BSD MEDICAL CORP
Form 10-K
November 14, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended August 31, 2013

[ ] 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 Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the

Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 x (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of February 28, 2013 was approximately $30,218,360.

As of November 9, 2013, the registrant had 34,006,202 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 2014 Annual Meeting of Shareholders, which is expected to be held February 6, 2014, are incorporated by reference into Part III hereof.

BSD MEDICAL CORPORATION
FORM 10-K

For the Year Ended August 31, 2013

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PART I

ITEM 1. BUSINESS

Forward-Looking Statements

This annual report on Form 10-K contains 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 Item 1A, “Risk Factors,” and Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

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.

In spite of the advances in cancer treatment technology, the five year survival rate for all cancers in the United States is only 67%. 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 40-45°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.

We are experiencing growth in our operating revenues from our MicroThermX® Microwave Ablation System ("MicroThermX") line of products as a result of an exclusive, long-term, multi-million dollar distribution agreement with Terumo Europe NV (Terumo), a wholly owned subsidiary of Terumo Corporation. The agreement with Terumo, which we announced in April 2013, covers 100 countries in Europe, Western Asia, and Northern Africa. In addition, MicroThermX revenues and sales of disposable SynchroWave antennas have increased in the US market as well.

The number of hyperthermia systems sold has decreased this year due to negative regulatory, economic and other healthcare industry factors. We have experienced declining hyperthermia revenues from our distributor in Europe, a related party. We have entered into distribution agreements for our hyperthermia systems in China, South Korea and Taiwan. We anticipate that these distribution agreements will result in increased hyperthermia sales in the future; however, certain regulatory approvals must first be obtained in these countries before we will realize increased sales, and we cannot currently predict the outcome of these efforts.

We recognize revenues from the sale of our ablation and hyperthermia cancer treatment systems and related parts and accessories (collectively, product sales), the sale of disposable devices used with certain of our systems, training, service support contracts and other miscellaneous revenues. We also recognize revenues from equipment rental, including fee-per-use rental income from our MicroThermX. Information regarding our revenues, assets, and results of our operations is contained in our financial statements and notes thereto and in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, included in this annual report on Form 10-K.

Our current corporate strategy includes the possibility of entering into additional collaborative arrangements with third parties to expand and improve the commercialization of all our products, including our hyperthermia systems. The recent signing of the master distribution agreement with Terumo for our MicroThermX line of products was a result of this strategy. Consistent with this strategy, we engaged Roth Capital Partners on June 1, 2013, to serve as our exclusive advisor with the goal to seek out, identify opportunities and, if possible, secure a transaction or transaction(s) relating to BSD's hyperthermia business, including, but not limited to, partnering or other collaborative agreements, a sale of assets and/or other strategic arrangements. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

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 estimated that during 2013 approximately 1,660,000 new cancer cases will be diagnosed and that approximately 580,000 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 is the second most common cause of death in the US, exceeded only by heart disease, accounting for nearly 1 of every 4 deaths. 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, which are used in conjunction with the heat therapy. Therapies currently used to treat cancer include radiation therapy, chemotherapy, surgery, ablation and hyperthermia.

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.

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.

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.

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 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 observed, and temperatures can be monitored through images colorized to depict gradation of temperature levels (thermography).

Our hyperthermia systems include the BSD-500 Hyperthermia System, which is used to treat certain cancers located on or near the surface of the body or areas that can be accessed using inserted antennae and the BSD-2000 Hyperthermia System family of products used to non-invasively deliver localized hyperthermia to solid tumors, including those located deep within the body.

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 Microwave Ablation System (“MicroThermX”) is a compact, mobile, state-of-the-art, proprietary system that includes a microwave generator, single-patient-use disposable antennas with cooling circuit, 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, proprietary, synchronous phased array technology that was developed and patented by us to provide scalable and more uniform zones of ablation during a single procedure.

The MicroThermX introduces into our product line an innovative SynchroWave 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. We expanded the MicroThermX market opportunity by introducing a new SynchroWave short tip ("ST") antenna that can be used to deliver smaller, spherical ablation zones that more accurately target smaller tumors. The existing SynchroWave long tip ("LT") antenna delivers larger ablation zones, reducing the need for multiple ablations on larger tumors. The multiple configurations of the SynchroWave antenna provide physicians the ability to precisely target the ablation zone to the numerous sizes and shapes of diseased tissue, significantly increasing the number of cases that can be treated with the MicroThermX®. The soft tissue ablation world market potential is estimated to exceed $2.3 billion.

Our Table Top MicroThermX® Microwave Ablation System ("T2") is designed for our fee-per-use rental program, which is more fully described below. Portability and ease of use are keys to successful implementation of the equipment rental program. The T2 is a small, lightweight, tabletop configuration that has the same advanced features as the original MicroThermX configuration.

In August 2010, the U.S. Food and Drug Administration ("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 (Conformité Européenne) 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. As further discussed below, we have established distribution in a number of countries and have accepted purchase orders for and have shipped both MicroThermX systems and SynchroWave antennas.

Clinicians have used microwave ablation systems to treat patients with cancers of the liver, lung, bone, and kidneys.

We have placed a select number of MicroThermX systems with pivotal, high-profile, interventional oncology opinion leaders. These medical facilities continue to reorder disposable SynchroWave antennas, validating the ongoing revenue stream we anticipate. Existing users of the MicroThermX continue to report positive clinical results in the treatment of cancerous tumors.

These evaluations represent an important milestone in the MicroThermX sales cycle. However, with hospital capital budgeting, committee review and other approvals, the sales cycle for the MicroThermX may extend to well over six months. Political and economic uncertainty in the industry due to recent government healthcare reform and increasing regulatory requirements throughout the world are also slowing hospital acquisition of capital equipment at all levels.

In April 2013, we announced an exclusive multi-million dollar master distribution agreement with Terumo Europe NV, a wholly owned subsidiary of Terumo Corporation, for our MicroThermX line of products in 100 countries in Europe, Western Asia and Northern Africa. Terumo Corporation is a global medical device leader with nearly $5 billion in annual sales and operations in over 160 countries. Terumo Europe NV has established itself as a pioneer in the field of interventional oncology. The potential market size for MicroThermX in these countries is estimated to be in excess of $1 billion in annual sales. We believe this distribution agreement validates the large market opportunity for MicroThermX ablation products and is expected to drive market adoption for the MicroThermX as a leading ablation therapy system and to drive revenue growth toward profitability.

With the initial success of our relationship with Terumo Europe NV, we will continue our strategy to seek out other master distribution arrangements in lucrative geographic medical device markets such as Asia and South America.

Domestically we have sales representatives covering the following key metropolitan areas: Florida, New York, New Jersey, Philadelphia, Chicago, Phoenix, Las Vegas, Southern California, Dallas and Houston, Ohio, Western Pennsylvania, Northern Kentucky and Oklahoma. We will continue to expand our sales force into other domestic metropolitan areas in the future.

In addition to selling our MicroThermX line we also offer a MicroThermX fee-per-use equipment rental program. The fee-per-use program allows hospitals to purchase disposable SynchroWave antennas and pay a fee-per-use equipment rental for the treatment of patients using the MicroThermX, dramatically shortening the sales cycle. This rental program has generated a revenue stream from sales of disposable SynchroWave antennas combined with highly profitable equipment rental fees. We continue to aggressively market and sell the rental program throughout the U.S.

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We are committed to "personal service" to new users of the microwave ablation technique. We provide all of our customers with extensive hands-on training to ensure success in clinical use of the MicroThermX system. Our representatives are experienced interventional sales representatives with seasoned contacts in the field of interventional oncology. Our senior sales management team includes professionals with a rich history in marketing medical devices and equipment worldwide.

Hyperthermia Systems

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. The BSD-500 is approved for use alone or in conjunction with radiation therapy in the palliative management of certain solid surface and subsurface malignant tumors (i.e., melanoma, squamous- or basal-cell carcinoma, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional therapy.

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.

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 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 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 used with a magnetic resonance system that provides non-invasive 3D thermometry imaging of the heated regions for image guided therapy, thus permitting the clinician to

view the heating pattern in the tumor and steer the energy to the tumor site.

We have received CE Marking for the BSD-2000 family of products, which allows us to market the BSD-2000 systems in the thirty countries that comprise the EU and the EFTA. CE Marking is also recognized in many countries outside of the EU, providing us the ability to market the BSD-2000 family of products to a number of international markets.

The BSD-2000 Hyperthermia System is approved in the EU as a cancer therapy to deliver targeted therapeutic in conjunction with chemotherapy and/or radiation therapy in order to destroy malignant tumors. The BSD-2000 is used to deliver therapeutic heat to patients who have certain deep and subsurface malignant tumors by the external application of electromagnetic energy. The BSD-2000 also monitors the temperature of target and surrounding tissues by means of invasive temperature sensors.

We have also obtained regulatory approval for the sale of the BSD-2000 in the People's Republic of China

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 Humanitarian Device Exemption ("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.

On November 21, 2011, we announced that the Company had obtained HDE marketing approval for the BSD-2000 from the FDA. The BSD-2000 is approved for use in conjunction with radiation therapy for the treatment of cervical cancer patients who normally would be treated with combined chemotherapy and radiation but are ineligible for chemotherapy due to patient related factors. The HDE approval authorizes the commercial sale of the BSD-2000. An HDE approval is obtained after a company has demonstrated the product's safety and probable benefit for the treatment of a disease affecting fewer than 4,000 people in the United States every year. 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 a PMA and/or 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.

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 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 non-invasively monitoring the tissue temperatures during 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 thermometry 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

MicroThermX®. Our U.S. network of direct sales representatives and one domestic specialty distribution firm provides nationwide sales coverage for the MicroThermX line of products.

In addition, we recently entered into an exclusive, long-term master distribution agreement with Terumo Europe NV in 100 countries in Europe, Western Asia and Northern Africa. We have a Director of International Sales and previously entered into agreements with other international specialty distribution firms. Our marketing and distribution strategy for our MicroThermX business includes seeking out and securing additional master distribution arrangements for our MicroThermX line of products in other parts of the world.

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 the Company has recognized revenues derived from sales to Dr. Sennewald Medizintechnik GmbH ("Medizintechnik") 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 India and other countries in Europe 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 from China's Food and Drug Administration (the "CFDA") 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. Orientech subsequently obtained CFDA approval, allowing the distributor to begin to market and sell the BSD-2000 system to hospitals in China. During the period of the original agreement BSD sold 17 BSD-2000s to Orientech. We renewed this exclusive distribution agreement in February 2012, which requires Orientech to purchase a minimum of 32 BSD-2000s over a 4 year period, commencing when Orientech receives renewal of their original approval to sell the BSD-2000 from China's Food and Drug Administration (the "CFDA"). CFDA approval has to be renewed every 4 years for all medical devices. Renewal from the CFDA is pending, and Orientech has obtained approval to import BSD-2000s on a limited basis.

In December 2011, we announced that we signed an exclusive agreement with Han Beam Technology, Inc. (formerly known as CyberKnife Korea) for the sale and distribution of our hyperthermia products in South Korea. Han Beam Technology, Inc. (Han Beam) is a premier distributor of sophisticated medical devices in South Korea and represents a number of major medical device companies. Han Beam is a leading distributor of oncology products in South Korea and has established strong relationships with radiation oncologists throughout the country. As part of the agreement, CKK is required to purchase a minimum number of hyperthermia systems from us each year. We are in the process of obtaining regulatory approval for the BSD-2000 in South Korea.

In August 2012, we announced that we had obtained approval to market our hyperthermia systems in the Russian Federation. The marketing approval covers all BSD-2000 Hyperthermia System configurations and the BSD-500 Hyperthermia System.

In March 2013, we announced that we signed an exclusive agreement with Linden Bioscience Co., Ltd. (“Linden”), a Taiwan Corporation, for the sale and distribution of our hyperthermia products in Taiwan. Linden’s primary focus will be licensing, marketing and selling the BSD-2000 in Taiwan. Per the agreement, Linden is required to purchase a minimum number of BSD-2000 systems annually over a five year period, totaling a cumulative $7.1 million in revenue to us. In May 2013, we received an initial purchase order from Linden, committing to purchase four BSD-2000 Hyperthermia Systems. Shipment of the first hyperthermia systems will coincide with Linden’s receipt of Taiwan FDA import license approval.

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.

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.

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.

Competition in the medical products industry is intense. We believe that established product lines and cancer therapies, governmental 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, and only a few companies besides BSD are marketing hyperthermia outside the U.S. 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. Several other companies have received IDEs in the United States or other international approvals for certain 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. There are other companies providing hyperthermia products in Europe and Asia.

Product Service

We generally provide a 12-month warranty and record a liability for the warranty following installation on all our cancer treatment systems and a 90-day limited warranty on individual components. We install and service the systems

we sell to domestic customers. In addition, we 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 international distributors install and service our systems sold to foreign customers and are responsible for managing their own warranty programs for their customers, including labor and travel expenses. We provide training, procedures and forms to the distributors providing these types of services. 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.

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 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 an HDE for our BSD-2000 system. Significant changes to the MicroThermX may require a new 510(k).

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. All medical devices must be manufactured in accordance with regulations and in compliance with other applicable standards. 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. After certification and CE Marking approval, an EU approved notified body reviews quality and design records annually to maintain certification, including design and manufacturing practices, labeling, record-keeping, and required reporting of adverse experiences. 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. In addition, regulations for sale of medical devices into the EU are being revised and the revisions will impose stricter requirements on medical device companies, and there can be no assurance that we will continue to maintain compliance with future regulatory requirements.

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 currently mandates a post approval study for PMA and HDE approved devices, and a post approval registry study was mandated by the FDA as part of our HDE approval for the BSD-2000 Hyperthermia System. Due to challenges enrolling patients and sites in a small population with this rare disease, no patients have yet been enrolled in the post-approval study. BSD is committed to its post-approval study and, as such, is in collaborative discussions with the FDA regarding how to restructure the framework of the study and how best to address these challenges.

The FDA also 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 other applicable standards.

In complying with the FDA, EU, and other country 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 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. International sales of medical devices are subject to FDA export requirements.

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 eight non-expired patents in the United States related to certain components or technology of our ablation and hyperthermia systems. We currently have one patent license from Duke University. Seven new U.S. patent applications are pending and six have been published in the United States, and one foreign patent is issued and others are pending. A total of 29 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 Clinitherm 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 Clinitherm 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 2013, 2012 and 2011 were $2,281,854, $2,364,608 and $1,483,659, 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.

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 SynchroWave short tip antenna used to deliver smaller, spherical ablation zones;
- incorporating new requirements into the design and manufacturing processes;
- designing and testing of new advanced cooled disposable microwave ablation antennas;
- supporting MicroThermX CE marking approval efforts;
- 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;
- supporting BSD-2000, BSD-2000/3D and BSD-2000/3D/MR CE Marking approval efforts;
- supporting product approvals for non-US governments;
- R&D projects not publicly 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.

At times, we have derived a significant portion of our revenues 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. However, we have recently experienced declining sales from this related party. For fiscal year 2013 we had sales of $99,896, or 3% of our total sales, from the sale of hyperthermia systems and various component parts sold to Medizintechnik, as compared to sales of $333,663, or 16% of our total sales, in fiscal 2012, and sales of $1,063,495, or 35% of our total sales, in fiscal 2011. Management believes the terms of the transactions with Medizintechnik were arm's 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, 2013, 2012 and 2011, export sales totaled $1,470,619, $694,629 and $1,135,372, or approximately 40%, 34% and 37% of total sales, respectively. During the year ended August 31, 2013, we had sales to one customer totaling 30.36% of total revenues. During the year ended August 31, 2012, we had sales to four customers totaling 16.11%, 12.64%, 11.05% and 10.86% of total revenues. During the year ended August 31, 2011, we had sales to three customers totaling 35.01%, 10.01% and 10.01% of total revenues.

During the years ended August 31, 2013, 2012 and 2011, domestic sales totaled $2,202,673, $1,376,563and $1,902,103, or approximately 60%, 66% and 63%, respectively.

Backlog

As of August 31, 2013, we had a sales backlog of $2.5 million.

Employees

As of August 31, 2013, we had 48 employees; 45 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 $45,628,938 at August 31, 2013. We reported net losses of $8,251,691, $7,960,660 and $5,285,517 in fiscal years 2013, 2012 and 2011, 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 MicroThermX® line of products and our hyperthermia systems 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.

We have obtained FDA clearance to market our MicroThermX® Microwave Ablation System, and have experienced early success in sales of the MicroThermX® family of products. We cannot be assured that our efforts to commercialize the MicroThermX® will be successful or that we will attain expected revenue levels.

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. We have experienced significant growth in revenues from our MicroThermX® family of products. Our MicroThermX® products represent a major part of our business plan moving forward and introduce 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.

Political and economic uncertainty in the healthcare industry due to government healthcare reform and the continuing worldwide economic turndown has made hospital acquisitions of capital equipment difficult at all levels. With hospital capital budgeting, committee review and other approvals, the sales cycle for the MicroThermX® may extend to well over six months. To accelerate revenues from the MicroThermX® line of products, we have a program that allows hospitals to purchase disposable SynchroWave antennas and pay a fee-per-use rental for the treatment of patients using the MicroThermX®. We expanded the equipment rental program throughout the U.S., hiring direct sales representatives in key major metropolitan areas who will provide “personal service” to new users of the microwave ablation technique. These are experienced interventional sales representatives with established contacts and relationships in the field of interventional oncology. We have experienced early success with this direct sales program and increasing revenues; however, we cannot be assured that we will attain expected revenue levels from the MicroThermX® line of products. If these efforts are not successful, our business will be adversely affected.

Our profitability will be driven in large part by international sales of our MicroThermX® family of products; therefore, we are dependent on our ability to successfully establish our international sales distribution channels.

With our United States direct sales network in place for our MicroThermX® family of products, we are placing significant emphasis on Europe and other international markets. 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. We believe that the distribution agreement with Terumo Europe NV will drive market adoption of the MicroThermX® product line. However, this agreement in in its early stages and the ultimate success of the Terumo relationship is yet to be determined. We also expect to reach distribution agreements with additional international distribution firms. If these efforts are not successful, our business will be adversely affected.

Our current strategy includes the possibility of entering into additional collaborative arrangements with third parties to expand and improve the commercialization of all our products; including our hyperthermia systems; however, there can be no assurance that such strategic alternatives will result in any successful agreements or transactions.

As demonstrated by our recent signing of the master distribution agreement with Terumo Europe NV for our MicroThermX® line of products, our current strategy includes the possibility of entering into additional collaborative arrangements with third parties to expand and improve the commercialization of all our products including our hyperthermia systems. Consistent with this strategy we engaged Roth Capital Partners on June 1, 2013 to serve as our exclusive advisor with the goal to seek out, identify opportunities and, if possible, secure a transaction or transaction(s) relating to our hyperthermia business including, but not limited to, partnering or other collaborative agreements, a sale of assets and/or other strategic arrangements. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

Our revenues can fluctuate significantly from period to period because historically our sales have been largely 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 historically our sales 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. We have experienced increasing revenues from our MicroThermX® line of products, but have been unable to sustain or grow revenues from our hyperthermia systems. 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 hyperthermia 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.

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 systems. This has contributed to a lack of growth in the worldwide sales of our hyperthermia systems and to a slower than anticipated introduction into the market place of our MicroThermX® line of products. To the extent that adverse economic conditions continue, we believe our sales of cancer treatment systems will continue to be negatively impacted.

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

We have experienced declining revenues from related parties. During the years ended August 31, 2013, 2012, and 2011, we had sales of $99,896, $333,663 and $1,063,495, respectively, to entities controlled by a significant stockholder and member of our Board of Directors. These related party transactions result from the sale of hyperthermia systems and related component parts and services and represent approximately 3%, 16% and 35% of total sales for each respective year.

A significant portion of our revenues are derived from sales to foreign customers. Export sales were $1,470,619, $694,629 and $1,135,372 in fiscal years 2013, 2012 and 2011, respectively. During fiscal year 2013, export sales to Belgium were approximately 30% of total sales. During fiscal years 2012 and 2011, export sales to Germany were approximately 16% and 35% 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.

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 payers. 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.

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.

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. At times 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; however, we have recently experienced declining hyperthermia revenues from this source. Medizintechnik is controlled by Dr. Sennewald, one of our directors.

Our Chinese distributor has yet to receive regulatory approval in China in an ongoing renewal application, and we have also experienced declining levels of sales in China.

Successful results from our exclusive agreement with a Taiwan corporation for sale and distribution of hyperthermia products in Taiwan are dependent on receipt of regulatory approval and reaching a successful level of sales.

In March 2013, we announced that we signed an exclusive agreement with a Taiwan corporation for the sale and distribution of our hyperthermia products in Taiwan. The distributor is required to purchase a minimum number of BSD-2000 systems annually over a five year period. In May 2013, we received an initial purchase order from the distributor, committing to purchase four BSD-2000 Hyperthermia Systems. Shipment of the first hyperthermia systems will coincide with the distributor’s receipt of Taiwan FDA import license approval. There can be no assurance that the import license approval will be received by the distributor and that the distributor will meet the purchase order commitments of the agreement.

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 and future 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 whether healthcare reform proposals will be successfully implemented or 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.

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 are also subject to ongoing compliance and review requirements with our CE Mark certifications. Failure to comply with these ongoing requirements could result in CE Mark imposed operating restrictions on us.

On January 2, 2013, following a protracted period of public comment, the EU issued a regulatory directive known as Restriction of Hazardous Substances (RoHS) that restricts the use of certain hazardous substances used in electrical equipment and mandated all medical devices sold in the EU meet RoHS compliance requirements on or before July 22, 2014. Medical devices subject to RoHS must have technical testing and accompanying documents, a declaration of conformity and DE marking affixed to the product to be deemed compliant. Noncompliant medical devices will be prohibited for sale in the EU community after July 22, 2014.

The Company's MTX products are in compliance with RoHS requirements. However the Company's hyperthermia products contain some of the substances defined as hazardous by RoHS standards. This presents a challenge for us

inasmuch as there is currently no RoHS information available from vendors of the non-compliant parts with no alternative replacement parts available or readily identifiable. Hence, in order to continue to sell its Hyperthermia Systems within the EU after July 22, 2014 the Company believes it will need to make significant changes in the component parts used in its hyperthermia products it offers for sale in the EU.

The Company can provide no assurances that it will be able to meet RoHS standards, if at all, in a timely manner to continue selling its hyperthermia products in the EU.

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, Sam Maravich, Jr., our Vice President of Sales and Marketing, Dixie Toolson Sells, our Vice President of Regulatory Affairs, William S. Barth, 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 20% 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. In April 2013 we completed a $5.0 million registered direct placement of our stock under our current universal shelf registration. Prior to the April 2013 offering we completed four offerings utilizing a universal shelf registration statement during calendar year 2010. Sales of substantial amounts of shares of our common stock or other securities under our current 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. MINE SAFETY DISCLOSURES

This item is not applicable to the Company.

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 2012 and 2013. 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, 2011	$ 3.28	$ 2.25
February 29, 2012	2.52	2.00
May 31, 2012	2.44	1.58
August 31, 2012	1.82	0.76
November 30, 2012	2.41	1.15
February 28, 2013	2.05	1.32
May 31, 2013	1.87	0.97
August 31, 2013	1.70	1.20

As of August 31, 2013, there were 470 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 13, 2013, the last reported sales price of our common stock on the Nasdaq Stock Market was $1.30 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, 2008. 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, 2008 to August 31, 2013) 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, 2013 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,				
	2013	2012	2011	2010	2009
Results of Operations Data:					
Revenues	$3,673,292	$2,071,192	$3,037,475	$1,582,276	$3,536,487
Loss from operations	(8,273,284)	(8,013,247)	(5,348,671)	(7,477,966)	(6,526,493)
Net loss	(8,251,691)	(7,960,660)	(5,285,517)	(7,456,948)	(11,384,870)
Loss per common share - diluted	$(0.26)	$(0.27)	$(0.18)	$(0.32)	$(0.52)
Dividends per common share	$-	$-	$-	$-	$-
Balance Sheet Data:					
Total Assets	$14,340,376	$15,366,049	$21,939,906	$12,702,169	$12,857,358
Long-term debt	-	-	-	-	-
Stockholders' equity	12,143,891	14,497,332	21,071,594	12,118,225	11,940,989

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 simi 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 Item 8 of this Form 10-K. All information presented herein is based on our fiscal year ended August 31, 2013. 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 radiofrequency (RF) and microwave energy. Our product lines include both ablation and hyperthermia treatment systems. Our microwave ablation system has been developed as a stand-alone therapy to employ precision-guided microwave energy 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 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.

As of August 31, 2013, we had a sales backlog of $2,488,750.

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 disposable devices used with certain of our systems, training, service support contracts and other miscellaneous revenues. We also recognize revenues from equipment rental, including fee-per-use rental income from our MicroThermX®.

Our revenues consisted of the following:

	Years Ended August 31,		
	2013	2012	2011
Product sales	$ 1,934,826	$ 1,358,604	$ 2,581,275
Disposable devices	1,109,750	344,751	155,424
Service contracts and other	330,116	238,487	190,569
	3,374,692	1,941,842	2,927,268
Equipment rental	298,600	129,350	110,207
Total	$ 3,673,292	$ 2,071,192	$ 3,037,475

Total revenues in fiscal year 2013 increased $1,602,100, or 77%, compared to total revenues in fiscal year 2012. The growth in revenue during fiscal year 2013 resulted primarily from increased MicroThermX® sales. During the third quarter of fiscal year 2013, we commenced shipping MicroThermX® systems and SynchroWave antennas to Terumo Europe pursuant to an exclusive distribution agreement covering 100 countries in Europe, Western Asia, and Northern Africa. Through fiscal year 2011 and the first part of fiscal year 2012, we had minimal revenues from our MicroThermX® family of products. However, with the successful introduction of our fee-per-use rental program and accelerating sales of disposable SynchroWave antennas, our revenues from our MicroThermX® family of products continue to grow.

Total revenues in fiscal year 2012 decreased by $966,283, or approximately 32%, compared to total revenues in fiscal year 2011. The overall decrease in revenues in fiscal year 2012 is due to the sale of fewer hyperthermia systems, partially offset by higher levels of equipment rental from our MicroThermX® fee-per-use rental program and increasing sales of disposable SynchroWave antennas.

Historically, our revenues have fluctuated significantly from period to period because our sales were 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. However, we have been unable to sustain an increase in the number of hyperthermia systems sold due to various factors, including: non-acceptance by cancer-treating physicians of hyperthermia therapy; inadequate reimbursement rates from third-party payers; the continuing worldwide economic downturn; and significant uncertainty in the U.S. healthcare industry due to recent governmental healthcare reform. We believe these difficulties may continue to negatively impact the sales of our hyperthermia systems and our operating results.

At times, we have derived a significant portion of our revenues from sales to related parties. All of our related party revenue results from the sale of hyperthermia systems and related component parts and services 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 $99,896, or approximately 3%, of our total revenue in the year ended August 31, 2013 from sales to related parties, compared to $333,663 or approximately 16%, in the year ended August 31, 2012, and $1,063,495 or approximately 35% in the year ended August 31, 2011. The growth in our revenues has come from non-related parties.

The following tables summarize the sources of our revenues for the years ended August 31, 2013, 2012 and 2011:

Non-Related Parties	2013	2012	2011
Product sales	$ 1,884,826	$ 1,063,754	$ 1,569,688
Consumable devices	1,087,100	316,701	116,724
Service contracts	259,550	202,613	141,224
Other	43,320	25,111	36,137
	3,274,796	1,608,179	1,863,773
Equipment rental	298,600	129,350	110,207
Total	$ 3,573,396	$ 1,737,529	$ 1,973,980

Related Parties	2013	2012	2011
Product sales	$ 50,000	$ 294,850	$ 1,011,587
Consumable devices	22,650	28,050	38,700
Other	27,246	10,763	13,208
Total	$ 99,896	$ 333,663	$ 1,063,495

Gross Margin

Our gross margin and gross margin percentage has fluctuated 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 $1,411,843, or 38% of total sales, for fiscal year 2013, $554,561, or 27% of total sales, for fiscal

year 2012, and $1,324,549, or 44%, for fiscal year 2011. The increase in gross margin and gross margin percentage in fiscal year 2013 compared to fiscal year 2012 resulted from increasing MicroThermX® sales, particularly sales of consumable devices and equipment rental. The decrease in gross margin and gross margin percentage in fiscal year 2012 compared to fiscal year 2011 resulted primarily from the decrease in hyperthermia product sales, partially offset by increasing MicroThermX® sales. 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, 2013 and 2012

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 2013 was $2,261,449 compared to $1,516,631 for fiscal 2012, an increase of $744,818, or approximately 49%. This increase resulted primarily from increasing MicroThermX® sales 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 remained relatively constant in the current fiscal year compared to the prior fiscal year. Research and development expenses were $2,281,854 for fiscal 2013 compared to $2,364,608, for fiscal 2012, a decrease of $82,754, or approximately 3%.

Selling, General and Administrative Expenses – Selling, general and administrative expenses were $7,403,273 for fiscal 2013 compared to $6,203,200 in fiscal 2012, an increase of $1,200,073, or approximately 19%. We continued to expand our MicroThermX® sales and marketing activities and support personnel and related operating expenses in the current year, with resulting MicroThermX® revenues as further discussed above. 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, 2013, and the increase may be significant.

Operating Costs and Expenses: Comparison of Fiscal Years ended August 31, 2012 and 2011

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 2012 was $1,516,631 compared to $1,712,926 for fiscal 2011, a decrease of $196,295, or approximately 11%. This decrease resulted primarily from the sale of fewer hyperthermia systems in fiscal year 2012 compared to fiscal year 2011.

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 $2,364,608 for fiscal 2012 compared to $1,483,659, for fiscal 2011, an increase of $880,949, or approximately 59%. Our research and development expenses for fiscal year 2011 have been partially offset by the $488,958 proceeds from two separate U.S. government grants under the QTDP Program received in November 2010. In addition, research and development expenses increased in fiscal year 2012 compared to fiscal year 2011, primarily due to new MicroThermX® product line enhancement projects, including development of the table top MicroThermX® and the SynchroWave short tip antenna.

Selling, General and Administrative Expenses – Selling, general and administrative expenses were $6,203,200 for fiscal 2012 compared to $5,189,561 in fiscal 2011, an increase of $1,013,639, or approximately 20%. We expanded our successful MicroThermX® equipment rental program throughout the U.S. by hiring new direct sales representatives in key metropolitan areas, adding a new Vice President of Sales and Marketing and incurring additional marketing, sales and related operating expenses.

Other Income (Expense)

Interest Income: Interest income earned on our money market funds and savings accounts is currently immaterial to our business, and was $32,225, $59,783, and $67,233 for the years ended August 31, 2013, 2012 and 2011, respectively.

Other Expense: Other expense is also immaterial to our business, and was $8,694, $6,208 and $3,279 for the years ended August 31, 2013, 2012 and 2011, respectively.

Income Tax (Provision) Benefit

For the years ended August 31, 2013, 2012 and 2011, we recorded an income tax provision of $1,938, $988 and $800, respectively. Due to our operating losses, our income tax provision is primarily related to state income taxes and is currently immaterial to our business.

Liquidity and Capital Resources

From inception through August 31, 2013, we have generated an accumulated deficit of $45,628,938 where our operating revenues have been insufficient to cover our operating expenses. We have financed our operations primarily through the sale of our common stock. As of August 31, 2013, we had cash and cash equivalents of $9,450,528, comprised primarily of money market funds and savings accounts.

As of August 31, 2013, we had current liabilities totaling $2,143,370, comprised of accounts payable, accrued liabilities, customer deposits and deferred revenue incurred in the normal course of our business. Our long-term liabilities consisted of deferred revenue of $53,115. We have no current or long-term debt.

Stock Offerings

Shelf Registration Statements

On October 1, 2009, a 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 (the “2009 Shelf Registration Statement”). We completed four stock offerings utilizing the universal shelf registration statement during calendar year 2010, and we received total net proceeds of approximately $19 million, including proceeds from the exercise of warrants issued in the stock offerings.

On September 28, 2012, we filed a universal shelf registration statement with 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. On October 11, 2012, the universal shelf registration statement was declared effective by the SEC. We may periodically offer one or more of these securities in amounts, prices and 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.

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April 2013 Offering

On April 9, 2013, we entered into a placement agency agreement (the "Agency Agreement") 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 up to 4,065,042 shares of our common stock and warrants to purchase up to 3,048,782 shares of our common stock in a registered direct public offering (the "Offering"). The Placement Agent was entitled to a cash fee of 6.5% of the gross proceeds paid to us for the securities sold in the Offering. We also reimbursed the Placement Agent for all reasonable and documented out-of-pocket expenses incurred by the Placement Agent in connection with the Offering, not to exceed the lesser of (i) $35,000 or (ii) 8% of the gross proceeds of the Offering, less the Placement Agent's placement fee.

The Agency Agreement contains customary representations, warranties and covenants by us. It also provides 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 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.

Also on April 9, 2013, we and certain institutional investors entered into a securities purchase agreement (the "Purchase Agreement") in connection with the Offering, pursuant to which we agreed to sell an aggregate of 4,065,042 shares of our common stock and warrants to purchase a total of 3,048,782 shares of our common stock to such investors for aggregate gross proceeds, before deducting fees to the Placement Agent and other estimated offering expenses payable by us, of approximately $5.0 million. 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. The purchase price was $1.23 per fixed combination. The warrants became exercisable six months and one day following the closing date of the Offering and will remain exercisable for five years thereafter at an exercise price of $1.65 per share. 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 exercisability of the warrants 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, subject to certain exceptions, we will not, within the 30 trading days following the closing of the Offering (which period may be extended in certain circumstances), enter into any agreement to issue or announce the issuance or proposed issuance of any securities.

We also 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 also agreed with each of the purchasers if we issue securities within the 12 months following the closing of the 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 Agreement.

We closed the Offering on April 12, 2013. The net proceeds to us from the Offering, after deducting placement agent fees and the offering expenses borne by us, were approximately $4.6 million.

The Offering was completed using our shelf registration statement on Form S-3, pursuant to a prospectus supplement filed with the SEC.

Cash Flows from Operating, Investing and Financing Activities

During the year ended August 31, 2013, we used net cash of $6,200,055 in operating activities, primarily as a result of our net loss of $8,251,691, decreased by non-cash expenses of $1,446,966, including depreciation and amortization, stock-based compensation and stock issued for services. Net cash used in operating activities also included increases in receivables of $601,326, inventories of $41,813, and other current assets of $79,959, partially offset by increases in accounts payable of $325,663, accrued liabilities of $149,182, customer deposits of $292,500, and deferred revenue of $560,423.

During the year ended August 31, 2012, we used net cash of $5,935,939 in operating activities, primarily as a result of our net loss of $7,960,660, decreased by non-cash expenses of $1,538,237, including depreciation and amortization, stock-based compensation, stock issued for services and loss on disposition of property and equipment. Net cash used in operating activities also included decreases in accounts payable of $106,182 and deferred revenue of $11,087, partially offset by decreases in receivables of $482,743, inventories of $2,257 and other current assets of $1,079, and increases in accrued liabilities of $92,694 and customer deposits of $24,980.

Net cash used in investing activities, resulting from the purchase of property and equipment, was $35,362 and $97,521 for the years ended August 31, 2013 and 2012, respectively.

Net cash provided by financing activities was $4,583,437 for the year ended August 31, 2013, comprised of net proceeds from the sale of common stock. We had no net cash provided by or used in financing activities for the year ended August 31, 2012.

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, 2013, we had no significant commitments for the purchase of property and equipment.

We had no material off balance sheet arrangements as of August 31, 2013.

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 product sales 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 disposable 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 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 review our inventory levels and usage, paying particular attention to slower-moving items. If projected sales do not materialize or if our 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 limited 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.

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Medical Device Taxes: A Medical Device Excise Tax (MDET) was enacted into law as part of the Health Care Education Reconciliation Act of 2010 and imposes an excise tax on medical device manufacturers on their sales in the U.S of certain devices after December 31, 2012. The tax is 2.3% of the taxable base. We estimate approximately 80 - 85% of our worldwide sales will be subject to the MDET which commenced on January 1, 2013.

Recent Accounting Pronouncements

No new accounting pronouncements were issued during the year ended August 31, 2013 and through the date of filing this report that we believe are applicable or would 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 belief that the distribution agreement with Terumo Europe NV will drive market adoption of the MicroThermX®;
- our expectations that we will continue and grow the successful results from our MicroThermX® fee-per-use equipment rental program throughout the U.S. that we have experienced to date;
- our expectations that the SynchroWave antennas used in conjunction with the MicroThermX® will represent a significant ongoing revenue stream;
- our expectations that we will reach agreements with additional international distribution firms;
- our expectations that additional international shipments of the MicroThermX® and supplies of SynchroWave antennas will occur in calendar year 2014;
- our belief that the level of our operating expenses, including selling, general and administrative expenses, will increase and that the increase may be significant;
- 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 2013 and 2012. 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.

	2013				2012			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Total revenues	$659,785	$819,259	$1,316,713	$877,535	$658,998	$271,883	$651,387	$488,924
Gross margin (loss)	186,591	399,878	600,302	225,072	288,120	(75,730)	200,604	141,567
Net loss	(2,218,664)	(1,861,397)	(1,969,746)	(2,201,884)	(1,687,405)	(2,102,598)	(2,097,854)	(2,072,803)
Loss per common share - diluted	$(0.07)	$(0.06)	$(0.06)	$(0.07)	$(0.06)	$(0.07)	$(0.07)	$(0.07)

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, 2013. Based on that evaluation, management concluded that our disclosure controls and procedures were effective as of August 31, 2013.

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, 2013, 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, 2013, 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.

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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 about our directors can be found under the captions "Directors," "Business Experience and Qualifications of Nominees for Election to the Board of Directors" and "Composition of the Board of Directors" in the Company's definitive Proxy Statement to be filed for the 2014 Annual Meeting of Stockholders (the "Proxy Statement"). That information is incorporated by reference. Information about our executive officers and significant employees appearing under the captions "Executive Officers" and "Significant Employees" in the Proxy Statement is incorporated by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information appearing under the captions “Director Compensation 2013,” “Director Compensation Table”, “Executive Compensation,” and “Compensation Committee Report,” in the Proxy Statement is incorporated by reference.

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

Information appearing under the captions “Equity Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” in the Proxy Statement is incorporated by reference.

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

Information appearing under the captions “Certain Relationships and Related Person Transactions” and “Affirmative Determinations Regarding Director Independence” in the Proxy Statement is incorporated by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information appearing under the captions “Principal Accountant Fees and Services” and “Pre-Approval Policies” in the Proxy Statement is incorporated by reference.

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 filed as part of this report or incorporated herein by reference as indicated:

Exhibit Number	Description
1.1	Placement Agency Agreement, dated as of April 9, 2013, by and among the Company and Roth Capital Partners, LLC. Incorporated by reference to Exhibit 1.1 to the BSD Medical Corporation Form 8-K, filed April 9, 2013.
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.
4.6	Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed April 9, 2013.
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*	Employment Agreement with Harold R. Wolcott dated May 22, 2013. Incorporated by reference to Exhibit 10.2 to BSD Medical Corporation's Quarterly Report on Form 10-Q filed July 10, 2013.
10.7	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 10-K filed on November 6, 2009.
10.8	Securities Purchase Agreement, dated as of April 9, 2013, by and between the Company 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 April 9, 2013.
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.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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

** The XBRL related information in Exhibit 101 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section and shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

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, 2013 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, 2013 By: /s/ Harold R. Wolcott
Harold R. Wolcott
President and Member of the Board of Directors
(principal executive officer)

Date: November 14, 2013 By: /s/ William S. Barth
William S. Barth
Chief Financial Officer (principal financial
and accounting officer)

Date: November 14, 2013 By: /s/ Timothy C. McQuay
Timothy C. McQuay
Chairman of the Board of Directors

Date: November 14, 2013 By: /s/ Gerhard W. Sennewald
Dr. Gerhard W. Sennewald
Member of the Board of Directors

Date: November 14, 2013 By: /s/ Steven G. Stewart
Steven G. Stewart
Member of the Board of Directors

Date: November 14, 2013 By: /s/ Michael Nobel
Dr. Michael Nobel
Member of the Board of Directors

Date: November 14, 2013 By: /s/ Douglas P. Boyd
Dr. Douglas P. Boyd
Member of the Board of Directors

Date: November 14, 2013 By: /s/ Damian E. Dupuy
Dr. Damian E. Dupuy

Member of the Board of Directors

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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, 2013, 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, 2013, 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, 2013 and 2012, 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, 2013, and our report dated November 14, 2013 expressed an unqualified opinion thereon.

/s/ TANNER LLC

Salt Lake City, Utah

November 14, 2013

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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 (the Company) as of August 31, 2013 and 2012, 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, 2013. 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, 2013 and 2012, and the results of its operations and its cash flows for each of the years in the three-year period ended August 31, 2013, 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, 2013, 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, 2013 expressed an unqualified opinion thereon.

/s/ TANNER LLC

Salt Lake City, Utah
November 14, 2013

BSD MEDICAL CORPORATION
Balance Sheets

ASSETS	August 31, 2013	2012
Current assets:		
Cash and cash equivalents	$9,450,528	$11,102,508
Accounts receivable, net of allowance for doubtful accounts of $20,000	899,969	289,587
Related party trade accounts receivable	24,201	33,257
Inventories, net	2,445,770	2,403,957
Other current assets	200,028	120,069
Total current assets	13,020,496	13,949,378
Property and equipment, net	1,319,880	1,412,639
Patents, net	-	4,032
Total assets	$14,340,376	$15,366,049
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$521,417	$195,754
Accrued liabilities	573,880	424,698
Customer deposits	317,480	24,980
Deferred revenue – current portion	730,593	96,865
Total current liabilities	2,143,370	742,297
Deferred revenue – net of current portion	53,115	126,420
Total liabilities	2,196,485	868,717
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, 34,006,202 and 29,777,522 shares issued, respectively	34,007	29,778
Additional paid-in capital	57,739,056	51,845,035
Treasury stock, 24,331 shares at cost	(234)	(234)
Accumulated deficit	(45,628,938)	(37,377,247)
Total stockholders' equity	12,143,891	14,497,332
Total liabilities and stockholders' equity	$14,340,376	$15,366,049

See accompanying notes to financial statements

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BSD MEDICAL CORPORATION
Statements of Comprehensive Loss

	Years Ended December 31,		
	2013	2012	2011
Revenues:			
Sales	$3,274,796	$1,608,179	$1,863,773
Sales to related parties	99,896	333,663	1,063,495
Equipment rental	298,600	129,350	110,207
Total revenues	3,673,292	2,071,192	3,037,475
Cost of revenues:			
Cost of sales	2,161,967	1,244,290	1,074,030
Cost of related party sales	87,694	260,553	618,823
Cost of equipment rental	11,788	11,788	20,073
Total cost of revenues	2,261,449	1,516,631	1,712,926
Gross margin	1,411,843	554,561	1,324,549
Operating costs and expenses:			
Research and development	2,281,854	2,364,608	1,483,659
Selling, general and administrative	7,403,273	6,203,200	5,189,561
Total operating costs and expenses	9,685,127	8,567,808	6,673,220
Loss from operations	(8,273,284)	(8,013,247)	(5,348,671)
Other income (expense):			
Interest income	32,225	59,783	67,233
Other expense	(8,694)	(6,208)	(3,279)
Total other income (expense)	23,531	53,575	63,954
Loss before income taxes	(8,249,753)	(7,959,672)	(5,284,717)
Income tax provision	(1,938)	(988)	(800)
Net loss and comprehensive loss	$(8,251,691)	$(7,960,660)	$(5,285,517)
Loss per common share:			
Basic	$(0.26)	$(0.27)	$(0.18)
Diluted	$(0.26)	$(0.27)	$(0.18)
Weighted average number of shares outstanding:			
Basic	31,414,000	29,717,000	28,838,000
Diluted	31,414,000	29,717,000	28,838,000

See accompanying notes to financial statements

BSD MEDICAL CORPORATION
Statements of Stockholders' Equity
Years Ended August 31, 2013, 2012 and 2011

	Common Stock		Additional Paid - In	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance, September 1, 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
Common stock issued for services	91,368	92	179,908	-	-	-	180,000
Stock-based compensation	-	-	1,206,398	-	-	-	1,206,398
Net loss	-	-	-	-	-	(7,960,660)	(7,960,660)
Balance, August 31, 2012	29,777,522	29,778	51,845,035	24,331	(234)	(37,377,247)	14,497,332
Common stock issued for:							
Services	163,638	164	179,838	-	-	-	