BSD MEDICAL CORP
Form 10-K
November 13, 2014

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, 2014

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

For the Transition Period From _____ to _____

Commission File Number: 001-32526

BSD MEDICAL CORPORATION
(Exact name of registrant as specified in its charter)

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

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

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

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant as of February 28, 2014 was approximately $30,731,822.

As of November 13, 2014, the registrant had 39,689,209 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 2015 Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission within 120 days after the Registrant’s fiscal year end, are incorporated by reference into Part III hereof.

BSD MEDICAL CORPORATION
FORM 10-K

For the Year Ended August 31, 2014

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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 68%. 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. 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.

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.

We have experienced recent growth in our operating revenues from our MicroThermX Microwave Ablation System ("MicroThermX") line of products partially 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, which covers 100 countries in Europe, Western Asia, and Northern Africa, along with increased MicroThermX revenue from other international distributors. In addition, revenues from sales of disposable SynchroWave antennas and fee per use charges for MicroThermX systems have increased in the US market.

The number of hyperthermia systems sold also increased this year. However, due to negative regulatory, economic, reimbursement and other healthcare industry factors, we expect that revenue growth of this product line will be difficult in the future. 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 may result in hyperthermia sales in the future; however, certain regulatory approvals are required before we will realize increased sales. Following several years of effort, we have now obtained necessary regulatory approvals in Taiwan and China.

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 April 2013 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 continue 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 Capital Market ("NASDAQ") under the symbol "BSDM."

Our Contributions to Cancer Therapy

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.

Since the founding of the Company, we have been heavily involved in developing technological advances to expand the use of heat 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.

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.

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. BSD management estimates the soft tissue ablation world market potential exceeds $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. BSD management estimates the potential market size for MicroThermX in these countries 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 other substantial geographic medical device markets.

Domestically, we have restructured our sales organization and efforts in 2014 by engaging independent, specialized distributors who sell and distribute medical products to healthcare providers. These specialized distributors typically have established relationships with interventional radiologists and other end users of cancer treatment products. Each of these distributors are overseen, trained and serviced by sales managers who are employees of the Company. We believe that we have now expanded our distributor network and direct sales efforts to cover all large metropolitan areas and states, with sales coverage throughout the entire United States. We will continue to adjust 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 profitable equipment rental fees. We continue to aggressively market and sell the rental program throughout the U.S.

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 long history in marketing medical devices and equipment worldwide.

Hyperthermia Systems

The BSD Hyperthermia family of products includes the BSD-500, BSD-2000, the BSD-2000/3D and the BSD-2000/3D/MR. These systems 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, or by applying radiofrequency ("RF") energy to certain cancerous tumors, including those located deep within the body.

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.

On November 21, 2011 the Company 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.

We have received CE Marking for the BSD-2000 family of products, which would allow us to market the BSD-2000 systems in the thirty countries that comprise the EU and the EFTA. However, effective July 22, 2014, the EU's Restriction of Hazardous Substances ("RoHS") regulatory mandate prohibits the Company from selling its hyperthermia products in the EU under their current configuration. Although the Company's MicroThermX products are in compliance with RoHS requirements, in order to continue to sell its hyperthermia systems within the EU after July 22, 2014, the Company would need to make significant and costly changes to component parts used in its hyperthermia products to become RoHS compliant. The Company does not believe that it is economically justifiable at this time to continue to offer hyperthermia systems in the EU, given RoHS requirements. The RoHS regulatory mandate allows the company to supply replacement parts for current installations. For the immediate future, the Company will continue to focus its marketing efforts for hyperthermia systems in Asian and domestic U.S. markets. However, the Company believes that sales of hyperthermia products in the U.S. face significant reimbursement challenges.

CE Marking is also recognized in many countries outside of the EU, which may provide us the ability to market the BSD-2000 family of products to other international markets.

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

Marketing and Distribution

MicroThermX. Our U.S. network of direct sales representatives and four domestic specialty distribution firms provide nationwide sales coverage for the MicroThermX line of products.

In addition, in April 2013 we 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 that

manages this relationship, as well as other 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 have utilized independent sales representatives supported by senior management of the Company. Our plan going forward is to minimize this effort in the U.S., due to regulatory, economic and reimbursement challenges and to focus on marketing and sales efforts of hyperthermia products through distributors in Asia.

Historically the Company has recognized revenues derived from sales to Dr. Sennewald Medizintechnik GmbH and its affiliated entities ("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.

Sales of hyperthermia products in the EU have been trending down as a percent of the Company's total sales since fiscal 2011. With the RoHS regulatory mandate, the Company is prohibited from selling its hyperthermia products in the EU in their current configuration.

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 was received August 28, 2014.

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. The Russian approval does not expire; however, any shipment into Russia also requires a GOST-R Quality Certificate. Our GOST-R Quality Certificate expires July 26, 2015, and would have to be renewed after that date if we continue to ship products into Russia.

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. Since Linden's receipt of Taiwan FDA import license approval in February 2014, we have shipped four (4) BSD-2000 systems to Linden.

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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. Obtaining reimbursement in the U.S. can be unpredictable and difficult for hyperthermia. Obtaining reimbursement for treatments using the BSD-2000 Hyperthermia System is particularly difficult in the U.S., as it has HDE approval from the FDA. In order to obtain reimbursement for an HDE-approved device, the hospital generally has to file an appeal after receiving an initial denial, and there is no guarantee that reimbursement can be obtained even after an appeal has been filed. Obtaining reimbursement for treatment with an HDE-approved device is difficult and resource intensive.

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 HS Hospital Service S.p.A. 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 training and support 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 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

Domestic Regulation of Our Products and Business - Food and Drug Administration

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act (the "FDCA"), as implemented and enforced by the FDA. Certain of our products sold in the United States require FDA clearance to market under Section 510(k) of the FDCA. FDA governs the following activities that we perform or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution; and

- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

There are numerous FDA regulatory requirements governing the approval or clearance and marketing of our products. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

- Quality System Regulation ("QSR") which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of a cleared product;

- approval of product modifications that affect the safety or effectiveness of an approved product;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval restrictions or conditions, including post-approval study commitments;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and

- notices of correction or removal and recall regulations.

We have registered our facility with the FDA as a medical device manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to announced and unannounced inspections by the FDA to determine our compliance with the QSR and other regulations and these inspections may include the manufacturing facilities of our suppliers.

FDA's premarket clearance and approval requirements. Unless an exemption applies, before we can commercially distribute medical devices in the United States, depending on the type of device, we must obtain either prior 510(k) clearance or PMA from the FDA, unless a specific exemption applies. The FDA classifies medical devices into one of three classes:

- Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against

adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;

- Class II devices, generally requiring 510(k) premarket clearance before they may be commercially marketed in the United States; and

- Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring submission of a PMA supported by clinical trial data.

510(k) clearance pathway

When a 510(k) clearance is required, we must submit a premarket notification demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. We have modified our devices since they received the FDA clearance. If the FDA were to disagree with any of our determinations that changes did not require a new 510(k), it could require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance or PMA approval for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

Premarket approval (PMA) pathway

A PMA or an HUD and HDE application must be submitted to the FDA if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the manufacturing facility or facilities to ensure compliance with the QSRs.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. There is no guarantee that the FDA will grant PMA approval of our future products and failure to obtain necessary approvals for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

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Humanitarian Device Exemption (HDE) Pathway

In order for a device to be eligible for an HDE, it must be intended for use in a qualifying target patient population of less than 4,000 patients per year for which there is no other comparable device available to treat the condition. This qualifying target patient population must be approved by the FDA. The FDA's approval of an HDE to treat that qualifying patient population then requires demonstration that the device is safe for its intended application, that it is potentially effective, and that the probable benefits outweigh the associated risks, which is a lower standard than is applied to a PMA. Within the regulations for an HDE, if a device becomes available through the PMA or 510(k) pathway that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market. An approved HDE authorizes sales of the device to any hospital after Institutional Review Board review and approval by the hospital. New HDEs or HDE supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design

Clinical Trials

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance and HDE approval. Such trials generally require an investigational device exemption application ("IDE"), approved in advance by the FDA for a specified number of patients and study sites, unless the product is deemed a nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board ("IRB") for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States.

Pervasive and continuing regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- Product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;

- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;

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approval of product modifications that affect the safety or effectiveness of one of our approved devices;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval restrictions or conditions, including post-approval study commitments;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

- regulations pertaining to voluntary recalls; and

- notices of corrections or removals.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

Furthermore, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

- unanticipated expenditures to address or defend such actions

- customer notifications for repair, replacement, refunds;

- recall, detention or seizure of our products;

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operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

The medical devices that we have developed and are developing are subject to extensive, rigorous, and unpredictable regulation by numerous governmental authorities, including the FDA and comparable foreign agencies.

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. 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 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-13485 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.

The RoHS regulatory mandate will prohibit the Company from selling its hyperthermia products in the EU under their current configuration. Although the Company’s MicroThermX products are in compliance with RoHS requirements, in order to continue to sell its hyperthermia systems within the EU after July 22, 2014, the Company would need to make significant and costly changes to component parts used in its hyperthermia products to become RoHS compliant and available for sale in the EU. The Company does not believe that it is economically justifiable at this time to continue to offer hyperthermia systems in the EU, given RoHS requirements.

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. As a condition of our HDE approval for the BSD-2000, the FDA required BSD to conduct a post-market registry study, “Deep Hyperthermia and Radiation in the Treatment of Cervical Cancer Patients." Due to challenges enrolling patients and sites in a small population with this rare disease, no patients were enrolled in this initial post-approval study. Because of these challenges, BSD initiated collaborative discussions with

FDA regarding the structure of the study. As a result, the initial post-market study structure has been revised, and we are in current discussions with our clinical sites regarding participation in the revised study. We are still experiencing challenges in enrolling patients and sites and have been unable to obtain participation in the restructured study as of the date of this filing. The status of BSD's post-approval study is listed as "progress inadequate" on the FDA's website. We plan to initiate additional discussions with the FDA regarding how best to address these challenges, but there can be no assurance that we will be able to successfully meet our Company's ongoing responsibilities for the post-approval study mandated by the FDA as part of our HDE approval. We have submitted all periodic updates to the FDA as required and in a timely manner.

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. 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. Eleven new U.S. patent applications 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 2014, 2013 and 2012 were $2,229,043, $2,281,854 and $2,364,608, respectively. Through the end of fiscal 2014, we have continued our efforts to enhance and improve our ablation products, sustain and fill current order requirements for our hyperthermia products, and to focus our product development, technology and engineering resources on 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 regulatory requirements;
- adaptation of our BSD-2000/3D/MR to both Siemens and GE MR configurations;
- sustaining engineering for our BSD-500 and BSD-2000 systems where necessary to maintain ongoing manufacturability;
- supporting product approvals for US and 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, in past fiscal years, we have derived a significant portion of our revenues from sales to Medizintechnik, which has been a significant distributor of our products in Europe, and which is owned by Dr. Gerhard W. Sennewald, one of our directors and a significant shareholder. However, with the exception of one BSD-2000 unit Medizintechnik purchased from us in fiscal 2014, we have experienced declining sales from this related party. For fiscal year 2014 we had sales of $419,549, or 8% of our total sales, from the sale of hyperthermia systems and various component parts sold to Medizintechnik. Excluding the purchase of the BSD-2000 unit, sales to Medizintechnik was $59,549, or 1% of our total sales in fiscal 2014, as compared to sales of $99,896, or 3% of our total sales, in fiscal 2013, and sales of $333,663, or 16% of our total sales, in fiscal 2012. Management believes the terms of these 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, 2014, 2013 and 2012, export sales totaled $3,381,563, $1,470,619 and $694,629, or approximately 63%, 40% and 34% of total sales, respectively. During the year ended August 31, 2014, we had sales to two foreign customers, each representing 23% of total revenues. During the year ended August 31, 2013, we had sales to one foreign customer totaling 30% of total revenues. During the year ended August 31, 2012, we had sales to four foreign customers totaling 16%, 13%, 11% and 11% of total revenues.

During the years ended August 31, 2014, 2013 and 2012, domestic sales totaled $1,946,790, $2,202,673 and $1,376,563, or approximately 37%, 60% and 66% of total revenues, respectively. In the year ended August 31, 2014, no single domestic customer accounted for more than 6% of total revenues.

Backlog

As of August 31, 2014, we had a sales backlog of $440,000.

Employees

As of August 31, 2014, we had 52 employees; 49 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 $52,771,770 at August 31, 2014. We reported net losses of $7,142,832, $8,251,691 and $7,960,660 in fiscal years 2014, 2013 and 2012, 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 510(k) 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 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., contracting with specialty medical products distributors and hiring direct sales representatives in key major metropolitan areas who 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 these sales programs 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 April 2013 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 have a 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.

At times, a significant portion of our revenues from sales of our hyperthermia products have been from related parties.

We have experienced declining revenues of hyperthermia products from related parties. These related party transactions result from the sale of hyperthermia systems and related component parts and services to entities controlled by a significant shareholder and member of our Board of Directors, and represent approximately 8%, 3% and 16% of total sales for the years ended August 31, 2014, 2013, and 2012. With the new RoHS regulatory mandate, we are prohibited from selling new hyperthermia systems in the EU. Our MicroThermX products are RoHS compliant.

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

A significant concentration of our revenues are from foreign countries.

A significant portion of our revenues are derived from sales to foreign customers. Export sales were $3,381,563, $1,470,619 and $694,629 in fiscal years 2014, 2013 and 2012, respectively. During fiscal year 2014, export sales to Taiwan and Belgium combined were approximately 46% of total sales. During fiscal years 2013 and 2012, export sales to Belgium and Germany were approximately 30% and 16% of total sales, respectively.

To the extent that we are unable to maintain or increase the level of our revenues derived from 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.

Continued sales of our hyperthermia systems in Asia depend on the effectiveness of our Asian distributors; however, we have had failures with the productivity of new channels of distribution in the past.

We believe that the success of our efforts to increase sales of our hyperthermia systems in the future depends on our ability to successfully utilize and support our sales distribution channels in Asia. Historically, we have had little success in establishing new sales channels, and recruiting and training new distributors can require considerable time and expense. As we pursue our hyperthermia products marketing plan, there can be no assurance that our channels of distribution will be reliable, or will to meet our plan for sales in Asia.

In addition, we believe that our channels of distribution for hyperthermia products that have been successful in the past will not 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 and will be unable to market hyperthermia systems in the EU following July 22, 2014, due to new RoHS regulations. Medizintechnik is controlled by Dr. Sennewald, one of our directors.

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

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 throughout the world is lengthy and expensive and our financial resources are limited. The FDA and other comparable agencies outside the U.S. are currently implementing and considering a number of reforms in its regulatory processes, which may make the approval process longer and more cumbersome for medical devices and increase the costs required to maintain those approvals.

Obtaining marketing approval from the FDA and other comparable agencies outside the U.S. is necessary for us to commercially market our systems in the United States. Obtaining and maintaining 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.

After a product is approved for commercial distribution by the FDA and other comparable agencies outside the U.S., we have ongoing responsibilities under applicable regulations, which may include 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 problems with our approvals outside the U.S., and in the U.S. 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 ISO-13485 and CE Mark certifications. The European Commission ("EC"), the executive body of the EU, drafts regulations that are then accepted or rejected by the European Council. Once a regulation has been accepted, it becomes a directive. We must remain current with both new directives and amendments to existing directives. The EC has recently implemented a number of significant changes in the regulations that govern medical devices, and the European Council has approved these changes. These changes make obtaining and maintaining required regulatory approvals more expensive and time consuming. The EC also recommended additional significant changes in the regulations that govern medical devices, which could increase the regulatory costs and risk for marketing products in the EU. Failure to comply with these ongoing requirements could result in marketing restrictions on us.

On January 2, 2013, following a protracted period of public comment, the EU issued RoHS, which 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 CE 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 MicroThermX 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 does not currently intend to make the significant and costly changes to component parts used in its hyperthermia products that would be necessary to become RoHS compliant so its hyperthermia systems can be available for sale in the EU. Because of this, our sales of new hyperthermia systems in the EU will cease, which will impact our results from operations.

U.S. Regulatory – FDA

If we fail to maintain regulatory approvals and clearances, or are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or product enhancements, our ability to commercially distribute and market these products could suffer.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received

clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or is the subject of an approved PMA unless the device is specifically exempt from those requirements. In addition, certain devices can be distributed under an HDE, rather than a PMA.

The FDA will clear marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to other 510(k)-cleared products. High risk devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device for its intended use.

In order for a device to be eligible for an HDE, it must be intended for use in a qualifying target patient population of less than 4,000 patients per year for which there is no other comparable device available to treat the condition. This qualifying target patient population must be approved by the FDA. The FDA's approval of an HDE to treat that qualifying patient population then requires demonstration that the device is safe for its intended application, that it is potentially effective, and that the probable benefits outweigh the associated risks, which is a lower standard than is applied to a PMA. Within the regulations for an HDE, if a device becomes available through the PMA process that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market. An approved HDE authorizes sales of the device to any hospital after Institutional Review Board review and approval by the hospital.

Our currently commercialized BSD-200 and MicroThermX Microwave Ablation System have been cleared through the 510(k) process. Our BSD-500 is the subject of an approved PMA application. Our BSD-2000 System is the subject of an approved HDE. Our HDE for the BSD-2000 could be withdrawn by FDA if the target patient population exceeds 4000 patients in a given year or if a competitive device receives PMA approval that addresses the same patient population as the BSD-2000.

Our failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our manufacturing facility are possible.

Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications to our products may require new regulatory approvals or clearances, including 510(k) clearances, premarket approvals, or HDE approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. For PMA approved products, any change that affects the safety or effectiveness of the device requires the approval of PMA Supplement. Depending on the type of change,

there are different PMA Supplements ranging from 30-Day Notices to full 180-Day Supplements. Where we determine that modifications to our products require a new 510(k) clearance, premarket approval, or HDE application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in tur