatments that address “unmet medical needs” or chronic and acute diseases; reduce long-term health care costs; represent a significant advance in finding a cure for cancer; advance U.S. competitiveness in the fields of life, biological, and medical sciences; or create or sustain well-paying jobs, either directly or indirectly. The QTDP was created by Congress in March 2010 as part of the Patient Protection and Affordable Care Act and provides a tax credit or a grant equal to 50% of eligible costs and expenses for tax years 2009 and 2010.

#### Critical Accounting Policies

The following is a discussion of our critical accounting policies and estimates that management believes are material to an understanding of our results of operations and which involve the exercise of judgment or estimates by management.

**Revenue Recognition:** Revenue from the sale of cancer treatment systems is recognized when a purchase order has been received, the system has been shipped, the selling price is fixed or determinable, and collection is reasonably

assured. Most system sales are F.O.B. shipping point; therefore, shipment is deemed to have occurred when the product is delivered to the transportation carrier. Most system sales do not include installation. If installation is included as part of the contract, revenue is not recognized until installation has occurred, or until any remaining installation obligation is deemed to be perfunctory. Some sales of systems may include training as part of the sale. In such cases, the portion of the revenue related to the training, calculated based on the amount charged for training on a stand-alone basis, is deferred and recognized when the training has been provided. The sales of our cancer treatment systems do not require specific customer acceptance provisions and do not include the right of return except in cases where the product does not function as warranted by us. To date, returns have not been significant.



Revenue from the sale of consumable devices is recognized when a purchase order has been received, the devices have been shipped, the selling price is fixed or determinable, and collection is reasonably assured. Currently, our customers are not required to purchase a minimum number of disposable devices in connection with the purchase of our systems.

Revenue from training services is recorded when an agreement with the customer exists for such training, the training services have been provided, and collection is reasonably assured.

Revenue from service support contracts is recognized on a straight-line basis over the term of the contract, which approximates recognizing it as it is earned.

Revenue from equipment rental under an operating lease is recognized when billed in accordance with the lease agreement.

Our revenue recognition policy is the same for sales to both related parties and non-related parties. We provide the same products and services under the same terms for non-related parties as with related parties.

Sales to distributors are recognized in the same manner as sales to end-user customers.

Deferred revenue and customer deposits payable include amounts from service contracts as well as cash received for the sales of products, which have not been shipped.

**Inventory Reserves:** We maintain a reserve for obsolete inventories to reduce excess and obsolete inventories to their estimated net realizable value. This reserve is a significant estimate and we periodically reviewed our inventory levels and usage, paying particular attention to slower-moving items. If projected sales do not materialize or if our hyperthermia systems do not receive increased market acceptance, we may be required to increase the reserve for obsolete inventories in future periods.

**Product Warranty:** We provide product warranties on our systems. These warranties vary from contract to contract, but generally consist of parts and labor warranties for one year from the date of installation. To date, expenses resulting from such warranties have not been material. We record a warranty expense at the time of each sale. This reserve is estimated based on prior history of service expense associated with similar units sold in the past.

**Allowance for Doubtful Accounts:** We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is a significant estimate and is regularly evaluated by us for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

**Stock-based Compensation:** Stock-based compensation cost of stock options and other stock-based awards to employees and directors is measured at the grant date based on the estimated value of the award granted, using the Black-Scholes option pricing model, and recognized over the period in which the award vests. For stock awards no longer expected to vest, any previously recognized stock compensation expense is reversed in the period of termination. The stock-based compensation expense has been allocated to the various categories of operating costs and expenses in a manner similar to the allocation of payroll expense. The Black-Scholes valuation model utilizes inputs that are subject to change over time, including the volatility of the market price of our common stock, risk free interest rates, requisite service periods and assumptions made by us regarding the assumed life and vesting of stock options and stock-based awards. As new options or stock-based awards are granted, additional non-cash compensation expense will be recorded by us.

**Income Taxes:** We account for income taxes using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

We maintain valuation allowances where it is more likely than not that all or a portion of a deferred tax asset will not be realized. Changes in valuation allowances are included in our income tax provision in the period of change. In determining whether a valuation allowance is warranted, we evaluate factors such as prior earnings history, expected future earnings and our ability to carry back reversing items within two years to offset income taxes previously paid.

To the extent that we have the ability to carry back current period taxable losses to offset income taxes previously paid, we record an income tax receivable and a current income tax benefit.

#### Recent Accounting Pronouncements

Accounting Standards Update (“ASU”) No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income, was issued in June 2011. This update eliminates the option to present the components of other comprehensive income in the statement of changes in equity and requires presentation of net income and other comprehensive income (and their respective components) either in a single continuous statement or in two separate but consecutive statements. The amendments in this update are to be applied retrospectively. For public entities, the amendments are effective for interim and annual periods beginning after December 15, 2011. Early adoption is permitted. The Company has adopted the practice of presenting a single continuous statement of comprehensive loss.

ASU No. 2011-08, Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment, was issued in September 2011. The objective of this update is to simplify how entities, both public and nonpublic, test goodwill for impairment. The amendments in the update permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in Topic 350. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. Previous guidance under Topic 350 required an entity to test goodwill for impairment, on at least an annual basis, by comparing the fair value of a reporting unit with its carrying amount, including goodwill (step one). If the fair value of a reporting unit is less than its carrying amount, then the second step of the test must be performed to measure the amount of the impairment loss, if any. Under the amendments in this update, an entity is not required to calculate the fair value of a reporting unit unless the entity determines that it is more likely than not that its fair value is less than its carrying amount. This update is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, or our fiscal quarter ending May 31, 2012. Early adoption is permitted. Since we currently have

no reported goodwill balances, we do not believe the adoption of this pronouncement will have a material impact on our financial statements.

## FORWARD-LOOKING STATEMENTS

With the exception of historical facts, the statements contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and other parts of this annual report on Form 10-K are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which reflect our current expectations and beliefs regarding our future results of operations, performance and achievements. These statements are subject to risks and uncertainties and are based upon assumptions and beliefs that may or may not materialize. These forward-looking statements include, but are not limited to, statements concerning:

- our belief about the market opportunities for our products;
- our anticipated financial performance and business plan;
- our expectations regarding the commercialization of, and the potential revenue from, the BSD-2000, BSD 500 and MicroThermX® systems;
- our expectations to further expand our developments to treat other forms of cancer and other diseases and medical conditions;
- our expectations that we will continue to incur expenses related to seeking governmental and regulatory approvals for our products;
- our belief that the MicroThermX® will be a major part of our business plan moving forward and that the growth in our revenues and our ultimate profitability will be largely dependent on the success of our MicroThermX® marketing and sales efforts;
- our expectations regarding the manufacturing, marketing, distribution, roll out and revenues for the MicroThermX® and the estimated timing thereof;
- our expectations that the disposable antenna to be used in conjunction with the MicroThermX® represents a significant ongoing revenue stream;
  - our belief that the increased number of clinical evaluations will result in sales of the MicroThermX®;
- our expectations that additional international shipments of the MicroThermX® and supplies of disposable antennas will occur later in calendar year 2011;
  - our intentions to continue to devote substantial sums to research and development;
- our belief that the level of our operating expenses, including selling, general and administrative expenses, will increase;

- our belief that, as sales volume increases, we will more fully absorb certain fixed operating costs that are included in cost of sales, thus increasing our gross profit percentage;
- our belief that our operating results, revenue and operating expenses may fluctuate in the future from year to year as well as from quarter to quarter; and
- our belief that our current cash and cash equivalents will be sufficient to finance our operations for the next twelve months.

We wish to caution readers that the forward-looking statements and our operating results are subject to various risks and uncertainties that could cause our actual results and outcomes to differ materially from those discussed or anticipated, including the factors set forth in Item 1A – “Risk Factors” in this Annual Report and our other filings with the Securities and Exchange Commission. We also wish to advise readers not to place any undue reliance on the forward-looking statements contained in this report, which reflect our beliefs and expectations only as of the date of this report. We assume no obligation to update or revise these forward-looking statements to reflect new events or circumstances or any changes in our beliefs or expectations, other than as required by law.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash and cash equivalents consist primarily of money market funds and savings accounts, which are investment grade securities. These accounts bear variable interest rates that are adjusted to market conditions and changes in financial market conditions and in market rates will affect interest income earned on these funds. We do not believe, however, that the interest income earned on our money market funds and savings accounts is material to the results of our operations. Further, we do not believe that we are currently exposed to changes in financial market conditions that expose our money market funds and savings accounts to material changes in the market value of their principal.

We do have significant sales to foreign customers and are therefore subject to the effects changes in foreign currency exchange rates may have on demand for our products and services. We currently do not utilize derivative instruments to offset the exposure to changes in foreign currency exchange rates. To minimize foreign exchange risk, our export sales are transacted in United States dollars.

#### ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Financial Statements of the Company called for by this item are contained in a separate section of this report. See “Index to Financial Statements” on Page F-1.

The following table presents selected unaudited quarterly financial data for each of the four quarters in our fiscal years 2011 and 2010. The selected quarterly financial data reflects, in the opinion of management, all adjustments necessary to fairly present the results of operations for such periods. Results of any one or more quarters are not necessarily indicative of continuing trends.

	2011				2010			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Total revenues	\$506,985	\$444,439	\$1,675,477	\$410,574	\$426,203	\$600,074	\$123,602	\$432,397
Gross margin (loss)	147,256	38,502	1,034,039	104,752	48,836	71,464	(223,339 )	184,305
Net loss	(947,301)	(1,553,965)	(817,540 )	(1,966,711)	(1,946,573)	(1,920,145)	(2,387,577)	(1,202,653)

Loss per common share - diluted																
	\$ (0.04	)	\$ (0.05	)	\$ (0.03	)	\$ (0.07	)	\$ (0.09	)	\$ (0.09	)	\$ (0.10	)	\$ (0.05	)

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

None.

### ITEM 9A. CONTROLS AND PROCEDURES

#### Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to provide reasonable assurance that information required to be disclosed in reports filed under the Securities Exchange Act of 1934 (the “Act”) is recorded, processed, summarized and reported within the specified time periods and accumulated and communicated to management, including our Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Accounting Officer), as appropriate, to allow timely decisions regarding required disclosure.

Management, under the supervision and with the participation of our Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Accounting Officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) promulgated under the Act), as of August 31, 2011. Based on that evaluation, management concluded that our disclosure controls and procedures were effective as of August 31, 2011.

Attached as exhibits to this Annual Report on Form 10-K are certifications of our Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Accounting Officer), which are required in accordance with Rule 13a-14 of the Act. This Disclosure Controls and Procedures section includes information concerning management’s evaluation of disclosure controls and procedures referred to in those certifications and, as such, should be read in conjunction with the certifications of our Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Accounting Officer).

#### Management’s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting of the Company. Management’s intent is to design this system 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 in the United States of America (GAAP).

Our internal control over financial reporting includes those policies and procedures that:

- 1.pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- 2.provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- 3.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.





A material weakness is a significant deficiency, or combination of significant deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Management performed an assessment of the effectiveness of the Company's internal control over financial reporting as of August 31, 2011, utilizing the criteria described in the "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The objective of this assessment was to determine whether our internal control over financial reporting was effective as of such date. In its assessment of the effectiveness of internal control over financial reporting as of August 31, 2011, management concluded that our internal control over financial reporting is effective.

Management's assessment of the effectiveness of our internal control over financial reporting has been audited by Tanner LLC, an independent registered public accounting firm, as stated in their report which is included herein.

#### Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as such item is defined in Rule 13a-15(f) under the Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with associated policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

#### ITEM 9B. OTHER INFORMATION

None.

### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item is incorporated by reference from the information in the Company's definitive Proxy Statement to be filed for the 2012 Annual Meeting of Stockholders.

#### ITEM 11. EXECUTIVE COMPENSATION

Information required by this item is incorporated by reference from the information in the Company's definitive Proxy Statement to be filed for the 2012 Annual Meeting of Stockholders.

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

Information required by this item is incorporated by reference from the information in the Company's definitive Proxy Statement to be filed for the 2012 Annual Meeting of Stockholders.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information in the Company's definitive Proxy Statement to be filed for the 2012 Annual Meeting of Stockholders.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by this item is incorporated by reference from the information in the Company's definitive Proxy Statement to be filed for the 2012 Annual Meeting of Stockholders.

### PART IV

#### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The Index to Financial Statements on page F-1 is incorporated herein by reference as the list of financial statements required as part of this report.

(2) Financial Statement Schedules

Financial statement schedules have been omitted because they are not required or are not applicable, or because the required information is shown in the financial statements or notes thereto.



(3) Exhibits

The following exhibits are incorporated herein by reference as indicated:

Exhibit Number	Description
1.1	Placement Agency Agreement, dated as of February 11, 2010, by and among BSD Medical Corporation and Roth Capital Partners, LLC. Incorporated by reference to Exhibit 1.1 to the BSD Medical Corporation Form 8-K, filed February 11, 2010.
1.2	Placement Agency Agreement, dated as of May 3, 2010, by and among BSD Medical Corporation and Roth Capital Partners, LLC. Incorporated by reference to Exhibit 1.1 to the BSD Medical Corporation Form 8-K, filed May 3, 2010.
1.3	Placement Agency Agreement, dated as of August 19, 2010, by and among BSD Medical Corporation and Roth Capital Partners, LLC. Incorporated by reference to Exhibit 1.1 to the BSD Medical Corporation Form 8-K, filed August 19, 2010.
1.4	Placement Agency Agreement, dated as of November 15, 2010, by and among BSD Medical Corporation and Roth Capital Partners, LLC. Incorporated by reference to Exhibit 1.1 to the BSD Medical Corporation Form 8-K, filed November 15, 2010.
3.1	Amended and Restated Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 of the BSD Medical Corporation Annual Report Form 10-KSB, filed December 1, 2003.
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BSD Medical Corporation. Incorporated by reference to Exhibit 3.1 to the BSD Medical Corporation Form 8-K, filed February 7, 2011.
3.3	By-Laws. Incorporated by reference to Exhibit 3.2 of the BSD Medical Corporation Registration Statement on Form S-1, filed October 16, 1986.
3.4	Amendment to Bylaws. Incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K filed January 4, 2008.
4.1	Specimen Common Stock Certificate. Incorporated by reference to Exhibit 4 of the BSD Medical Corporation Registration Statement on Form S-1, filed October 16, 1986.
4.2	Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed February 11, 2010.
4.3	Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed May 3, 2010.
4.4	Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed August 19, 2010.
4.5	Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed November 15, 2010.
10.1*	BSD Medical Corporation Fourth Amended and Restated 1998 Director Stock Plan. Incorporated by reference to Exhibit A of the BSD Medical Corporation Schedule 14A, filed December 28, 2009.
10.2*	BSD Medical Corporation Third Amended and Restated 1998 Stock Incentive Plan. Incorporated by reference to Exhibit B of the BSD Medical Corporation Schedule 14B, filed December 28, 2009.
10.3*	BSD Medical Corporation Form of Employee Stock Option Grant. Incorporated by reference to Exhibit 10.7 to BSD Medical Corporation's Annual Report on Form 10-K filed November 14, 2008.
10.4*	BSD Medical Corporation Form of Director Stock Option Grant. Incorporated by reference to Exhibit 10.8 to BSD Medical Corporation's Annual Report on Form 10-K

filed November 14, 2008.

- 10.5\* Employment Agreement dated November 2, 1988 between BSD Medical Corporation and Paul F. Turner. Incorporated by reference to Exhibit 10.8 to BSD Medical Corporation's Registration Statement on Form SB-2 filed January 27, 2004.
- 10.6\* Offer Letter, dated April 7, 2009, between BSD Medical Corporation and Harold R. Wolcott. Incorporated by reference to Exhibit 10.2 of Current Report on Form 8-K filed on April 8, 2009.
- 10.7 Securities Purchase Agreement, dated as of February 11, 2010, by and between BSD Medical Corporation and each of the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed February 11, 2010.
- 10.8 Securities Purchase Agreement, dated as of May 3, 2010, by and between BSD Medical Corporation and each of the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed May 3, 2010.
- 10.9 Securities Purchase Agreement, dated as of August 19, 2010, by and between BSD Medical Corporation and each of the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed August 19, 2010.
- 10.10 Securities Purchase Agreement, dated as of November 15, 2010, by and between BSD Medical Corporation and each of the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed November 15, 2010.
- 10.11 Exclusive Distribution Agreement with Dr. Sennewald Medizintechnik GmbH dated May 13, 2009. Incorporated by reference to Exhibit 10.11 to BSD Medical Corporation's Annual Report on Form Form 10-K filed on November 6, 2009.
- 21.1 Subsidiary List. Incorporated by reference to Exhibit 21.1 of the BSD Medical Corporation Annual Report on Form 10-KSB filed December 1, 2003.
- 23.1 Consent of Independent Registered Public Accounting Firm.
- 31.1 Certification of Chief Executive Officer of BSD pursuant to Rule 13a-14.
- 31.2 Certification of Chief Financial Officer of BSD pursuant to Rule 13a-14.
- 32.1 Certification of Chief Executive Officer attached pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
- 32.2 Certification of the Chief Financial Officer of BSD pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Exhibits marked with an asterisk (\*) are management contracts or compensatory plans or arrangements.

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.

BSD MEDICAL CORPORATION

Date: November 14, 2011

By: /s/ Harold R. Wolcott  
Harold R. Wolcott  
President and Member of the Board of Directors  
(principal executive officer)

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.

Date: November 14, 2011

By: /s/ Harold R. Wolcott  
Harold R. Wolcott  
President and Member of the Board of Directors  
(principal executive officer)

Date: November 14, 2011

By: /s/ Dennis P. Gauger  
Dennis P. Gauger  
Chief Financial Officer (principal financial and  
accounting officer)

Date: November 14, 2011

By: /s/ Timothy C. McQuay  
Timothy C. McQuay  
Chairman of the Board of Directors

Date: November 14, 2011

/s/ Gerhard W. Sennewald  
Dr. Gerhard W. Sennewald  
Member of the Board of Director

Date: November 14, 2011

By: /s/ Steven G. Stewart  
Steven G. Stewart  
Member of the Board of Directors

Date: November 14, 2011

By: /s/ Michael Nobel  
Dr. Michael Nobel  
Member of the Board of Directors

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Date: November 14, 2011

By: /s/ Douglas P. Boyd  
Dr. Douglas P. Boyd  
Member of the Board of Directors

Date: November 14, 2011

By: /s/ Damian E. Dupuy  
Dr. Damian E. Dupuy  
Member of the Board of Directors

BSD MEDICAL CORPORATION  
Index to Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER  
FINANCIAL REPORTING

To the Board of Directors and Stockholders  
of BSD Medical Corporation

We have audited the internal control over financial reporting of BSD Medical Corporation (the Company) as of August 31, 2011, based on criteria established in Internal Control--Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. 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 (3) 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. Also, 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.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of August 31, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of the Company as of August 31, 2011 and 2010, and the related statements of comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended August 31, 2011, and our report dated November 14, 2011 expressed an unqualified opinion thereon.

/s/ TANNER LLC

Salt Lake City, Utah  
November 14, 2011

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders  
of BSD Medical Corporation

We have audited the accompanying balance sheets of BSD Medical Corporation as of August 31, 2011 and 2010, and the related statements of comprehensive loss, stockholders' equity and cash flows for each of the years in the three-year period ended August 31, 2011. 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BSD Medical Corporation as of August 31, 2011 and 2010, and the results of its operations and its cash flows for each of the years in the three-year period ended August 31, 2011, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of BSD Medical Corporation's internal control over financial reporting as of August 31, 2011, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated November 14, 2011 expressed an unqualified opinion thereon.

/s/ TANNER LLC

Salt Lake City, Utah  
November 14, 2011

BSD MEDICAL CORPORATION  
Balance Sheets

	August 31,	
ASSETS	2011	2010
Current assets:		
Cash and cash equivalents	\$ 17,135,968	\$ 8,483,565
Accounts receivable, net of allowance for doubtful accounts of \$20,000	397,264	307,530
Related party trade accounts receivable	408,323	83,834
Income tax receivable	-	50,000
Inventories, net	2,406,214	2,238,254
Other current assets	121,148	135,050
Total current assets	20,468,917	11,298,233
Property and equipment, net	1,445,897	1,352,731
Patents, net	25,092	51,205
	\$ 21,939,906	\$ 12,702,169
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 301,936	\$ 197,082
Accrued liabilities	332,004	223,920
Deferred revenue – current portion	42,214	89,591
Total current liabilities	676,154	510,593
Deferred revenue – net of current portion	192,158	73,351
Total liabilities	868,312	583,944
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock; \$.001 par value, 80,000,000 shares authorized, 29,686,154 and 26,178,679 shares issued, respectively	29,686	26,179
Additional paid-in capital	50,458,729	36,223,350
Treasury stock, 24,331 shares at cost	(234 )	(234 )
Accumulated deficit	(29,416,587)	(24,131,070)
Total stockholders' equity	21,071,594	12,118,225
	\$ 21,939,906	\$ 12,702,169

See accompanying notes to financial statements



BSD MEDICAL CORPORATION  
Statements of Comprehensive Loss

	Years Ended August 31	
	2011	2010
Revenues:		
Sales	\$1,863,773	\$1,273,017
Sales to related parties	1,063,495	309,259
Equipment rental	110,207	-
Total revenues	3,037,475	1,582,276
Cost of revenues:		
Cost of sales	1,074,030	1,182,328
Cost of related party sales	618,823	318,682
Cost of equipment rental	20,073	-
Total cost of revenues	1,712,926	1,501,010
Gross margin	1,324,549	81,266
Operating costs and expenses:		
Research and development	1,483,659	2,429,215
Selling, general and administrative	5,189,561	5,130,017
Total operating costs and expenses	6,673,220	7,559,232
Loss from operations	(5,348,671 )	(7,477,966 )
Other income (expense):		
Interest and investment income	67,233	11,042
Other income (expense)	(3,279 )	3,405
Realized loss on investments	-	-
Total other income (expense)	63,954	14,447
Loss before income taxes	(5,284,717 )	(7,463,519 )
Income tax (provision) benefit	(800 )	6,571
Net loss	(5,285,517 )	(7,456,948 )
Other comprehensive income – decrease in unrealized loss on investments, net of income tax	-	-
Net comprehensive loss	\$(5,285,517 )	\$(7,456,948 )
Loss per common share:		
Basic	\$(0.18 )	\$(0.32 )
Diluted	\$(0.18 )	\$(0.32 )
Weighted average number of shares outstanding:		
Basic	28,838,000	23,257,000
Diluted	28,838,000	23,257,000

See accompanying notes to financial statements

BSD MEDICAL CORPORATION  
Statements of Stockholders' Equity  
Years Ended August 31, 2011, 2010 and 2009

	Common Shares	Stock Amount	Additional Paid-in Capital	Treasury Shares	Stock Amount	Other Comprehensive Income (Loss)	Accumulated Deficit	Total
Balance, September 1, 2008	21,388,958	\$21,389	\$27,565,373	24,331	\$(234)	\$(2,141,416)	\$(5,289,252 )	\$20,155,860
Common stock issued for:								
Services	32,915	33	105,147	-	-	-	-	105,180
Cashless option exercises	617,428	618	(618 )	-	-	-	-	-
Stock-based compensation	-	-	1,117,839	-	-	-	-	1,117,839
Income tax provision from exercise of stock options	-	-	(194,436 )	-	-	-	-	(194,436 )
Unrealized gain on investments net of income tax	-	-	-	-	-	2,141,416	-	2,141,416
Net loss	-	-	-	-	-	-	(11,384,870)	(11,384,870)
Balance, August 31, 2009	22,039,301	22,040	28,593,305	24,331	(234)	-	(16,674,122)	11,940,989
Common stock issued for:								
Services	93,170	93	149,907	-	-	-	-	150,000
Cash, net of offering costs of \$762,528	4,046,208	4,046	6,489,677	-	-	-	-	6,493,723
Stock-based compensation	-	-	990,461	-	-	-	-	990,461
Net loss	-	-	-	-	-	-	(7,456,948 )	(7,456,948 )
Balance, August 31, 2010	26,178,679	26,179	36,223,350	24,331	(234)	-	(24,131,070)	12,118,225



Common  
stock issued  
for:

Services	36,538	36	150,129	-	-	-	-	150,165
Cash, net of offering costs of \$744,844	1,750,000	1,750	9,700,906	-	-	-	-	9,702,656
Exercise of warrants for cash	1,501,134	1,501	2,987,905	-	-	-	-	2,989,406
Exercise of options for cash	213,000	213	331,907	-	-	-	-	332,120
Cashless option exercises	6,803	7	(7 )	-	-	-	-	-
Stock-based compensation	-	-	1,064,539	-	-	-	-	1,064,539
Net loss	-	-	-	-	-	-	(5,285,517 )	(5,285,517 )
Balance, August 31, 2011	29,686,154	\$29,686	\$50,458,729	24,331	\$(234)	\$-	\$(29,416,587)	\$21,071,594

See accompanying notes to financial statements

BSD MEDICAL CORPORATION  
Statements of Cash Flows

	Years Ended August 31,		
	2011	2010	2009
Cash flows from operating activities:			
Net loss	\$(5,285,517 )	\$(7,456,948 )	\$(11,384,870)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	147,501	148,602	134,759
Stock issued for services	150,165	150,000	105,180
Stock-based compensation	1,064,539	990,461	1,117,839
Realized loss on investments	-	-	6,501,586
Decrease (increase) in:			
Receivables	(414,223 )	(60,731 )	846,589
Income tax receivable	50,000	1,365,758	(200,198 )
Inventories	(167,960 )	(443,778 )	(369,323 )
Other current assets	13,902	(40,514 )	19,293
Increase (decrease) in:			
Accounts payable	104,854	(29,823 )	5,300
Accrued liabilities	108,084	(324,159 )	(37,698 )
Customer deposits	-	-	(427,677 )
Deferred revenue	71,430	21,557	45,406
Net cash used in operating activities	(4,157,225 )	(5,679,575 )	(3,643,814 )
Cash flows from investing activities:			
Purchase of property and equipment	(214,554 )	(122,521 )	(36,478 )
Sales of investments	-	-	10,150,957
Purchases of investments	-	-	(23,935 )
Purchase of patents	-	-	(49,444 )
Net cash (used in) provided by investing activities	(214,554 )	(122,521 )	10,041,100
Cash flows from financing activities:			
Net proceeds from the sale of common stock	9,702,656	6,493,723	-
Proceeds from the exercise of warrants	2,989,406	-	-
Proceeds from the exercise of options	332,120	-	-
Net cash provided by financing activities	13,024,182	6,493,723	-
Net increase in cash and cash equivalents	8,652,403	691,627	6,397,286
Cash and cash equivalents, beginning of year	8,483,565	7,791,938	1,394,652
Cash and cash equivalents, end of year	\$ 17,135,968	\$ 8,483,565	\$ 7,791,938

See accompanying notes to financial statements

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BSD MEDICAL CORPORATION  
Notes to Financial Statements

Note 1: Organization and Significant Accounting Policies

**Organization and Business** – BSD Medical Corporation (the Company) was incorporated in the State of Delaware on July 3, 1986. We develop, manufacture, market, and service systems to treat cancer and benign diseases using heat therapy delivered using focused microwave and radiofrequency (RF) energy. Our product lines include both hyperthermia and ablation treatment systems. Our hyperthermia cancer treatment systems, which have been in use for several years in the United States, Europe and Asia, are used to treat certain tumors with heat (hyperthermia) while increasing the effectiveness of other therapies such as radiation therapy. Our microwave ablation system has been developed as a stand-alone therapy to ablate and destroy soft tissue. We have developed extensive intellectual property, multiple products in the market and well established distribution in the United States, Europe and Asia. Certain of our products have received regulatory approvals in the United States, Europe and China.

**Cash and Cash Equivalents** – Cash and cash equivalents consist of cash and investments with original maturities to the Company of three months or less.

**Investments** – Investments with scheduled maturities greater than three months, but not greater than one year, are recorded as short-term investments. As of August 31, 2011 and 2010, we had no investments. Investments are carried at fair value based on quoted market prices, with net unrealized gains and losses reported as other comprehensive income (loss) in stockholders' equity in our balance sheets. Realized gains and losses are included in our statements of comprehensive loss.

**Accounts Receivable** – Trade accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a monthly basis. Management estimates an allowance for doubtful accounts by identifying troubled accounts and by using historical experience applied to an aging of accounts. Trade accounts receivable are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded when received. Interest is not charged on trade receivables that are outstanding beyond their due date.

**Inventories** – Parts and supplies inventories are stated at the lower of cost or market. Cost is determined using the average cost method. Work-in-process and finished goods are stated at the lower of the accumulated manufacturing costs or market. We maintain a reserve for obsolete inventories to reduce excess and obsolete inventories to their estimated net realizable value. The reserve was \$100,000 at August 31, 2011 and 2010.

**Property and Equipment** – Property and equipment are stated at cost less accumulated depreciation. Depreciation is determined using the straight-line method over the following estimated useful lives of the assets.

Equipment	2 – 5 years
Rental equipment	5 years
Furniture and fixtures	5 years
Building improvements	15 years
Building	40 years

Expenditures for maintenance and repairs are expensed when incurred and betterments are capitalized. Gains and losses on sales of property and equipment are reflected in operations.

The cost and accumulated depreciation of property and equipment sold or otherwise retired are removed from the accounts and any related gain or loss on disposition is reflected in net income or loss for the period.

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Patents – Patents are carried at cost and are being amortized over their remaining legal life, up to a period of 17 years.

Warranty Reserve – We provide limited warranties to our customers for products sold. Estimated future warranty obligations are accrued each period. As of August 31, 2011 and 2010, the accrued warranty reserve was \$28,867 and \$21,183, respectively. During the fiscal years ended August 31, 2011, 2010, and 2009, total warranty expense was \$34,303, \$28,509 and \$58,002, respectively.

Income Taxes – We account for income taxes using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Income (Loss) Per Common Share – The computation of basic income (loss) per common share is based on the weighted average number of shares outstanding during each year.

The computation of diluted earnings per common share is based on the weighted average number of shares outstanding during the year, plus the common stock equivalents that would arise from the exercise of stock options and warrants outstanding, using the treasury stock method and the average market price per share during the year. Common stock equivalents are not included in the diluted loss per share calculation when their effect is anti-dilutive. Options and warrants to purchase 5,260,762, 5,236,043 and 2,379,087 shares of common stock at prices ranging from \$1.20 to \$7.95, \$0.56 to \$7.95, and \$0.56 to \$7.95 per share were outstanding at August 31, 2011, 2010 and 2009, respectively.

The shares used in the computation of the basic and diluted earnings per share are reconciled as follows:

	Years Ended August 31,		
	2011	2010	2009
Weighted average number of shares outstanding – basic	28,838,000	23,257,000	21,887,000
Dilutive effect of stock options and warrants	-	-	-
Weighted average number of shares outstanding, assuming dilution	28,838,000	23,257,000	21,887,000

Stock-Based Compensation - Stock-based compensation is measured at the grant date based on the value of the award granted using the Black-Scholes option pricing model, and recognized over the period in which the award vests. For stock awards no longer expected to vest, any previously recognized stock compensation expense is reversed in the period of termination. The stock-based compensation expense is allocated to the various categories of operating costs and expenses in a manner similar to the allocation of payroll expense.

Revenue Recognition – We recognize revenue from the sale of medical systems, the sale of parts and accessories related to the systems, equipment rental, providing training, and service support contracts. Total product sales, including related party product sales, were \$2,581,275, \$1,261,490 and \$3,293,116 for the years ended August 31, 2011, 2010 and 2009, respectively. Equipment rental income was \$110,207 for the year ended August 31,

2011. Total service and other revenues, including related party service and other revenues, were \$345,993, \$320,786 and \$243,371 for the years ended August 31, 2011, 2010 and 2009, respectively.

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Revenue from the sale of cancer treatment systems is recognized when a purchase order has been received, the system has been shipped, the selling price is fixed or determinable, and collection is reasonably assured. Most system sales are F.O.B. shipping point; therefore, shipment is deemed to have occurred when the product is delivered to the transportation carrier. Most system sales do not include installation. If installation is included as part of the contract, revenue is not recognized until installation has occurred, or until any remaining installation obligation is deemed to be perfunctory. Some sales of systems may include training as part of the sale. In such cases, the portion of the revenue related to the training, calculated based on the amount charged for training on a stand-alone basis, is deferred and recognized when the training has been provided. The sales of our cancer treatment systems do not require specific customer acceptance provisions and do not include the right of return except in cases where the product does not function as warranted by us. To date, returns have not been significant.

Revenue from the sale of consumable devices is recognized when a purchase order has been received, the devices have been shipped, the selling price is fixed or determinable, and collection is reasonably assured. Currently, our customers are not required to purchase a minimum number of disposable devices in connection with the purchase of our systems.

Revenue from training services is recorded when an agreement with the customer exists for such training, the training services have been provided, and collection is reasonably assured.

Revenue from service support contracts is recognized on a straight-line basis over the term of the contract, which approximates recognizing it as it is earned.

Revenue from equipment rental under an operating lease is recognized when billed in accordance with the lease agreement.

Our revenue recognition policy is the same for sales to both related parties and non-related parties. We provide the same products and services under the same terms for non-related parties as with related parties.

Sales to distributors are recognized in the same manner as sales to end-user customers.

Deferred revenue and customer deposits payable include amounts from service contracts as well as cash received for the sales of products, which have not been shipped.

Concentration of Credit Risk – Financial instruments that potentially subject us to concentration of credit risk consists primarily of trade receivables. In the normal course of business, we provide credit terms to our customers. Accordingly, we perform ongoing credit evaluations of our customers and maintain allowances for possible losses.

We have cash in the bank and short-term investments that exceed federally insured limits. We have not experienced any losses in such accounts.

Advertising and Promotion – Advertising and promotion costs, which are principally included in sales expenses, are expensed as incurred. Advertising and promotion expense was \$275,393, \$61,294 and \$86,287 for the years ended August 31, 2011, 2010 and 2009, respectively.

Use of Estimates in the Preparation of Financial Statements – The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the



reporting period. Actual results could differ from those estimates.

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Comprehensive Income (Loss) – Comprehensive income (loss) consists of net income (loss) and the net change in other comprehensive income (loss) resulting from net unrealized gains and losses on our investments, and is reported in the accompanying statements of comprehensive loss.

Reclassifications – Certain amounts in the prior years have been reclassified to conform with the current year presentation.

## Note 2: Detail of Certain Balance Sheet Accounts

Details of certain balance sheet accounts are as follows:

	August 31,	
	2011	2010
Accounts receivable:		
Trade receivables – non-related party	\$ 416,495	\$ 313,419
Other receivables	769	13,683
Accrued interest receivable	-	428
Allowance for doubtful accounts	(20,000 )	(20,000 )
	\$ 397,264	\$ 307,530

### Inventories:

Parts and supplies	\$ 1,248,534	\$ 1,164,697
Work-in-process	1,110,362	1,130,320
Finished goods	147,318	43,237
Reserve for obsolete inventories	(100,000 )	(100,000 )
	\$ 2,406,214	\$ 2,238,254

### Accrued liabilities:

Warranty reserve	\$ 28,867	\$ 21,183
Training and installation reserve	9,341	4,907
Accrued taxes payable	34,685	22,282
Payroll and other	259,111	175,548
	\$ 332,004	\$ 223,920



## Note 3: Property and Equipment

Property and equipment consists of the following:

	August 31,	
	2011	2010
Equipment	\$ 1,314,814	\$ 1,181,985
Rental equipment	58,940	-
Furniture and fixtures	298,576	298,576
Building improvements	47,005	24,220
Building	956,000	956,000
Land	244,000	244,000
	2,919,335	2,704,781
Less accumulated depreciation	(1,473,438)	(1,352,050)
	\$ 1,445,897	\$ 1,352,731

Depreciation expense for the years ended August 31, 2011, 2010 and 2009 totaled \$121,388, \$122,174 and \$125,618, respectively.

## Note 4: Patents

We have certain patents recorded net of accumulated amortization. The patents are being amortized on a straight-line basis over their remaining legal life, up to a period of 17 years. Amortization expense was \$26,113, \$26,428 and \$9,141 for the years ended August 31, 2011, 2010, and 2009, respectively. Amortization expense relating to the patents for the next five years is expected to be as follows:

Year ending August 31,	
2012	\$ 21,060
2013	993
2014	588
2015	588
2016	588
	\$ 23,817

## Note 5: Stockholders' Equity

The Company has 10,000,000 authorized shares of \$.001 par value preferred stock. As of August 31, 2011 and 2010, there were no shares of preferred stock outstanding.

In February 2011, the stockholders of the Company approved an amendment to the Company's Amended and Restated Certificate of Incorporation to increase the number of shares of authorized \$.001 par value common stock from 40,000,000 to 80,000,000.

## Stock Offerings

On October 1, 2009, our universal shelf registration statement was declared effective by the SEC for the issuance of common stock, preferred stock, warrants, senior debt, subordinated debt and units up to an aggregate amount of \$50.0 million. We may periodically offer one or more of these securities in amounts, prices and on terms to be announced when and if the securities are offered. At the time any of the securities covered by the registration statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering. We have previously completed four offerings utilizing our universal shelf registration statement. Each of these offerings was completed during calendar year 2010.

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On each of February 11, 2010, May 3, 2010, August 19, 2010, and November 15, 2010, we entered into a placement agency agreement (collectively, the “Agency Agreements”) with Roth Capital Partners, LLC (the “Placement Agent”), pursuant to which the Placement Agent agreed to use its reasonable efforts to arrange for the sale of shares of our common stock and warrants in registered direct public offerings. These offerings are referred to herein as the “February Offering,” “May Offering,” “August Offering” and “November Offering” (each, an “Offering” and collectively the “2010 Offerings”). In connection with each of the Offerings, we and certain institutional investors also entered into securities purchase agreements (collectively, the “Purchase Agreements”) pursuant to which we agreed to sell shares of our common stock and warrants to purchase additional shares of our common stock to the investors. The common stock and warrants were sold in fixed combinations, with each combination consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock (0.50 shares in the case of the November Offering). The warrants became exercisable six months and one day following the closing date of the Offering and will remain exercisable for five years thereafter. The exercise price of the warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

The number of shares of our common stock and number of shares of our common stock issuable upon exercise of the warrants as well as the purchase price per fixed combination and the exercise price associated with each warrant which were sold the 2010 Offerings are shown below:

2010 Offerings	Shares of Common Stock	Warrants – Shares of Common Stock Issuable upon Exercise of the Warrants	Purchase Price per Fixed Combination	Warrant Exercise Price (Per Share)
February Offering	1,176,471	882,354	\$ 1.70	\$ 2.04
May Offering	1,644,737	1,233,553	\$ 1.52	\$ 1.94
August Offering	1,225,000	918,750	\$ 2.25	\$ 3.27
November Offering	1,750,000	875,000	\$ 5.97	\$ 7.73

The Placement Agent was entitled to a cash fee of 6.5% of the gross proceeds paid to us for the securities we would sell in each of the Offerings. We would also reimburse the Placement Agent for all reasonable and documented out-of-pocket expenses that would be incurred by the Placement Agent in connection with each of the Offerings, which could not exceed in the case of each of the Offerings the lesser of (i) \$75,000 (\$30,000 in the case of November Offering and in the case of the February Offering, \$75,000 less a \$25,000 cash advance for expenses), or (ii) 8% of the gross proceeds of the Offering, less the Placement Agent’s placement fee (and in the case of the February Offering, also less the \$25,000 cash advance for expenses). Each of the Agency Agreements contains customary representations, warranties and covenants by us. They also provide for customary indemnification by us and the Placement Agent for losses or damages arising out of or in connection with the sale of the securities being offered. We also agreed to indemnify the Placement Agent against liabilities under the Securities Act of 1933, as amended. We also agreed to contribute to payments the Placement Agent may be required to make in respect of such liabilities.

The exercisability of the warrants sold in the 2010 Offerings may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.9% of our common stock.

We agreed with each of the purchasers that while the warrants are outstanding, we will not affect or enter into an agreement to affect a “Variable Rate Transaction,” which means a transaction in which we:

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- issue or sell any convertible securities either (A) at a conversion, exercise or exchange rate or other price that is based upon and/or varies with the trading prices of, or quotations for, the shares of our common stock at any time after the initial issuance of such convertible securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such convertible securities or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for our common stock, other than pursuant to a customary “weighted average” anti-dilution provision; or
- enter into any agreement (including, without limitation, an equity line of credit) whereby we may sell securities at a future determined price (other than standard and customary “preemptive” or “participation” rights).

We agreed with each of the purchasers if we issue securities within the 12 months following the closing of an Offering, the purchasers shall have the right to purchase all of the securities on the same terms, conditions and price provided for in the proposed issuance of securities.

We also agreed to indemnify each of the purchasers against certain losses resulting from our breach of any of our representations, warranties, or covenants under agreements with each of the purchasers, as well as under certain other circumstances described in the Purchase Agreements.

We closed the February Offering on February 17, 2010. The aggregate gross proceeds to us from the February Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$2 million. The net proceeds to us from the February Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$1.7 million.

We closed the May Offering on May 6, 2010. The aggregate gross proceeds to us from the May Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$2.5 million. The net proceeds to us from the May Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$2.3 million.

We closed the August Offering on August 24, 2010. The aggregate gross proceeds to us from the August Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$2.75 million. The net proceeds to us from the August Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$2.5 million.

We closed the November Offering on November 18, 2010. The aggregate gross proceeds to us from the November Offering, before deducting fees to the Placement Agent and other offering expenses payable by us, were approximately \$10.45 million. The net proceeds to us from the November Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately \$9.7 million.

#### Warrant Exercises

During our fiscal year ended August 31, 2011, investors exercised warrants to purchase a total of 1,501,134 common shares, with net proceeds to the Company of approximately \$3.0 million. As of November 14, 2011, we have issued 772,060 shares of our common stock as a result of the exercise of warrants issued in the February Offering, and 729,074 shares of our common stock as a result of the exercise of warrants issued in the May Offering.



A summary of the outstanding warrants issued in the stock offerings as of August 31, 2011 and changes during the year then ended is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (Years)
Outstanding at August 31, 2010	3,034,657	\$ 2.37	
Granted	875,000	7.73	
Exercised	(1,501,134)	1.99	
Forfeited or expired	-	-	
Outstanding and exercisable at August 31, 2011 (all exercisable)	2,408,523	\$ 4.56	4.48

#### Note 6: Deferred Revenue

We have entered into certain service contracts for which we have received payment in advance. We are recognizing these service revenues over the life of the service agreements.

As of August 31, 2011 and 2010, we had deferred revenue of \$234,372 and \$162,942, respectively.

#### Note 7: Major Customers and Foreign Sales

We had the following customer revenue concentrations:

	Years Ended August 31,		
	2011	2010	2009
Customer A	35.01 %	19.55 %	17.05 %
Customer B	*	22.75 %	16.40 %
Customer C	*	*	13.73 %
Customer D	*	*	10.18 %
Customer E	*	19.15 %	*
Customer F	*	15.86 %	*
Customer G	*	12.04 %	*
Customer H	10.01 %	*	*

Customer I	10.01 %	*	*
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\*Sales to customers were less than 10%.

Export sales were \$1,135,372, \$678,893 and \$1,668,547 in fiscal years 2011, 2010 and 2009, respectively.

During fiscal year 2011, export sales to Germany were approximately 35% of total sales. During fiscal year 2010, export sales to China and Germany were approximately 23% and 12% of total sales, respectively. During fiscal year 2009, export sales to China, Switzerland and Poland were approximately 16%, 13% and 14% of total sales, respectively.

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## Note 8: Related Party Transactions

During the years ended August 31, 2011, 2010, and 2009, we had sales of \$1,063,495, \$309,259 and \$603,000, respectively, to entities controlled by a significant stockholder and member of the Board of Directors. These related party transactions represent 35%, 20% and 17% of total sales for each respective year.

At August 31, 2011 and 2010, receivables include \$408,323 and \$83,834, respectively, from these related parties.

## Note 9: Income Taxes

The components of the income tax (provision) benefit are as follows:

	Years Ended August 31,		
	2011	2010	2009
Current:			
Federal	\$ -	\$ -	\$ 1,346,000
State	(800 )	6,571	33,000
	(800 )	6,571	1,379,000
Deferred:			
Federal	-	-	(229,000 )
	\$ (800 )	\$ 6,571	\$ 1,150,000

The income tax (provision) benefit differs from the amount computed at federal statutory rates as follows:

	Years Ended August 31,		
	2011	2010	2009
Income tax benefit at federal statutory rate	\$ 1,797,000	\$ 2,538,000	\$ 4,262,000
Stock-based compensation	(249,000 )	(205,000 )	(252,000 )
State income taxes, net of federal benefit	174,000	246,000	447,000
Research and development credit	102,000	209,000	309,000
Valuation allowance	(1,688,000)	(3,127,000)	(3,809,000)
Other	(136,800 )	345,571	193,000

\$ (800 ) \$ 6,571 \$ 1,150,000

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Deferred tax assets (liabilities) are comprised of the following:

	August 31,	
	2011	2010
Current Asset:		
Accruals and reserves	\$ 21,000	\$ 54,000
Deferred revenue	87,000	60,000
Inventories	85,000	90,000
Research and development and other tax credits	1,651,000	1,676,000
Net operating loss carryforwards	5,903,000	5,165,000
Valuation allowance	(7,747,000)	(7,045,000)
	\$ -	\$ -
Long-Term Asset:		
Deferred compensation	\$ 505,000	\$ 426,000
Long-Term Liability:		
Depreciation and amortization	(9,000 )	(16,000 )
Valuation allowance	(496,000 )	(410,000 )
	\$ -	\$ -

The ultimate realization of the deferred tax assets is dependent, in part, upon the tax laws in effect, our future earnings, and other events. As of August 31, 2011, we recorded a valuation allowance of \$7,747,000 against current deferred tax assets and a valuation allowance of \$496,000 against net long-term deferred tax assets. The increase in the valuation allowance for the year ended August 31, 2011 relates primarily to our operating losses. In recording the valuation allowance, we were unable to conclude that it is more likely than not that our deferred tax assets will be realized.

At August 31, 2011, we had a net operating loss carryforward available to offset future taxable income of approximately \$15,000,000, which will begin to expire in 2029. If substantial changes in the Company's ownership should occur, there would be an annual limitation of the amount of the net operating loss carryforward which could be utilized.

We perform a review of our material tax positions in accordance with recognition and measurement standards established by authoritative accounting literature, which requires a company to determine whether it is more likely than not that a tax position will be sustained upon examination based upon the technical merits of the position. If the more-likely-than-not threshold is met, a company must measure the tax position to determine the amount to recognize in the financial statements. Based upon our review and evaluation, during the years ended August 31, 2011, 2010 and 2009, we concluded the Company had no unrecognized tax benefit which would affect its effective tax rate if recognized.

We classify any interest and penalties arising from the underpayment of income taxes in our statements of comprehensive loss in other income (expense). As of August 31, 2011 and 2010, we had no accrued interest or penalties related to uncertain tax positions.

We file income tax returns in the U.S. federal jurisdiction and various state jurisdictions. U.S. federal income tax returns from the year ended August 31, 2006 through the year ended August 31, 2011 are subject to examination.

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## Note 10: Stock-Based Compensation

Our Third Amended and Restated 1998 Stock Incentive Plan (the “Plan”) authorizes the granting of incentive stock options to certain key employees and non-employees who provide services to the Company. The Plan, as amended, provides for the granting of options for an aggregate of 6,337,300 shares. The options vest subject to management’s discretion.

Our Fourth Amended and Restated 1998 Directors Stock Plan (the “Director Plan”) provides an annual retainer of \$60,000 to each non-employee director with the exception of the Audit Committee Chairman who is to receive \$65,000. The cash portion of the compensation of \$30,000 (\$35,000 for the Audit Committee Chairman) is paid 50% twice each year, with \$30,000 of compensation paid in common stock of the Company once each year. Prior to February 4, 2009, the annual compensation consisted of \$15,000 cash (\$20,000 for the Audit Committee Chairman) paid 50% twice each year, with \$15,000 in common stock of the Company. Prior to February 4, 2009, the Director Plan also granted each non-employee outside director 30,000 options each year at an exercise price equal to the fair market value of the common stock at the date the option was granted. The options vest according to a set schedule over a five-year period and expire upon the director’s termination, or after ten years from the date of grant. The Director Plan, as amended, allows for an aggregate of 1,750,000 shares to be granted.

Stock-based compensation cost is measured at the grant date based on the estimated value of the award granted, using the Black-Scholes option pricing model, and recognized over the period in which the award vests. For stock awards no longer expected to vest, any previously recognized stock compensation expense is reversed in the period of termination. The stock-based compensation expense has been allocated to the various categories of operating costs and expenses in a manner similar to the allocation of payroll expense as follows for the years ended August 31:

	2011	2010	2009
Cost of sales	\$ 38,273	\$ 40,617	\$ 72,988
Research and development	185,406	174,026	186,690
Selling, general and administrative	840,860	775,818	858,161
Total	\$ 1,064,539	\$ 990,461	\$ 1,117,839

During the year ended August 31, 2011, we granted 906,000 stock options to employees with exercise prices ranging from \$3.53 to \$4.81 per share and with one third vesting each year for the next three years. The weighted average estimated grant-date fair value per share of these stock options was \$2.20, and our assumptions used in the Black-Scholes valuation model to determine this estimated fair value are shown below:

Expected volatility	64.76%
Expected dividends	0%
Expected term	5.6 Years
	2.07%

Risk-free  
interest  
rate

The expected volatility rate was estimated based on the historical volatility of our common stock. The expected term was estimated based on historical experience of stock option exercise and forfeitures. The risk-free interest rate is the rate provided by the U.S. Treasury for Daily Treasury Yield Curve Rates commonly referred to as “Constant Maturity Treasury” rate in effect at the time of grant with a remaining term equal to the expected option term.

Unrecognized stock-based compensation expense expected to be recognized over the estimated weighted-average amortization period of 1.64 years is approximately \$2,652,000 at August 31, 2011.

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A summary of the time-based stock option awards as of August 31, 2011, and changes during the year then ended, is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (Years)	Aggregate Intrinsic Value
Outstanding at September 1, 2010	2,201,386	\$ 3.19		
Granted	906,000	4.59		
Exercised	(221,547 )	1.55		\$ 725,230
Forfeited or expired	(33,600 )	4.90		
Outstanding at August 31, 2011	2,852,239	\$ 3.74	6.83	\$ 1,423,668
Exercisable at August 31, 2011	1,097,467	\$ 3.66	5.57	\$ 678,118

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value, based on the Company's closing stock price of \$2.93 as of August 31, 2011, which would have been received by the holders of in-the-money options had the option holders exercised their options as of that date.

During the year ended August 31, 2011, employees and directors exercised options to purchase a total of 221,547 common shares, with net proceeds to the Company of \$332,120.

#### Note 11: Grant Awards

In November 2010, we were awarded two separate U.S. government grants under the Qualifying Therapeutic Discovery Project ("QTDP") Program. We submitted grant applications for our BSD-2000 Hyperthermia System and our MicroThermX® Microwave Ablation System, and both applications were approved for the maximum award for a single program of \$244,479, or a total of \$488,958. In order to qualify for the QTDP grants, the project must have the potential to develop new treatments that address "unmet medical needs" or chronic and acute diseases; reduce long-term health care costs; represent a significant advance in finding a cure for cancer; advance U.S. competitiveness in the fields of life, biological, and medical sciences; or create or sustain well-paying jobs, either directly or indirectly. The QTDP was created by Congress in March 2010 as part of the Patient Protection and Affordable Care Act and provides a tax credit or a grant equal to 50% of eligible costs and expenses for tax years 2009 and 2010.

#### Note 12: Realized Loss on Investments

We liquidated 100% of our investments in mutual funds in March and May 2009 and recognized a loss on investments in our statements of comprehensive loss of \$6,501,586 for the year ended August 31, 2009. The cost basis of these investments was \$16,652,543, determined on a specific identification basis. Proceeds of \$10,150,957 from these sales of investments were deposited in money market funds.



## Note 13: Supplemental Cash Flow Information

Actual amounts paid for interest and income taxes are as follows:

	Years Ended August 31,		
	2011	2010	2009
Interest expense	\$ -	\$ -	\$ 1,675
Income taxes	\$ 800	\$ -	\$ 17,132

During the year ended August 31, 2010 we had no non-cash financing and investing activities. We had the following non-cash financing and investing activities for the years ended August 31, 2011 and 2009:

During the year ended August 31, 2011, we:

- Increased common stock and decreased additional paid-in capital by \$7.

During the year ended August 31, 2009, we:

- Decreased income tax receivable and additional paid-in capital by \$194,436.
- Increased other comprehensive loss and decreased investments by \$4,360,170.
- Increased common stock and decreased additional paid-in capital by \$618.

## Note 14: Commitments and Contingencies

We entered into an employment agreement with our Senior Vice President and Chief Technical Officer (“CTO”) dated November 2, 1988. The agreement sets the CTO’s annual base salary for each year until October 1, 1993 and provides that after October 1, 1993 the CTO’s annual base salary will be based upon a reasonable mutual agreement between the CTO and the Company. The CTO’s annual base salary was raised to \$210,000 effective September 1, 2006. In the event of termination of the CTO’s employment with the Company without cause (as defined in the agreement) or the CTO’s resignation for good reason (as defined in the agreement), the agreement provides that the CTO will receive severance pay for a one-year period, which pay includes an extension of all of his rights, privileges and benefits as an employee (including medical insurance). The one-year severance pay shall be equal to the CTO’s average annual salary for the 12-month period immediately prior to the termination. The agreement also requires us to pay the CTO for any accrued, unused vacation at the time of termination. We are also obligated to pay the CTO \$1,000 (or the equivalent value in stock options) for each newly issued patent obtained by us as a result of the CTO’s efforts (the CTO receives only \$500 if multiple inventors are involved). The CTO’s agreement includes a non-competition covenant prohibiting him from competing with us for one year following his termination. We may continue the non-competition period for up to four additional years by notifying the CTO in writing and by continuing the severance payments for the additional years during which the non-competition period is extended.

We have an exclusive worldwide license for a unique temperature probe. The license has no determinable life. We pay royalties based upon sales of this probe. Accrued royalties were \$700 and \$1,225 as of August 31, 2011 and 2010, respectively. Royalty expense amounted to \$3,535, \$3,360 and \$6,180 for the years ended August 31, 2011,

2010 and 2009, respectively.

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Note 15: Recent Accounting Pronouncements

Accounting Standards Update (“ASU”) No. 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income, was issued in June 2011. This update eliminates the option to present the components of other comprehensive income in the statement of changes in equity and requires presentation of net income and other comprehensive income (and their respective components) either in a single continuous statement or in two separate but consecutive statements. The amendments in this update are to be applied retrospectively. For public entities, the amendments are effective for interim and annual periods beginning after December 15, 2011. Early adoption is permitted. The Company has adopted the practice of presenting a single continuous statement of net comprehensive loss.

ASU No. 2011-08, Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment, was issued in September 2011. The objective of this update is to simplify how entities, both public and nonpublic, test goodwill for impairment. The amendments in the update permit an entity to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in Topic 350. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. Previous guidance under Topic 350 required an entity to test goodwill for impairment, on at least an annual basis, by comparing the fair value of a reporting unit with its carrying amount, including goodwill (step one). If the fair value of a reporting unit is less than its carrying amount, then the second step of the test must be performed to measure the amount of the impairment loss, if any. Under the amendments in this update, an entity is not required to calculate the fair value of a reporting unit unless the entity determines that it is more likely than not that its fair value is less than its carrying amount. This update is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011, or our fiscal quarter ending May 31, 2012. Early adoption is permitted. Since we currently have no reported goodwill balances, we do not believe the adoption of this pronouncement will have a material impact on our financial statements.

Note 16: Subsequent Events

Employee Stock Options - Subsequent to August 31, 2011, we granted 50,000 stock options to employees with an exercise price of \$2.58 per share and with one third vesting each year for the next three years.