

BSD MEDICAL CORP  
Form 10-K  
November 13, 2014

---

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended August 31, 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  
(State or other jurisdiction of incorporation or organization)

75-1590407  
(I.R.S. Employer Identification No.)

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

84119  
(Zip Code)

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

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

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

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

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

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

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

Edgar Filing: BSD MEDICAL CORP - Form 10-K

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

TABLE OF CONTENTS

Part I

Item 1.	Business	2
Item 1A	Risk Factors	18
Item 1B	Unresolved Staff Comments	31
Item 2.	Properties	31
Item 3.	Legal Proceedings	31
Item 4.	Mine Safety Disclosures	31

Part II

Item 5.	Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	32
Item 6.	Selected Financial Data	33
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	34
Item 7A.	Quantitative and Qualitative Disclosure About Market Risk	44
Item 8.	Financial Statements and Supplementary Data	44
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	44
Item 9A.	Controls and Procedures	44
Item 9B.	Other Information	46

Part III

Item 10.	Directors, Executive Officers and Corporate Governance	46
Item 11.	Executive Compensation	46
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	46

Item 13.	Certain Relationships and Related Transactions, and Director Independence	46
Item 14.	Principal Accountant Fees and Services	46
Part IV		
Item 15.	Exhibits and Financial Statement Schedules	47
Signatures		49

## 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 SynchronWave 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.

4

---

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.

6

---

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.



### 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.



### 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;
-

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;
-

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

Edgar Filing: BSD MEDICAL CORP - Form 10-K

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 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 turn would harm our future growth.

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.

Some of our new products may require FDA clearance of a 510(k). Other products may require the approval of a PMA. In addition some of our new products may require clinical trials to support regulatory approval and we may not successfully complete these clinical trials. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Clinical trials necessary to support a PMA application will be expensive and will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support a future PMA application or to obtain additional safety and efficacy data beyond that typically required for a 510(k) clearance will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Clinical trials conducted in the United States, generally require an 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 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 that complies with FDA requirements, state and federal privacy regulations and human subject protection regulations.

Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, FDA may not consider our data adequate to

demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

BSD is currently sponsoring an IDE-approved clinical study of the BSD-2000 Hyperthermia System, “Hyperthermia Combined with Radiotherapy for the Treatment of Locally Advanced, Persistent, or Recurrent Deep Tumors of the Pelvis; i.e., Cervical, Prostate, Rectal, and Bladder.” The Phase II study is designed to enroll subjects who have advanced, persistent, or recurrent deep tumors of the pelvis and thus have already failed other standard therapy or would not be considered candidates for other standard therapy.

Our facility and our clinical investigational sites operate under procedures that govern the conduct and management of FDA-regulated clinical studies under 21 CFR Parts 50 and 812, and Good Clinical Practices. FDA may conduct Bioresearch Monitoring (BIMO) inspections of us and/or our clinical sites to assess compliance with 21 CFR Parts 50 and 812, our procedures, and the clinical protocol. If the FDA were to find that we or our clinical investigators are not operating in compliance with applicable regulations, we could be subject to the above FDA enforcement action as well as refusal to accept all or part of our data in support our 510(k) or PMA and/or we may need to conduct additional studies.

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. Additionally, we may decide at any time, for business or other reasons, to terminate a study. 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 clearance or approval to market the product in the United States. Following completion of a study, we would need to collect, analyze and present the data in an appropriate submission to the FDA, either a 510(k) premarket notification or a PMA. Even if a study is completed and submitted to the FDA, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient to obtain approval of our product.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We do not have the ability to independently conduct our pre-clinical and clinical trials for our products and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product

candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

With respect to our marketed products, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations or QSR for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. The FDA enforces the QSR and other regulations through periodic inspections. Our facility in Salt Lake City, Utah, is regularly inspected by the FDA. The most recent FDA inspection was conducted December 17–19, 2012. There were no deficiencies noted by the FDA as a result of this inspection and no Form 483 was issued.

The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues could result in, among other things, any of the following enforcement actions:

- 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;
- 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 or HDE or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully

commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional 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 addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

For most products that receive PMA or HDE approval, FDA imposes post-market study requirements as a condition of approval. As a condition of our HDE approval for the BSD-2000 Hyperthermia System, 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 registry 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. BSD is still experiencing challenges in enrolling patients and sites and plans to initiate additional discussions with FDA regarding how best to address these challenges. 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 FDA as required and in a timely manner.

Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which require reports to be submitted to the FDA and can result in voluntary corrective actions or FDA enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our

similar devices were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

Our promotional materials and training methods for physicians must comply with FDA and other applicable laws and regulations. We believe that the specific surgical procedures for which our 510(k)-cleared products are marketed fall within the scope of the surgical applications that have been cleared by the FDA and that our PMA approved products are marketed in accordance with their approved labeling. However, the FDA could disagree and require us to stop promoting our products for those specific procedures until we obtain FDA clearance or approval for them. In addition, 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 and 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.

Legislative or Regulatory reforms may adversely affect our ability to sell our products profitably.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

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

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

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

successfully protect our rights in litigation could reduce our ability to be competitive and generate sales and profitability.

A product liability settlement could exceed our ability to pay.

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

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

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

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

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

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



If the closing bid price of our stock continues to remain below \$1.00 per share, our common stock may be subject to delisting from the NASDAQ Stock Market.

Shares of our common stock are listed on the NASDAQ Capital Market (“Nasdaq”) under the symbol “BSDM”. We are required to comply with Nasdaq’s listing standards in order to maintain the listing of our common stock on the exchange. Nasdaq has the authority pursuant to Nasdaq Rule 5550(a)(2) to delist our common stock if, during any period of 30 consecutive trading days, the closing bid price falls below a minimum bid price of \$1.00 per share.

On August 8, 2014, we received a letter from the staff of Nasdaq notifying us that, for the previous 30 consecutive business days, the bid price for the Company’s common stock had closed below the minimum \$1.00 per share requirement for continued listing on Nasdaq under Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until February 4, 2015, to regain compliance. If at any time before February 4, 2015, the bid price of our common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days, the Staff will provide us with written confirmation of compliance and the matter will be closed.

We are actively monitoring the bid price of our common stock and will consider any and all options available to us to achieve compliance. To the extent that we are unable to resolve the listing deficiency, there is a risk that our common stock may be delisted from Nasdaq and would likely trade only on the over-the-counter market (the “OTC”). If our common stock were to trade on the OTC, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and security analysts’ coverage of us may be reduced. In addition, in the event our common stock is delisted, broker-dealers transacting in our common stock would be subject to certain additional regulatory burdens, which may discourage them from effecting transactions in our common stock, thus further limiting the liquidity of our common stock and potentially resulting in lower prices and larger spreads in the bid and ask prices for our common stock.

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

Our directors and executive officers own approximately 18% of our outstanding voting power. Accordingly, these stockholders, individually and as a group, may be able to influence the outcome of stockholder votes involving the election of directors, the adoption or amendment of provisions in our certificate of incorporation and bylaws and the approval of certain mergers or other similar transactions, such as a sale of substantially all of our assets. Such control by existing stockholders could have the effect of delaying, deferring or preventing a change in control of our company.

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

We currently have the ability to offer and sell up to \$50.0 million of common stock, preferred stock, warrants, senior debt, subordinated debt or units under a currently effective universal shelf registration statement. In July 2014 we completed a \$5.2 million registered direct placement of our stock under our current universal shelf registration. Prior to the July 2014 offering we completed five offerings utilizing a universal shelf registration statement during calendar years 2010 and 2013. Sales of substantial amounts of shares of our common stock or other securities under our current universal shelf registration statement could lower the market price of our common stock and impair our ability to raise capital.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

This item is not applicable to the Company.

## PART II

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

Our common shares trade on the NASDAQ under the symbol "BSDM". The following table sets forth the high and low sales prices, as provided by NASDAQ for the quarters in fiscal years 2013 and 2014. The amounts reflect inter-dealer prices, without retail mark-up, markdown or commission, and may not represent actual transactions.

Quarter Ended:	High	Low
November 30, 2012	\$ 2.41	\$ 1.15
February 28, 2013	2.05	1.32
May 31, 2013	1.87	0.97
August 31, 2013	1.70	1.20
November 30, 2013	1.78	1.18
February 28, 2014	1.45	1.03
May 31, 2014	1.66	.95
August 31, 2014	1.19	.55

As of August 31, 2014, there were 464 holders of record of our common stock. We have not paid any cash dividends on our common stock since our inception, and we currently plan to retain our future earnings, if any, to fund the growth of our business.

On November 12, 2014, the last reported sales price of our common stock on NASDAQ was \$0.45 per share.

## Repurchases of Equity Securities

None.

## Recent Sales of Unregistered Securities

None.

## Performance Graph

The following graph shows a comparison of the five-year cumulative total return for the Company's common stock, the S&P 500 Index, and the S&P Health Care Equipment Index, assuming an investment of \$100 on August 31, 2009. The cumulative return of the Company was computed by dividing the difference between the price of the Company's common stock at the end and the beginning of the measurement period (August 31, 2009 to August 31, 2014) by the price of the Company's common stock at the beginning of the measurement period.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data as of and for each of the fiscal years in the five year period ended August 31, 2014 were derived from the Company's financial statements audited by Tanner LLC, independent registered public accountants. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 of this Form 10-K and the financial statements and notes thereto included in Item 8 of this Form 10-K.

	Years Ended August 31,				
	2014	2013	2012	2011	2010
<b>Results of Operations</b>					
<b>Data:</b>					
Revenues	\$ 5,328,353	\$ 3,673,292	\$ 2,071,192	\$ 3,037,475	\$ 1,582,276
Loss from operations	(7,148,198)	(8,273,284)	(8,013,247)	(5,348,671)	(7,477,966)
Net loss	(7,142,832)	(8,251,691)	(7,960,660)	(5,285,517)	(7,456,948)
<b>Loss per common share - diluted</b>					
	\$ (0.20)	\$ (0.26)	\$ (0.27)	\$ (0.18)	\$ (0.32)
<b>Dividends per common share</b>					
	\$ -	\$ -	\$ -	\$ -	\$ -
<b>Balance Sheet Data:</b>					
Total Assets	\$ 12,248,794	\$ 14,340,376	\$ 15,366,049	\$ 21,939,906	\$ 12,702,169
Long-term debt	-	-	-	-	-
Stockholders' equity	10,662,266	12,143,891	14,497,332	21,071,594	12,118,225

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

### Overview

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this annual report on Form 10-K contain forward-looking statements that involve risks and uncertainties. Forward-looking statements can also be identified by words such as "anticipates," "expects," "believes," "plans," "predicts," and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in the subsection entitled "Forward-Looking Statements" below and the Item 1A "Risk Factors" above. The following discussion should be read in conjunction with our financial statements and notes thereto included in Item 8 of this Form 10-K. All information presented herein is based on our fiscal year ended August 31, 2014. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

We develop, manufacture, market and service systems to treat cancer and benign diseases using heat therapy delivered using focused RF and microwave energy. Our product lines include both ablation and hyperthermia treatment systems. Our microwave ablation system has been developed as a stand-alone therapy to employ precision-guided microwave energy to ablate (destroy) soft tissue. Our hyperthermia cancer treatment systems, which have been in use for several years in the United States, Europe and Asia, are used to treat certain tumors with heat (hyperthermia), while increasing the effectiveness of other therapies such as radiation therapy. We have developed extensive intellectual property, multiple products in the market and established distribution in the United States, Europe and Asia. Certain of our products have received regulatory approvals and clearances in the United States, Europe and China.

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

### Results of Operations

#### Fluctuation in Operating Results

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

#### Revenues

We recognize revenue from the sale of our ablation and hyperthermia cancer treatment systems and related parts and accessories (collectively, product sales), the sale of disposable devices used with certain of our systems, training, service support contracts and other miscellaneous revenues. We also recognize revenues from equipment rental, including fee-per-use rental income from our MicroThermX.



Our revenues consisted of the following:

	Years Ended August 31,		
	2014	2013	2012
Product sales	\$3,019,525	\$1,934,826	\$1,358,604
Disposable devices	1,568,481	1,109,750	344,751
Service contracts and other	375,747	330,116	238,487
	4,963,753	3,374,692	1,941,842
Equipment rental	364,600	298,600	129,350
Total	\$5,328,353	\$3,673,292	\$2,071,192

Total revenues in fiscal year 2014 increased \$1,655,061, or 45%, compared to total revenues in fiscal year 2013. The growth in revenue during fiscal year 2014 resulted primarily from the shipment in fiscal 2014 of several BSD-2000 units that were in backlog at the end of fiscal 2014, along with higher revenues from disposable SynchroWave antennas and from our fee-per-use rental program for MicroThermX generators. These higher revenues were partially offset by lower revenues from sales of MicroThermX generators.

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

Historically, our revenues have fluctuated significantly from period to period because our sales were based upon a relatively small number of hyperthermia systems, the sales price of each being substantial enough to greatly impact revenue levels in the periods in which they occur. However, we have been unable to sustain an increase in the number of hyperthermia systems sold due to various factors, including: non-acceptance by cancer-treating physicians of hyperthermia therapy; inadequate reimbursement rates from third-party payers; and significant uncertainty in the U.S. healthcare industry due to recent governmental healthcare reform. We believe these difficulties will continue to negatively impact the sales of our hyperthermia systems and our operating results.

At times, we have derived a significant portion of our revenues from sales to related parties. All of our related party revenue results from the sale of hyperthermia systems and related component parts and services to Dr. Sennewald Medizintechnik GmbH. Dr. Sennewald, one of our directors and significant stockholders, is a stockholder, executive officer and a director of Medizintechnik. We derived \$419,549, or approximately 8% of our total revenue in the year ended August 31, 2014 from sales to Medizintechnik. Excluding their purchase of a BSD-2000 unit in fiscal 2014, 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. The growth in our revenues has come primarily from non-related parties.

The following tables summarize the sources of our revenues for the years ended August 31, 2014, 2013 and 2012:

Non-Related Parties	2014	2013	2012
Product sales	\$2,659,525	\$1,884,826	\$1,063,754
Consumable devices	1,532,455	1,087,100	316,701
Service contracts	303,109	259,550	202,613
Other	49,115	43,320	25,111
	4,544,204	3,274,796	1,608,179
Equipment rental	364,600	298,600	129,350
<b>Total</b>	<b>\$4,908,804</b>	<b>\$3,573,396</b>	<b>\$1,737,529</b>
Related Parties	2014	2013	2012
Product sales	\$ 360,000	\$ 50,000	\$ 294,850
Consumable devices	36,026	22,650	28,050
Other	23,523	27,246	10,763
<b>Total</b>	<b>\$ 419,549</b>	<b>\$ 99,896</b>	<b>\$ 333,663</b>

### Gross Margin

Our gross margin and gross margin percentage has fluctuated from period to period depending on the mix of revenues reported for the period and the type and configuration of the hyperthermia systems sold during the period. Our total gross margin was \$2,389,488, or 45% of total sales, for fiscal year 2014, \$1,411,843, or 38% of total sales, for fiscal year 2013, and \$554,561, or 27%, for fiscal year 2012. The increase in gross margin and gross margin percentage in fiscal year 2014 compared to fiscal year 2013 resulted from increasing sales of MicroThermX consumable devices and equipment rental, and higher sales in 2014 of higher margin hyperthermia products. The increase in gross margin and gross margin percentage in fiscal year 2013 compared to fiscal year 2012 resulted primarily from the decrease in hyperthermia product sales, partially offset by increasing MicroThermX sales. In addition, as sales volume increases, we believe we will more fully absorb certain fixed operating costs that are included in cost of sales, thus increasing our gross profit percentage.

### Operating Costs and Expenses: Comparison of Fiscal Years ended August 31, 2014 and 2013

Cost of Sales – Cost of sales include raw material, labor and allocated overhead costs. We calculate and report separately cost of sales for both non-related and related party sales, which are sales to Medizintechnik. Cost of sales as a percentage of sales will fluctuate from period to period depending on the mix of sales for the period and the type and configuration of the hyperthermia systems sold during the period. Total cost of sales for fiscal 2014 was \$2,938,865 compared to \$2,261,449 for fiscal 2013, an increase of \$677,416, or approximately 30%. This increase resulted from the increased sales volume of both hyperthermia and MicroThermX products in the current fiscal year compared to the last fiscal year, as further discussed above.

Research and Development Expenses – Research and development expenses include expenditures for new product development and development of enhancements to existing products. Our research and development expenses remained relatively constant in the current fiscal year compared to the prior fiscal year. Research and development expenses were \$2,229,043 for fiscal 2014 compared to \$2,281,854, for fiscal 2013, a decrease of \$52,811, or

approximately 2%.

36

---

Selling, General and Administrative Expenses – Selling, general and administrative expenses were \$7,308,643 for fiscal 2014 compared to \$7,403,273 in fiscal 2013, a decrease of \$94,630, or approximately 1%. While these total expenses were relatively constant from year to year, we continued to expand our MicroThermX sales and marketing activities and support personnel and related operating expenses in the current year. We believe that the level of our selling, general and administrative expenses may increase over the levels reported for the year ended August 31, 2014, if sales volumes increase in fiscal 2015.

#### Operating Costs and Expenses: Comparison of Fiscal Years ended August 31, 2013 and 2012

Cost of Sales – Cost of sales include raw material, labor and allocated overhead costs. We calculate and report separately cost of sales for both non-related and related party sales, which are sales to Medizintechnik. Cost of sales as a percentage of sales will fluctuate from period to period depending on the mix of sales for the period and the type and configuration of the hyperthermia systems sold during the period. Total cost of sales for fiscal 2013 was \$2,261,449 compared to \$1,516,631 for fiscal 2012, an increase of \$744,818 or approximately 49%. This increase resulted primarily from increasing MicroThermX sales in fiscal year 2013, compared to fiscal year 2012.

Research and Development Expenses – Research and development expenses include expenditures for sustaining engineering, enhancements to existing products, support of regulatory requirements and product approvals and development of new manufacturing processes. Research and development expenses were \$2,281,854 for fiscal 2013 compared to \$2,364,608, for fiscal 2012, a decrease of \$82,754, or approximately 3%.

Selling, General and Administrative Expenses – Selling, general and administrative expenses were \$7,403,273 for fiscal 2013 compared to \$6,203,200 in fiscal 2012, an increase of \$1,200,073, or approximately 19%. We continued to expand our MicroThermX sales and marketing activities and support personnel and related operating expenses in fiscal 2013, with resulting MicroThermX revenues as further discussed above. We also expanded our MicroThermX equipment rental program throughout the U.S. by hiring new direct sales representatives in key metropolitan areas, and incurred additional marketing, sales and related operating expenses.

#### Other Income (Expense)

Interest Income: Interest income earned on our money market funds and savings accounts is currently immaterial to our business, and was \$22,491, \$32,225 and \$59,783 for the years ended August 31, 2014, 2013 and 2012, respectively.

Other Expense: Other expense is also immaterial to our business, and was \$15,125, \$8,694 and \$6,208 for the years ended August 31, 2014, 2013 and 2012, respectively.

#### Income Tax (Provision) Benefit

For the years ended August 31, 2014, 2013 and 2012, we recorded an income tax provision of \$2,000, \$1,938 and \$988, respectively. Due to our operating losses, our income tax provision is primarily related to state income taxes and is currently immaterial to our business.

#### Liquidity and Capital Resources

From inception through August 31, 2014, we have generated an accumulated deficit of \$52,771,770 since our operating revenues have been insufficient to cover our operating expenses. We have financed our operations primarily through the sale of our common stock. As of August 31, 2014, we had cash and cash equivalents of \$8,130,416, comprised primarily of money market funds and savings accounts.

As of August 31, 2014, we had current liabilities totaling \$1,586,528, comprised of accounts payable, accrued liabilities, note payable, customer deposits and deferred revenue incurred in the normal course of our business. As of August 31, 2014, we had no long-term liabilities.

## Stock Offerings

### Shelf Registration Statements

On October 1, 2009, a universal shelf registration statement was declared effective by the SEC for the issuance of common stock, preferred stock, warrants, senior debt, subordinated debt and units up to an aggregate amount of \$50.0 million (the “2009 Shelf Registration Statement”). We completed four stock offerings utilizing the universal shelf registration statement during calendar year 2010, and we received total net proceeds of approximately \$19 million, including proceeds from the exercise of warrants issued in the stock offerings.

On September 28, 2012, we filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, senior debt, subordinated debt and units up to an aggregate amount of \$50.0 million. On October 11, 2012, the universal shelf registration statement was declared effective by the SEC. We may periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. At the time any of the securities covered by the registration statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

### April 2013 Offering

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

The Agency Agreement contains customary representations, warranties and covenants by us. It also provides for customary indemnification by us and the Placement Agent for losses or damages arising out of or in connection with the sale of the securities being offered. We agreed to indemnify the Placement Agent against liabilities under the Securities Act of 1933, as amended. We also agreed to contribute to payments the Placement Agent may be required to make in respect of such liabilities.

Also on April 9, 2013, we and certain institutional investors entered into a securities purchase agreement (the “Purchase Agreement”) in connection with the Offering, pursuant to which we agreed to sell an aggregate of 4,065,042 shares of our common stock and warrants to purchase a total of 3,048,782 shares of our common stock to such investors for aggregate gross proceeds, before deducting fees to the Placement Agent and other estimated offering expenses payable by us, of approximately \$5.0 million. The common stock and warrants were sold in fixed combinations, with each combination consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock. The purchase price was \$1.23 per fixed combination. The warrants became exercisable six months and one day following the closing date of the Offering and will remain exercisable for five years thereafter at an exercise price of \$1.65 per share. The exercise price of the warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

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

We agreed with each of the purchasers that, subject to certain exceptions, we will not, within the 30 trading days following the closing of the Offering (which period may be extended in certain circumstances), enter into any agreement to issue or announce the issuance or proposed issuance of any securities.

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

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

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

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

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

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

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

#### May 2014 Offering

On May 9, 2014, the Company entered into an At-the-Market Issuance Sales Agreement (the "ATM Agreement") with MLV & Co. LLC ("MLV"). Under this sales agreement, we could issue and sell from time to time, up to \$8,000,000 of common stock. These shares are registered under the universal shelf registration filed with the SEC on September 28, 2012. MLV would act as sales agent, using commercially reasonable efforts consistent with its normal trading and sales practices. The Agreement provided that our common shares would be sold at market prices prevailing at the time of the sale of our common stock, at no discount to market and no warrants attached. We were not obligated to make any sales under the sales agreement. We paid MLV a commission rate of 3.0% of the gross proceeds from the sale of common stock sold through MLV as sales agent under the sales agreement, reimbursed MLV for certain expenses incurred in connection with entering into the sales agreement, and provided MLV with customary indemnification rights. The full terms and text of the sales agreement was filed by the Company on a Current Report on Form 8-K on May 9, 2014. Through June 22, 2014, the Company sold 46,622 shares of common stock at an average price per share of \$1.074, for gross proceeds of \$50,068. The ATM Agreement was terminated on June 22, 2014.

#### June 2014 Offering

On June 25, 2014, the Company and certain institutional investors entered into a securities purchase agreement (the "June Offering") in which the Company agreed to sell, pursuant to a securities purchase agreement (the "Purchase Agreement"), an aggregate of 5,500,000 shares of its common stock and warrants to purchase a total of 4,400,000 shares of its common stock to such investors for aggregate gross proceeds of approximately \$5.2 million, and net proceeds of approximately \$4.7 million, after deducting placement agency fees and other costs associated with the transaction. The common stock and warrants were sold in fixed combinations, with each combination consisting of one share of common stock and a warrant to purchase 0.8 shares of common stock. The purchase price was \$0.95 per fixed combination. The warrants will become exercisable six months and one day following the closing date of the June Offering and will remain exercisable for five years thereafter at an exercise price of \$1.10 per share. The exercise price of the warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The exercisability of the warrants may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.99% of the Company's common stock. The warrants are contingently puttable at the option of the holders upon the occurrence of a fundamental transaction (as defined in the warrant agreements). The Company considers that all of the fundamental transactions are within the Company's sole control, and that the probability of any fundamental transaction occurring and the put being exercised are both remote.

Under the Purchase Agreement, the Company has agreed with each of the purchasers that, subject to certain exceptions, it will not, within the 75 days following the closing of the June Offering enter into any agreement to issue or announce the issuance or proposed issuance of any securities. The Company also agreed with each of the purchasers that for a period of four years from the date of the Purchase Agreement, the Company will not effect or enter into an agreement to effect a “Variable Rate Transaction,” which means a transaction in which it:

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

enters into any agreement (including, without limitation, an equity line of credit) whereby the Company may sell securities at a future determined price.

The Company has also agreed to indemnify each of the purchasers against certain losses resulting from its breach of any of its representations, warranties, or covenants under agreements with each of the purchasers, as well as under certain other circumstances described in the Purchase Agreement. The transaction closed on July 1, 2014 and the net proceeds were transferred to the Company.

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

During the year ended August 31, 2014, we used net cash of \$5,916,395 in operating activities, primarily as a result of our net loss of \$7,142,832, decreased by non-cash expenses of \$1,150,422, including depreciation and amortization, stock-based compensation, stock issued for services and gain on disposition of property and equipment. Net cash used in operating activities also included decreases in customer deposits of \$275,699 and deferred revenue of \$687,665, partially offset by decreases in receivables of \$548,961, inventories of \$116,581, other current assets of \$53,709, and increases in accounts payable of \$27,480 and accrued liabilities of \$292,648.

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

Net cash used in investing activities, resulting from the purchase of property and equipment, was \$73,574 and \$35,362 for the years ended August 31, 2014 and 2013, respectively.

Net cash provided by financing activities was \$4,669,857 for the year ended August 31, 2014, comprised of net proceeds of \$4,636,579 from the sale of common stock and \$74,052 of proceeds from short term financing of an insurance policy, and payments on the short term financing of \$40,774. Net cash provided by financing activities for the year ended August 31, 2013 was \$4,583,437, comprised of net proceeds from the sale of common stock.

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

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

As of August 31, 2014, we had no significant commitments for the purchase of property and equipment.

We had no material off-balance sheet arrangements as of August 31, 2014.

#### Critical Accounting Policies

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## Recent Accounting Pronouncements

No new accounting pronouncements were issued during the year ended August 31, 2013 and through the date of filing this report that we believe are applicable or would have a material impact on our financial statements.

In May 2014, FASB issued ASU 2014-09 Revenue from Contracts with Customers. The amendments in ASU 2014-09 affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards (e.g., insurance contracts or lease contracts). This ASU will supersede the revenue recognition requirements in Topic 605 Revenue Recognition and most industry-specific guidance, and creates a Topic 606 Revenue from Contracts with Customers.

The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps:

- Step 1: Identify the contract(s) with a customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. The Company has not yet determined how its financial statements will be affected by the adoption of ASU 2014-09.

## FORWARD-LOOKING STATEMENTS

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

- our belief about the market opportunities for our products;
- our anticipated financial performance and business plan;
- our belief that the distribution agreement with Terumo Europe NV will drive market adoption of the MicroThermX;
- our expectations that we will continue and grow the successful results from our MicroThermX fee-per-use equipment rental program throughout the U.S. that we have experienced to date;
- our expectations that the SynchroWave antennas used in conjunction with the MicroThermX will represent a significant ongoing revenue stream;
- our expectations that we will reach agreements with additional international distribution firms;
- our expectations that additional international shipments of the MicroThermX and supplies of SynchroWave antennas will occur in the future;
- our belief that the level of our operating expenses, including selling, general and administrative expenses, will increase and that the increase may be significant;
- our belief that our operating results, revenue and operating expenses may fluctuate in the future from year to year as well as from quarter to quarter; and
- our belief that our current cash and cash equivalents will be sufficient to finance our operations for the next twelve months.

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

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

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

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

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

The following table presents selected unaudited quarterly financial data for each of the four quarters in our fiscal years 2014 and 2013. The selected quarterly financial data reflects, in the opinion of management, all adjustments necessary to fairly present the results of operations for such periods. Results of any one or more quarters are not necessarily indicative of continuing trends.

	2014				2013			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Total revenues	\$ 1,330,645	\$ 1,690,724	\$ 1,253,189	\$ 1,053,795	\$ 659,785	\$ 819,259	\$ 1,316,713	\$ 877,000
Gross margin	691,333	769,092	505,270	423,793	186,591	399,878	600,302	225,000
Net loss	(1,512,861)	(1,470,103)	(1,988,850)	(2,171,018)	(2,218,664)	(1,861,397)	(1,969,746)	(2,201,000)
Loss per common share								
– diluted	\$ (0.04)	\$ (0.04)	\$ (0.06)	\$ (0.06)	\$ (0.07)	\$ (0.06)	\$ (0.06)	\$ (0.06)

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

## Disclosure Controls and Procedures

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

Management, under the supervision and with the participation of our Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Accounting Officer), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) promulgated under the Act), as of August 31, 2014. Based on that evaluation, management concluded that our disclosure controls and procedures were effective as of August 31, 2014.

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

Management is responsible for establishing and maintaining adequate internal control over financial reporting of the Company. Management's intent is to design this system to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America ("GAAP").

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

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

A material weakness is a significant deficiency, or combination of significant deficiencies, in internal controls over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. Management performed an assessment of the effectiveness of the Company's internal control over financial reporting as of August 31, 2014, utilizing the criteria described in the "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The objective of this assessment was to determine whether our internal control over financial reporting was effective as of such date. In its assessment of the effectiveness of internal control over financial reporting as of August 31, 2014, management concluded that our internal control over financial reporting is effective.

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

## Changes in Internal Control Over Financial Reporting

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

## Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal controls will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Controls can also

be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with associated policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## ITEM 9B. OTHER INFORMATION

On November 7, 2014 the Company signed an agreement (“Consulting Agreement”), effective November 10, 2014, to engage its former Chief Executive Officer, Harold R. Wolcott, as an independent contractor to provide consulting services to the Company. These services will consist generally of transition services, development and maintenance of strategic business relationships, advice concerning product lines and personnel, and the Company’s general business efforts, as directed by the Company’s Chief Executive Officer and the Company’s Chairman of the Board of Directors. The term of the Consulting Agreement is for 24 months beginning November 10, 2014, with a provision to renew for an additional 12 month period unless either party cancels. The Company will pay a retainer fee of \$2,500 per month for up to 20 hours per month of time expended by Mr. Wolcott, and \$125 per hour for documented hours in excess of 20 hours per month. The Company will also reimburse Mr. Wolcott for actual, reasonable and documented out-of-pocket expenses incurred in connection with providing services to the Company. Under this Consulting Agreement, stock options that have been granted to Mr. Wolcott will continue to vest and be exercisable, until 90 days after the expiration of the Consulting Agreement. Mr. Wolcott will be allowed, at no cost to him, to receive benefits for the term of this Consulting Agreement, under the Company’s present employee benefit plans, to the extent permitted by the terms of such plans.

## PART III

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

Information about our directors can be found under the captions “Directors,” “Business Experience and Qualifications of Nominees for Election to the Board of Directors” and “Composition of the Board of Directors” in the Company’s definitive Proxy Statement to be filed for the 2015 Annual Meeting of Stockholders (the “Proxy Statement”). That information is incorporated by reference. Information about our executive officers and significant employees appearing under the captions “Executive Officers” and “Significant Employees” in the Proxy Statement is incorporated by reference.

### ITEM 11. EXECUTIVE COMPENSATION

Information appearing under the captions “Director Compensation 2014,” “Director Compensation Table,” “Executive Compensation,” and “Compensation Committee Report,” in the Proxy Statement is incorporated by reference.

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

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

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

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

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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



PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

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

(2) Financial Statement Schedules

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

(3) Exhibits

The following exhibits are filed as part of this report or incorporated herein by reference as indicated:

Exhibit

Number Description

- |     |   |
|-----|---|
| 3.1 | Amended and Restated Certificate of Incorporation of BSD Medical Corporation. Incorporated by reference to Exhibit 3.1 of the BSD Medical Corporation Annual Report Form 10-KSB, filed December 1, 2003.                |
| 3.2 | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of BSD Medical Corporation. Incorporated by reference to Exhibit 3.1 to the BSD Medical Corporation Form 8-K, filed February 7, 2011. |
| 3.3 | By-Laws. Incorporated by reference to Exhibit 3.2 of the BSD Medical Corporation Registration Statement on Form S-1, filed October 16, 1986.  |
| 3.4 | Amendment to Bylaws of BSD Medical Corporation. Incorporated by reference to Exhibit 3.1 of Current Report on Form 8-K filed January 4, 2008.   |
| 4.1 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed June 26, 2014.   |
| 4.2 | Specimen Common Stock Certificate. Incorporated by reference to Exhibit 4 of the BSD Medical Corporation Registration Statement on Form S-1, filed October 16, 1986.  |
| 4.3 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed February 11, 2010.   |
| 4.4 | Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed May 3, 2010.   |
| 4.5 |   |

Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed August 19, 2010.

4.6 Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed November 15, 2010.

4.7 Form of Common Stock Purchase Warrant. Incorporated by reference to Exhibit 4.1 to the BSD Medical Corporation Form 8-K, filed April 9, 2013.

10.1\* Letter Agreement, dated April 28, 2014, between the Company and Harold R. Wolcott. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed April 29, 2014.

10.2 At-the-Market Issuance Sales Agreement between BSD Medical Corporation and MLV & Co. LLC, dated May 9, 2014. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed May 9, 2014.

- 10.3 Termination of At-the-Market Issuance Sales Agreement, dated June 22, 2014, by and between BSD Medical Corporation and MLV & Co. LLC. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed June 23, 2014.
- 10.4 Settlement Agreement, dated as of June 20, 2014, by and between BSD Medical Corporation and Cranshire Capital Master Fund, Ltd. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed June 23, 2014.
- 10.5 Securities Purchase Agreement, dated as of June 25, 2014, by and among the Company and each of the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed June 26, 2014.
- 10.6\* Employment Agreement, dated September 16, 2014, between the Company and William S. Barth. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed September 19, 2014.
- 10.7\* Consulting Agreement, dated November 7, 2014, by and between BSD Medical Corporation and Harold R. Wolcott.
- 10.8\* Stock Option Grant by Company to Clinton E. Carnell Jr., dated November 10, 2014.
- 10.9\* BSD Medical Corporation Fourth Amended and Restated 1998 Director Stock Plan. Incorporated by reference to Appendix A of the BSD Medical Corporation Schedule 14A, filed December 28, 2009.
- 10.10\* BSD Medical Corporation Third Amended and Restated 1998 Stock Incentive Plan. Incorporated by reference to Appendix B of the BSD Medical Corporation Schedule 14A, filed December 28, 2009.
- 10.11\* BSD Medical Corporation Form of Employee Stock Option Grant. Incorporated by reference to Exhibit 10.7 to BSD Medical Corporation's Annual Report on Form 10-K filed November 14, 2008.
- 10.12\* BSD Medical Corporation Form of Director Stock Option Grant. Incorporated by reference to Exhibit 10.8 to BSD Medical Corporation's Annual Report on Form 10-K filed November 14, 2008.
- 10.13\* Employment Agreement dated November 2, 1988 between BSD Medical Corporation and Paul F. Turner. Incorporated by reference to Exhibit 10.8 to BSD Medical Corporation's Registration Statement on Form SB-2 filed January 27, 2004.
- 10.14\* Employment Agreement dated May 22, 2013 by and between BSD Medical Corporation and Harold R. Wolcott. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation's Form 8-K filed May 29, 2013.

10.15 Exclusive Distribution Agreement by and between Sennewald/Medizintechnik GmbH dated May 13, 2009. Incorporated by reference to Exhibit 10.1 to BSD Medical Corporation's Quarterly Report on Form 10-Q filed on July 10, 2009.

10.16 Securities Purchase Agreement, dated as of April 9, 2013, by and between the Company and each of the purchasers identified on the signature pages thereto. Incorporated by reference to Exhibit 10.1 to the BSD Medical Corporation Form 8-K, filed April 9, 2013.

21.1 Subsidiaries of the Registrant

23.1 Consent of Independent Registered Public Accounting Firm.

31.1 Certification of Chief Executive Officer of BSD pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification of Chief Financial Officer of BSD pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1 Certification of Principal Executive Officer attached pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

32.2 Certification of the Principal Financial Officer of BSD pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101.INS\*\* XBRL Instance Document

101.SCH\*\*XBRL Taxonomy Extension Schema

101.CAL\*\*XBRL Taxonomy Extension Calculation Linkbase

101.DEF\*\*XBRL Taxonomy Extension Definition Linkbase Document

101.LAB\*\*XBRL Taxonomy Extension Label Linkbase

101.PRE\*\*XBRL Taxonomy Extension Presentation Linkbase

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

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BSD MEDICAL CORPORATION

Date: November 13, 2014                      By: /s/ Clinton E. Carnell Jr. .  
Clinton E. Carnell Jr.  
President, Chief Executive Officer and Member of  
the Board of Directors  
(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date: November 13, 2014                      By: /s/ Clinton E. Carnell Jr. .  
Clinton E. Carnell Jr.  
President, Chief Executive Officer and Member of  
the Board of Directors  
(principal executive officer)

Date: November 13, 2014                      By: /s/ William S. Barth  
William S. Barth  
Chief Financial Officer (principal financial and  
accounting officer)

Date: November 13, 2014                      By: /s/ Timothy C. McQuay  
Timothy C. McQuay  
Chairman of the Board of Directors

Date: November 13, 2014                      By: /s/ Harold R. Wolcott  
Harold R. Wolcott  
Member of the Board of Directors

Date: November 13, 2014                      By: /s/ Gerhard W. Sennewald  
Dr. Gerhard W. Sennewald  
Member of the Board of Directors

Date: November 13, 2014                      By: /s/ Steven G. Stewart  
Steven G. Stewart  
Member of the Board of Directors

Date: November 13, 2014                      By: /s/ Michael Nobel  
Dr. Michael Nobel  
Member of the Board of Directors

Date: November 13, 2014                      By: /s/ Douglas P. Boyd  
Dr. Douglas P. Boyd

Edgar Filing: BSD MEDICAL CORP - Form 10-K

Member of the Board of Directors

Date: November 13, 2014

By: /s/ Damian E. Dupuy

Dr. Damian E. Dupuy

Member of the Board of Directors

49

---

BSD MEDICAL CORPORATION  
Index to Financial Statements

	Page
Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting	F-2
Report of Independent Registered Public Accounting Firm	F-3
Balance Sheets	F-4
Statements of Comprehensive Loss	F-5
Statements of Stockholders' Equity	F-6
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

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

To the Board of Directors and Stockholders  
of BSD Medical Corporation

We have audited the internal control over financial reporting of BSD Medical Corporation (the Company) as of August 31, 2014, based on criteria established in Internal Control–Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management’s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of August 31, 2014, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of the Company as of August 31, 2014 and 2013, and the related statements of comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended August 31, 2014, and our report dated November 13, 2014 expressed an unqualified opinion thereon.

/s/ TANNER LLC

Salt Lake City, Utah

November 13, 2014

F - 2

---

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders  
of BSD Medical Corporation

We have audited the accompanying balance sheets of BSD Medical Corporation (the Company) as of August 31, 2014 and 2013, and the related statements of comprehensive loss, stockholders' equity and cash flows for each of the years in the three-year period ended August 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of BSD Medical Corporation as of August 31, 2014 and 2013, and the results of its operations and its cash flows for each of the years in the three-year period ended August 31, 2014, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of BSD Medical Corporation's internal control over financial reporting as of August 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated November 13, 2014 expressed an unqualified opinion thereon.

/s/ TANNER LLC

Salt Lake City, Utah  
November 13, 2014

BSD MEDICAL CORPORATION  
Balance Sheets

ASSETS	August 31,	
	2014	2013
Current assets:		
Cash and cash equivalents	\$ 8,130,416	\$ 9,450,528
Accounts receivable, net of allowance for doubtful accounts of \$20,000	366,887	899,969
Related party trade accounts receivable	8,322	24,201
Inventories, net	2,329,189	2,445,770
Other current assets	146,319	200,028
Total current assets	10,981,133	13,020,496
Property and equipment, net	1,267,661	1,319,880
Total assets	\$ 12,248,794	\$ 14,340,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 548,897	\$ 521,417
Accrued liabilities	866,528	573,880
Note payable	33,279	-
Customer deposits	41,781	317,480
Deferred revenue – current portion	96,043	730,593
Total current liabilities	1,586,528	2,143,370
Deferred revenue – net of current portion	-	53,115
Total liabilities	1,586,528	2,196,485
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, \$.001 par value, 80,000,000 shares authorized, 39,713,540 and 34,006,202 shares issued, respectively	39,714	34,007
Additional paid-in capital	63,394,556	57,739,056
Treasury stock, 24,331 shares at cost	(234)	(234)
Accumulated deficit	(52,771,770)	(45,628,938)
Total stockholders' equity	10,662,266	12,143,891
Total liabilities and stockholders' equity	\$ 12,248,794	\$ 14,340,376

See accompanying notes to financial statements



BSD MEDICAL CORPORATION  
Statements of Comprehensive Loss

	Years Ended August 31,		
	2014	2013	2012
<b>Revenues:</b>			
Sales	\$ 4,544,204	\$ 3,274,796	\$ 1,608,179
Sales to related parties	419,549	99,896	333,663
Equipment rental	364,600	298,600	129,350
Total revenues	5,328,353	3,673,292	2,071,192
<b>Cost of revenues:</b>			
Cost of sales	2,613,921	2,161,967	1,244,290
Cost of related party sales	313,156	87,694	260,553
Cost of equipment rental	11,788	11,788	11,788
Total cost of revenues	2,938,865	2,261,449	1,516,631
Gross margin	2,389,488	1,411,843	554,561
<b>Operating costs and expenses:</b>			
Research and development	2,229,043	2,281,854	2,364,608
Selling, general and administrative	7,308,643	7,403,273	6,203,200
Total operating costs and expenses	9,537,686	9,685,127	8,567,808
Loss from operations	(7,148,198)	(8,273,284)	(8,013,247)
<b>Other income (expense):</b>			
Interest income	22,491	32,225	59,783
Other expense	(15,125)	(8,694)	(6,208)
Total other income (expense)	7,366	23,531	53,575
Loss before income taxes	(7,140,832)	(8,249,753)	(7,959,672)
Income tax provision	(2,000)	(1,938)	(988)
Net loss and comprehensive loss	\$ (7,142,832)	\$ (8,251,691)	\$ (7,960,660)
<b>Loss per common share:</b>			
Basic	\$ (0.20)	\$ (0.26)	\$ (0.27)
Diluted	\$ (0.20)	\$ (0.26)	\$ (0.27)
<b>Weighted average number of shares outstanding:</b>			
Basic	34,967,000	31,414,000	29,717,000
Diluted	34,967,000	31,414,000	29,717,000

See accompanying notes to financial statements



BSD MEDICAL CORPORATION  
 Statements of Stockholders' Equity  
 Years Ended August 31, 2014, 2013 and 2012

	Common Stock		Additional	Treasury Stock		Accumulated	Total
	Shares	Amount	Paid - In Capital	Shares	Amount	Deficit	
Balance, September 1, 2011	29,686,154	\$ 29,686	\$ 50,458,729	24,331	\$ (234)	\$(29,416,587)	\$ 21,071,594
Common stock issued for services	91,368	92	179,908	-	-	-	180,000
Stock-based compensation	-	-	1,206,398	-	-	-	1,206,398
Net loss	-	-	-	-	-	(7,960,660)	(7,960,660)
Balance, August 31, 2012	29,777,522	29,778	51,845,035	24,331	(234)	(37,377,247)	14,497,332
Common stock issued for:							
Services	163,638	164	179,838	-	-	-	180,002
Cash, net of offering costs of \$416,565	4,065,042	4,065	4,579,372	-	-	-	4,583,437
Stock-based compensation	-	-	1,134,811	-	-	-	1,134,811
Net loss	-	-	-	-	-	(8,251,691)	(8,251,691)
Balance, August 31, 2013	34,006,202	34,007	57,739,056	24,331	(234)	(45,628,938)	12,143,891
Common stock issued for:							
Services	160,716	161	179,839	-	-	-	180,000
Cash, net of offering costs of \$638,488	5,546,622	5,546	4,631,033	-	-	-	4,636,579
Stock-based compensation	-	-	844,628	-	-	-	844,628
Net loss	-	-	-	-	-	(7,142,832)	(7,142,832)
Balance, August 31, 2014	39,713,540	\$ 39,714	\$ 63,394,556	24,331	\$ (234)	\$(52,771,770)	\$ 10,662,266

See accompanying notes to financial statements

BSD MEDICAL CORPORATION  
Statements of Cash Flows

	Years Ended August 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net loss	\$ (7,142,832)	\$ (8,251,691)	\$ (7,960,660)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	125,824	132,153	151,721
Stock issued for services	180,000	180,002	180,000
Stock-based compensation	844,628	1,134,811	1,206,398
Loss (gain) on disposition of property and equipment	(30)	-	118
Decrease (increase) in:			
Receivables	548,961	(601,326)	482,743
Inventories	116,581	(41,813)	2,257
Other current assets	53,709	(79,959)	1,079
Increase (decrease) in:			
Accounts payable	27,480	325,663	(106,182)
Accrued liabilities	292,648	149,182	92,694
Customer deposits	(275,699)	292,500	24,980
Deferred revenue	(687,665)	560,423	(11,087)
Net cash used in operating activities	(5,916,395)	(6,200,055)	(5,935,939)
Cash flows from investing activities:			
Purchase of property and equipment	(75,599)	(35,362)	(97,521)
Proceeds from disposition of property and equipment	2,025	-	-
Net cash used in investing activities	(73,574)	(35,362)	(97,521)
Cash flows from financing activities:			
Net proceeds from the sale of common stock	4,636,579	4,583,437	-
Proceeds from note payable	74,052	-	-
Payments on note payable	(40,774)	-	-
Net cash provided by financing activities	4,669,857	4,583,437	-
Net increase (decrease) in cash and cash equivalents	(1,320,112)	(1,651,980)	(6,033,460)
Cash and cash equivalents, beginning of year	9,450,528	11,102,508	17,135,968
Cash and cash equivalents, end of year	\$ 8,130,416	\$ 9,450,528	\$ 11,102,508

See accompanying notes to financial statements

## BSD MEDICAL CORPORATION

## Notes to Financial Statements

## Note 1: Organization and Significant Accounting Policies

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

**Cash and Cash Equivalents** – Cash and cash equivalents consist of cash and investments with original maturities to the Company of three months or less. As of August 31, 2014, we had \$25,000 in a restricted bank account.

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

**Inventories** – Parts and supplies inventories are stated at the lower of cost or market. Cost is determined using the average cost method. Work-in-process and finished goods are stated at the lower of the accumulated manufacturing costs or market. We maintain a reserve for obsolete inventories to reduce excess and obsolete inventories to their estimated net realizable value. The reserve was \$150,000 as of August 31, 2014 and \$100,000 as of August 31, 2013.

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

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

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

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

**Patents** – Patent costs are expensed as incurred.



Warranty Reserve – We provide limited warranties to our customers for products sold. Estimated future warranty obligations are accrued each period. As of August 31, 2014 and 2013, the accrued warranty reserve was \$75,728 and \$50,968, respectively. During the fiscal years ended August 31, 2013, 2012, and 2011, total warranty expense was \$41,471, \$80,276 and \$43,334, respectively.

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

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

The computation of diluted earnings per common share is based on the weighted average number of shares outstanding during the year, plus the common stock equivalents that would arise from the exercise of stock options and warrants outstanding, using the treasury stock method and the average market price per share during the year. Common stock equivalents are not included in the diluted loss per share calculation when their effect is anti-dilutive. Options and warrants to purchase 13,720,225, 9,669,878 and 5,590,762 shares of common stock at prices ranging from \$0.99 to \$7.95 were excluded from the calculation of diluted earnings per share for the years ended August 31, 2014, 2013 and 2012, respectively, because their effect was anti-dilutive.

Since we had no dilutive effect of stock options and warrants for the years ended August 31, 2014, 2013 and 2012, our basic weighted average number of common shares outstanding is the same as our diluted weighted average number of common shares outstanding.

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

Revenue Recognition – We recognize revenue from the sale of medical systems, disposable devices related to the systems, parts, and accessories, and equipment rental, training, and service support contracts. Our revenues consisted of the following:

	Years Ended August 31,		
	2014	2013	2012
Product sales	\$ 3,019,525	\$ 1,934,826	\$ 1,358,604
Disposable devices	1,568,481	1,109,750	344,751
Service contracts and other	375,747	330,116	238,487
	4,963,753	3,374,692	1,941,842
Equipment rental	364,600	298,600	129,350
Total	\$ 5,328,353	\$ 3,673,292	\$ 2,071,192

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

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

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

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

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

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

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

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

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

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

Advertising and Promotion – Advertising and promotion costs, which are principally included in sales expenses, are expensed as incurred. Advertising and promotion expense was \$206,099, \$205,442 and \$179,669 for the years ended August 31, 2014, 2013 and 2012, respectively.

Use of Estimates in the Preparation of Financial Statements – The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Comprehensive Loss – Comprehensive loss is the same as net loss for all years presented.

## Note 2: Detail of Certain Balance Sheet Accounts

Details of certain balance sheet accounts are as follows:

	August 31,	
	2014	2013
Accounts receivable:		
Trade receivables – non-related party	\$ 364,170	\$ 890,985
Other receivables	22,717	28,984
Allowance for doubtful accounts	(20,000)	(20,000)
	\$ 366,887	\$ 899,969
Inventories:		
Parts and supplies	\$ 1,369,960	\$ 1,353,614
Work-in-process	880,751	990,668
Finished goods	228,478	201,488
Reserve for obsolete inventories	(150,000)	(100,000)
	\$ 2,329,189	\$ 2,445,770
Accrued liabilities:		
Warranty reserve	\$ 75,728	\$ 50,968
Training and installation reserve	4,716	5,528
Accrued taxes payable	59,745	44,677
Payroll, commissions and other	726,339	472,707
	\$ 866,528	\$ 573,880

## Note 3: Property and Equipment

Property and equipment consist of the following:

	August 31,	
	2014	2013
Equipment	\$ 1,468,528	\$ 1,401,811
Rental equipment	58,940	58,940
Furniture and fixtures	303,226	300,061
Building improvements	54,736	54,736
Building	956,000	956,000
Land	244,000	244,000
	3,085,430	3,015,548
Less accumulated depreciation	(1,817,769)	(1,695,668)
	\$ 1,267,661	\$ 1,319,880

Depreciation expense for the years ended August 31, 2014, 2013 and 2012 totaled \$125,824, \$128,121 and \$130,661, respectively.

## Note 4: Patents

Patent costs are expense as incurred. In prior years we had certain patents recorded net of accumulated amortization. The patents were being amortized on a straight-line basis over their estimated legal life, up to a period of 17 years. Amortization expense was \$0, \$4,032 and \$21,060 for the years ended August 31, 2014, 2013, and 2012, respectively.

## Note 5: Stockholders' Equity

The Company has 10,000,000 authorized shares of \$.001 par value preferred stock. As of August 31, 2014 and 2013, there were no shares of preferred stock outstanding. The Company also has 80,000,000 authorized shares of \$.001 par value common stock.

## Shelf Registration Statements

On October 1, 2009, a universal shelf registration statement was declared effective by the SEC for the issuance of common stock, preferred stock, warrants, senior debt, subordinated debt and units up to an aggregate amount of \$50.0 million (the “2009 Shelf Registration Statement”). We completed four stock offerings utilizing the universal shelf registration statement during calendar year 2010, and we received total net proceeds of approximately \$19 million, including proceeds from the exercise of warrants issued in the stock offerings.

On September 28, 2012, we filed a universal shelf registration statement with the SEC for the issuance of common stock, preferred stock, warrants, senior debt, subordinated debt and units up to an aggregate amount of \$50.0 million. On October 11, 2012, the universal shelf registration statement was declared effective by the SEC. We may periodically offer one or more of these securities in amounts, prices and terms to be announced when and if the securities are offered. At the time any of the securities covered by the registration statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

## April 2013 Offering

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

The Agency Agreement contains customary representations, warranties and covenants by us. It also provides for customary indemnification by us and the Placement Agent for losses or damages arising out of or in connection with the sale of the securities being offered. We agreed to indemnify the Placement Agent against liabilities under the Securities Act of 1933, as amended. We also agreed to contribute to payments the Placement Agent may be required to make in respect of such liabilities.

Also on April 9, 2013, we and certain institutional investors entered into a securities purchase agreement (the “Purchase Agreement”) in connection with the April 2013 Offering, pursuant to which we agreed to sell an aggregate of 4,065,042 shares of our common stock and warrants to purchase a total of 3,048,782 shares of our common stock to such investors for aggregate gross proceeds, before deducting fees to the Placement Agent and other estimated offering expenses payable by us, of approximately \$5 million. The common stock and warrants were sold in fixed combinations, with each combination consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock. The purchase price was \$1.23 per fixed combination. The warrants became exercisable six months and one day following the closing date of the April 2013 Offering and will remain exercisable for five years thereafter at an exercise price of \$1.65 per share. The exercise price of the warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

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

We agreed with each of the purchasers that, subject to certain exceptions, we will not, within the 30 trading days following the closing of the April 2013 Offering (which period may be extended in certain circumstances), enter into any agreement to issue or announce the issuance or proposed issuance of any securities.

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

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

We also agreed with each of the purchasers if we issue securities within the 12 months following the closing of the April 2013 Offering, the purchasers shall have the right to purchase all of the securities on the same terms, conditions and price provided for in the proposed issuance of securities.

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

We closed the April 2013 Offering on April 12, 2013 and received net proceeds of approximately \$4.6 million, after deducting placement agent fees and the offering expenses borne by us.

The April 2013 Offering was completed using our shelf registration statement on Form S-3, pursuant to a prospectus supplement filed with the SEC.

#### May 2014 Offering

On May 9, 2014, the Company entered into an At-the-Market Issuance Sales Agreement (the "ATM Agreement") with MLV & Co. LLC ("MLV"). Under this sales agreement, we could issue and sell from time to time, up to \$8,000,000 of common stock. These shares are registered under the universal shelf registration filed with the SEC on September 28, 2012. MLV would act as sales agent, using commercially reasonable efforts consistent with its normal trading and sales practices. The Agreement provided that our common shares would be sold at market prices prevailing at the time of the sale of our common stock, at no discount to market and no warrants attached. We were not obligated to make any sales under the sales agreement. We paid MLV a commission rate of 3.0% of the gross proceeds from the sale of common stock sold through MLV as sales agent under the sales agreement, reimbursed MLV for certain expenses incurred in connection with entering into the sales agreement, and provided MLV with customary indemnification rights. The full terms and text of the sales agreement was filed by the Company on a Current Report on Form 8-K on May 9, 2014. Through June 22, 2014, the Company sold 46,622 shares of common stock at an

average price per share of \$1.074, for gross proceeds of \$50,068. The ATM Agreement was terminated on June 22, 2014.

F - 14

---

## June 2014 Offering

On June 25, 2014, the Company and certain institutional investors entered into a securities purchase agreement (the “June Offering”) in which the Company agreed to sell, pursuant to a securities purchase agreement (the “Purchase Agreement”), an aggregate of 5,500,000 shares of its common stock and warrants to purchase a total of 4,400,000 shares of its common stock to such investors for aggregate gross proceeds of approximately \$5.2 million, and net proceeds of approximately \$4.7 million, after deducting placement agency fees and other costs associated with the transaction. The common stock and warrants were sold in fixed combinations, with each combination consisting of one share of common stock and a warrant to purchase 0.8 shares of common stock. The purchase price was \$0.95 per fixed combination. The warrants will become exercisable six months and one day following the closing date of the June Offering and will remain exercisable for five years thereafter at an exercise price of \$1.10 per share. The exercise price of the warrants is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The exercisability of the warrants may be limited if, upon exercise, the holder or any of its affiliates would beneficially own more than 4.99% of the Company’s common stock. The warrants are contingently puttable at the option of the holders upon the occurrence of a fundamental transaction (as defined in the warrant agreements). The Company considers that all of the fundamental transactions are within the Company’s sole control, and that the probability of any fundamental transaction occurring and the put being exercised are both remote.

Under the Purchase Agreement, the Company has agreed with each of the purchasers that, subject to certain exceptions, it will not, within the 75 days following the closing of the June Offering enter into any agreement to issue or announce the issuance or proposed issuance of any securities. The Company also agreed with each of the purchasers that for a period of four years from the date of the Purchase Agreement, the Company will not effect or enter into an agreement to effect a “Variable Rate Transaction,” which means a transaction in which it:

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

The Company has also agreed to indemnify each of the purchasers against certain losses resulting from its breach of any of its representations, warranties, or covenants under agreements with each of the purchasers, as well as under certain other circumstances described in the Purchase Agreement. The transaction closed on July 1, 2014 and the net proceeds were transferred to the Company.

## Warrants

A summary of the outstanding warrants issued in our stock offerings as of August 31, 2014 and changes during the year then ended is as follows:

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contract Term (Years)
Outstanding as of August 31, 2013	5,457,305	\$ 2.93	
Granted	4,400,000	1.10	
Exercised	-	-	
Forfeited or expired	-	-	
Outstanding as of August 31, 2014	9,857,305	\$ 2.11	4.02
Exercisable as of August 31, 2014	5,457,305	\$ 2.93	2.96

## Note 6: Deferred Revenue

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

As of August 31, 2014 and 2013, we had deferred revenue of \$96,043 and \$783,708, respectively.

## Note 7: Major Customers and Foreign Sales

During the year ended August 31, 2014, we had sales to two foreign customers totaling 23.46% and 22.92% of total revenues. During the year ended August 31, 2013, we had sales to one customer totaling 30.36% of total revenues. During the year ended August 31, 2012, we had sales to four customers totaling 16.11%, 12.64%, 11.05% and 10.86% of total revenues.

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 combined were approximately 30% and 16% of total sales, respectively.

As of August 31, 2014 the highest account receivable due from one customer was approximately 26% of total accounts receivable. As of August 31, 2013 approximately 72% of accounts receivable was due from one customer.

## Note 8: Related Party Transactions

During the years ended August 31, 2014, 2013, and 2012, we had sales of \$419,549, \$99,896 and \$333,663, respectively, to entities controlled by a significant stockholder and member of the Board of Directors. These related party transactions represent approximately 8%, 3%, and 16% of total sales for each respective year.

As of August 31, 2014 and 2013, receivables include \$8,322 and \$24,201, respectively, from these related parties.

F - 16

---

## Note 9: Income Taxes

The income tax provision of \$2,000, \$1,938 and \$988 for the years ended August 31, 2014, 2013 and 2012, respectively, is comprised of a current provision for state income taxes.

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

	Years Ended August 31,		
	2014	2013	2012
Income tax benefit at federal statutory rate	\$ 2,428,000	\$ 2,805,000	\$ 2,706,000
Stock-based compensation	(287,000)	(335,000)	(324,000)
State income taxes, net of federal benefit	236,000	272,000	263,000
Research and development credit	99,000	106,000	88,000
Change in valuation allowance	(2,480,000)	(2,905,000)	(3,000,000)
Other	2,000	55,062	266,012
	\$ (2,000)	\$ (1,938)	\$ (988)

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

	August 31,	
	2014	2013
<b>Current Asset:</b>		
Accruals and reserves	\$ 62,000	\$ 26,000
Deferred revenue	33,000	266,000
Inventories	90,000	68,000
Valuation allowance	(185,000)	(360,000)
	\$ -	\$ -
<b>Long-Term Asset (Liability):</b>		
Deferred compensation	\$ 601,000	\$ 601,000
Research and development and other tax credits	1,896,000	1,804,000
Net operating loss carryforwards	13,938,000	11,380,000
Depreciation and amortization	8,000	3,000
Valuation allowance	(16,443,000)	(13,788,000)
	\$ -	\$ -

The ultimate realization of the deferred tax assets is dependent, in part, upon the tax laws in effect, our future earnings, and other events. As of August 31, 2014, we recorded a valuation allowance of \$185,000 against current deferred tax assets, and a valuation allowance of \$16,443,000 against net long-term deferred tax assets. The increase in the valuation allowance for the year ended August 31, 2014 relates primarily to our operating losses. In recording the valuation allowance, we were unable to conclude that it is more likely than not that our deferred tax assets will be realized.



In addition to the deferred tax assets listed above, the Company has unrecorded tax benefits of approximately \$2,600,000 attributable to the difference between the amount of the financial statement expense and the allowable tax deduction associated with stock-based compensation. As a result of net operating loss carryforwards, the Company was not able to recognize the excess tax benefits of share-based compensation deductions because the deductions did not reduce income tax payable. Although not recognized for financial reporting purposes, this unrecorded tax benefit is available to reduce future income and is incorporated into the disclosed amounts of the Company's net operating loss carryforwards, discussed below. If subsequently realized, the benefit will be recorded to contributed capital.

As of August 31, 2014, we had a net operating loss carryforward available to offset future taxable income of approximately \$37,800,000, which will begin to expire in 2029. If substantial changes in the Company's ownership should occur, there would be an annual limitation of the amount of the net operating loss carryforward which could be utilized.

We perform a review of our material tax positions in accordance with recognition and measurement standards established by authoritative accounting literature, which requires a company to determine whether it is more likely than not that a tax position will be sustained upon examination based upon the technical merits of the position. If the more-likely-than-not threshold is met, a company must measure the tax position to determine the amount to recognize in the financial statements. Based upon our review and evaluation, during the years ended August 31, 2014, 2013 and 2012, we concluded the Company had no unrecognized tax benefit which would affect its effective tax rate if recognized.

We classify any interest and penalties arising from the underpayment of income taxes in our statements of comprehensive loss in other income (expense). As of August 31, 2014 and 2013, we had no accrued interest or penalties related to uncertain tax positions.

We file income tax returns in the U.S. federal jurisdiction and various state jurisdictions. U.S. federal income tax returns from the year ended August 31, 2011 through the year ended August 31, 2014 are subject to examination.

#### Note 10: Stock-Based Compensation

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

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

Stock-based compensation cost is measured at the grant date based on the estimated value of the award granted, using the Black-Scholes option pricing model, and recognized over the period in which the award vests. For stock awards no longer expected to vest, any previously recognized stock compensation expense is reversed in the period of termination.

The stock-based compensation expense has been allocated to the various categories of operating costs and expenses in a manner similar to the allocation of payroll expense as follows for the years ended August 31:

	2014	2013	2012
Cost of sales	\$ 61,427	\$ 67,119	\$ 64,090
Research and development	183,371	212,569	202,453
Selling, general and administrative	599,830	855,123	939,855
Total	\$ 844,628	\$ 1,134,811	\$ 1,206,398

During the year ended August 31, 2014, we granted a total of 127,000 stock options to employees with exercise prices ranging from \$.99 to \$1.34 per share and with one third vesting each year for the next three years. The weighted average estimated grant-date fair value per share of these stock options was \$0.62, and our assumptions used in the Black-Scholes valuation model to determine this estimated fair value are shown below:

Expected volatility	64.29%
Expected dividends	0.00%
Expected term	7.35 Years
Risk-free interest rate	2.20%

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

Unrecognized stock-based compensation expense expected to be recognized over the estimated weighted-average amortization period of 0.72 years is approximately \$742,697 as of August 31, 2014.

A summary of the time-based stock option awards as of August 31, 2014, and changes during the year then ended, is as follows:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (Years)	Aggregate Intrinsic Value
Outstanding as of September 1, 2013	4,212,573	\$ 2.85		
Granted	127,000	1.19		
Exercised	-	-		-
Forfeited or expired	(476,653)	2.18		
Outstanding as of August 31, 2014	3,862,920	\$ 2.88	6.32	\$ -
Exercisable as of August 31, 2014	2,742,920	\$ 3.45	5.39	\$ -

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value, based on the Company’s closing stock price of \$0.65 as of August 31, 2014, which would have been received by the holders of in-the-money options had the option holders exercised their options as of that date.

#### Note 11: Supplemental Cash Flow Information

During the years ended August 31, 2014, 2013 and 2012, we paid no amounts for interest. During the years ended August 31, 2014, 2013 and 2012 we paid \$2,000, \$1,938 and \$988 for income taxes.

During the years ended August 31, 2014, 2013 and 2012 we had no non-cash financing and investing activities.



Note 12: Commitments and Contingencies

Employment Agreement - CEO

On May 22, 2013, we entered into an employment agreement with our President and Chief Executive Officer. The Employment Agreement sets the CEO's base salary at \$275,000, with a review at least annually by the Compensation Committee of the Board of Directors. The agreement provides that the CEO is entitled to participate in any annual incentive bonus programs, employee benefit plans adopted or maintained by the Company, and the Company's Stock Incentive Plan. Additional provisions of the agreement include indemnification for expenses associated with defending certain claims made against the CEO as a result of his position with the Company, and directors' and officers' liability insurance providing coverage during the term of the Employment Agreement and for a period of six years following the termination of the Employment Agreement. The Employment Agreement also provides that if he is terminated by the Company other than for cause, or if he resigns for good reason and complies with certain requirements, the Company is obligated to pay him an amount equal to his base salary (the "CEO Severance Payment") and provide employee benefits for one year following termination. If the Employment Agreement is terminated for cause, he shall receive only the portion of his base salary that is due to him through the effective date of his termination. If the Employment Agreement is terminated by reason of his death, his estate shall receive his salary through the end of the month in which he died plus all employee benefits due to him through the end of such month. If a Change in Control (as defined in the Employment Agreement) occurs with respect to the Company, and during the six months immediately following the Change of Control, (i) the Company terminates him without cause; (ii) he terminates his employment with good reason; or (iii) he terminates the Employment Agreement but also agrees to continue serving as President and Chief Executive Officer for the longer of (a) six months and (b) until a new President and Chief Executive Officer is appointed, then in addition to the CEO Severance Payment, all options or incentive awards granted to him will immediately vest and become exercisable for a period of 180 days following the termination. The Employment Agreement also contains a confidentiality agreement, and a one-year non-competition and non-solicitation agreement. The Employment Agreement contains a claw back provision that enables the Company to claw back any incentive-based compensation or other compensation from him if required by any law, government regulation, stock exchange listing requirement, or Company policy adopted as required by such law, government regulation, or stock exchange listing requirement.

On April 29, 2014, the Company announced that the Company's President and Chief Executive Officer, Mr. Harold R. Wolcott, will relinquish his positions as President and Chief Executive Officer of the Company upon the Company's hiring of a new President and Chief Executive Officer. Mr. Wolcott will continue to serve on the Company's board of directors and on the search committee responsible for finding the Company's next chief executive officer. On April 28, 2014, the Company entered into a letter agreement with Mr. Wolcott, pursuant to which Mr. Wolcott will receive severance benefits that supersede the severance benefits Mr. Wolcott was previously entitled to receive under his employment agreement. Pursuant to the letter agreement, if Mr. Wolcott ceases to serve as President and Chief Executive Officer of the Company for any reason (other than for cause), the Company will pay to Mr. Wolcott an amount equal to his current base salary, and the vesting of his equity awards will immediately vest and become exercisable. Notwithstanding the foregoing, if Mr. Wolcott voluntarily terminates his service with the Company without good reason before the first to occur of (1) the expiration of six months from the date of the letter agreement, or (2) the selection of a new chief executive officer by the Company, then the Company will not be obligated to pay the severance benefits described in this paragraph.

Employment Agreement – CFO

On September 16, 2014, the Company entered into an employment agreement with its Chief Financial Officer. The employment agreement provides that his base salary shall be \$200,000, to be reviewed at least annually by the Compensation Committee of the Board of Directors. The agreement provides that the CFO is entitled to participate in

any annual incentive bonus programs, employee benefit plans adopted or maintained by the Company, and the Company's Stock Incentive Plan. Additional provisions of the agreement include indemnification for expenses associated with defending certain claims made against the CFO as a result of his position with the Company, and directors' and officers' liability insurance providing coverage during the term of the Employment Agreement and for a period of six years following the termination of the Employment Agreement. If the CFO is terminated by the Company other than for cause, or resigns for good reason, and complies with certain requirements, the Company is obligated to pay him an amount equal to his base salary (the "CFO Severance Payment") and provide employee benefits for one year following termination. If the Employment Agreement is terminated for cause, he shall receive only the portion of his base salary that is due to him through the effective date of his termination. If the Employment Agreement is terminated by reason of his death, his estate shall receive his salary through the end of the month in which he died plus all employee benefits due to him through the end of such month. If a Change in Control (as defined in the Employment Agreement) occurs with respect to the Company, and during the six months immediately following the Change of Control, (i) the Company terminates him without cause; (ii) he terminates his employment with good reason; or (iii) he terminates the Employment Agreement but also agrees to continue serving as CFO for the longer of (a) six months and (b) until a new CFO is appointed, then in addition to the CFO Severance Payment, all options or incentive awards granted to him will immediately vest and become exercisable for a period of 180 days following the termination. The Employment Agreement also contains a confidentiality agreement, and a one-year non-competition and non-solicitation agreement. The Employment Agreement contains a claw back provision that enables the Company to claw back any incentive-based compensation or other compensation from him if required by any law, government regulation, stock exchange listing requirement, or Company policy adopted as required by such law, government regulation, or stock exchange listing requirement.

#### Employment Agreement – CTO

We entered into an employment agreement with our Chief Technical Officer ("CTO") dated November 2, 1988. The agreement sets the CTO's annual base salary for each year until October 1, 1993 and provides that after October 1, 1993 the CTO's annual base salary will be based upon a reasonable mutual agreement between the CTO and the Company. The CTO's annual base salary was raised to \$220,500 effective August 5, 2013. In the event of termination of the CTO's employment with the Company without cause (as defined in the agreement) or the CTO's resignation for good reason (as defined in the agreement), the agreement provides that the CTO will receive severance pay for a one-year period, which pay includes an extension of all of his rights, privileges and benefits as an employee (including medical insurance). The one-year severance pay shall be equal to the CTO's average annual salary for the 12-month period immediately prior to the termination. The agreement also requires us to pay the CTO for any accrued, unused vacation at the time of termination. We are also obligated to pay the CTO \$1,000 (or the equivalent value in stock options) for each newly issued patent obtained by us as a result of the CTO's efforts (the CTO receives only \$500 if multiple inventors are involved). The CTO's agreement includes a non-competition covenant prohibiting him from competing with us for one year following his termination. We may continue the non-competition period for up to four additional years by notifying the CTO in writing and by continuing the severance payments for the additional years during which the non-competition period is extended.

License Agreement - Probes

We have an exclusive worldwide license for a unique temperature probe. The license has no determinable life. We pay royalties based upon sales of this probe. Accrued royalties were \$3,395 and \$840 as of August 31, 2014 and 2013, respectively. Royalty expense amounted to \$3,745, \$1,960 and \$2,275 for the years ended August 31, 2014, 2013 and 2012, respectively.

Note 13: Recent Accounting Pronouncements

In May 2014, FASB issued ASU 2014-09 Revenue from Contracts with Customers. The amendments in ASU 2014-09 affects any entity that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards (e.g., insurance contracts or lease contracts). This ASU will supersede the revenue recognition requirements in Topic 605 Revenue Recognition and most industry-specific guidance, and creates a Topic 606 Revenue from Contracts with Customers.

The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps:

- Step 1: Identify the contract(s) with a customer.<sup>3</sup>
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is not permitted. The Company has not yet determined how its financial statements will be affected by the adoption of ASU 2014-09.

Note 14: Subsequent Events

On September 16, 2014, the Company entered into an employment agreement with its Chief Financial Officer, William S. Barth (see Note 12 – Commitments and Contingencies, Employment Agreement - CFO).

On November 10, 2014, the Company entered into a consulting agreement with its former Chief Executive Officer, Harold R. Wolcott, who resigned effective November 10, 2014.

The Company has evaluated events occurring after the date of our accompanying balance sheets through the date of the filing of this Annual Report on Form 10-K. No material subsequent events requiring adjustment to our accompanying financial statements were identified.