

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

BSD MEDICAL CORP
Form 10KSB
November 29, 2004

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

FORM 10-KSB

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

For the Fiscal Year Ended August 31, 2004

Commission file number 0-10783

BSD MEDICAL CORPORATION
(Name of small business issuer in its charter)

Delaware
(State of incorporation)

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

2188 West 2200 South
Salt Lake City, UT
(Address of principal executive offices)

84119
(Zip Code)

Issuer's telephone number: (801) 972-5555

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

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

Common Stock, \$0.001 par value

(Title of class)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained herein, and no disclosure will 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-KSB or any amendment to this Form 10-KSB.

Issuer's revenues for its most recent fiscal year: \$1,630,648

The approximate aggregate market value of the issuer's common stock held by non-affiliates, computed by reference to the price at which the stock was sold, or the average bid and asked prices of such stock, as of November 10, 2004, was \$13,415,112.

As of November 10, 2004, there were 20,057,333 shares of the issuer's common stock, par value \$0.001, outstanding.

Documents Incorporated by Reference: Portions of the issuer's proxy statement to be filed in connection with its annual meeting of stockholders are incorporated by reference into Part III of this Form 10-KSB.

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Transitional Small Business Disclosure Format: Yes [] No [X]

PART I

ITEM 1. BUSINESS

Overview

We develop, manufacture, market and service systems that deliver focused electromagnetic energy for use in a variety of medical therapies and applications. Focused electromagnetic energy (non-ionizing electromagnetic radiation) is used to heat diseased sites in the body to temperatures as required by a number of medical therapies. Our business objectives are to commercialize our products developed for the treatment of cancer, and further expand our developments to treat other diseases and medical conditions. For convenience, the terms "company," "BSD," "we" and "our" refer to BSD Medical Corporation.

We pioneered the use of microwave thermal therapy for the treatment of the symptoms associated with enlarged prostate, and are responsible for much of the technology that has created a substantial medical industry using that therapy. Since the inception of our company, our primary research has centered on the application of focused electromagnetic energy for the treatment of cancer. Our technology can be used both as a combination therapy with existing cancer treatments or as a stand-alone cancer therapy. Current and possible expansion of our cancer treatment sites include cancers of the prostate, breast, head, neck, bladder, cervix, colon/rectum, esophagus, liver, brain, bone, stomach and lung.

In addition, although we have not entered these markets, we believe our technology has application for numerous other medical purposes, including the treatment of such conditions as psoriasis, arthritis, fibroids, hemorrhoids, menorrhagia (excessive menstrual bleeding), benign tumors and cysts. We believe our technology is also applicable in treating special medical problems such as sleep apnea, and in the treatment of varicose veins and cosmetic skin tightening without surgery (face lifts). Our objective is to commercialize our developed products and further expand our developments into new markets.

Sale of TherMatrx

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

We determined early in our planning that we would treat our BPH development as a spin-off business with the intent of providing an asset that would fund our other business objectives. As a result, we introduced the opportunity to investment groups and subsequently on October 31, 1997 entered into an agreement with investors Oracle Strategic Partners, L. P. and Charles Manker. Together we established a new company, TherMatrx, Inc. TherMatrx received capital from these investors to conduct clinical trials, and after

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

obtaining FDA approval in July 2001, the funding to commercialize the development. We were compensated for providing manufacturing, regulatory and engineering support to assure the success of the new company.

On July 15, 2004, American Medical Systems Holdings, Inc., or AMS, acquired TherMatrx for \$40 million in cash plus future payments contingent upon the combined entity's future sales of TherMatrx's DOT systems. The sale included all of our TherMatrx shares. Our approximate 30% ownership in TherMatrx was reduced to approximately 25% because of the exercise of outstanding options to

1

acquire common stock of TherMatrx at the closing. We received an initial cash payment, after the withholding of escrow funds and the payment of other initial obligations, of approximately \$9 million. We may also receive future contingent payments. Contingent payments to TherMatrx shareholders will be four times quarterly sales of TherMatrx's DOT systems during the six quarters beginning July 5, 2004 and ending December 31, 2005. We will receive quarterly contingent payments when the accumulated value of four times quarterly sales has exceeded the initial \$40 million payment to TherMatrx shareholders. The contingent payments are also subject to certain set-off rights in favor of AMS. The aggregate maximum amount of the initial payment and any contingent payments is \$250 million.

While the contingent payments are not guaranteed and are subject to the future sales of TherMatrx products, we have offered the following projections. If the sale of TherMatrx products were to remain flat at the recent sales rates, the total payment for our TherMatrx shares would be about \$30 million, including the initial payment of approximately \$9 million. Since the sale of TherMatrx products has been increasing in the current year over previous years, we have projected a continued growth trend during the earn-out period. If that growth trend were realized, the projected total payment for our TherMatrx shares would be about \$40 million, including the initial payment of approximately \$9 million. However, any future payments are not guaranteed and are subject to uncertainties, and we may not receive any contingent payments in addition to the initial \$9 million, which is the only amount guaranteed. If TherMatrx sales exceed our projections, the maximum payout that we could receive from the sale of our TherMatrx shares is approximately \$62.5 million. If TherMatrx sales fall below our projections and the past sales rates, there is no guarantee of payment beyond the initial payment, which is non-refundable. AMS has reported that TherMatrx sales for the first quarter since the sale of TherMatrx were \$5.2 million, which is consistent with our projection.

Cancer Therapy Systems

Since the inception of our company we have engineered systems designed to increase the effectiveness of cancer treatment through the use of focused electromagnetic energy. This focused energy is used to selectively heat cancerous tissue. Heat is used to destroy cancer cells directly, and also to condition tumors for more effective treatment by radiation and chemotherapy. Heat stimulates tumor blood flow and the consequent absorption of chemotherapy drugs. Heating also increases the presence of oxygen in the tumor needed to form the hydroxide radicals used to destroy cancer cell DNA in radiation treatments.

We have developed various technologies for heating cancerous tumors, depending on their location in the body. Through our development efforts, cancers such as melanomas or recurrent breast cancer located near the surface of the body can be treated with superficial cancer treatment applicators and

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

systems. Cancers that can be accessed through natural body orifices, or that are accessible through catheters inserted into the tumor as part of invasive radiation techniques (such as used to treat prostate cancer or head and neck cancer) can be treated with tiny, inserted antennae that we have developed to deliver focused electromagnetic energy into the cancerous tissue. We have also developed systems to non-invasively treat cancers located deep in the body by focusing electromagnetic energy on the cancer through a cylindrical applicator that surrounds the body. This cylindrical applicator contains an array of multiple antennae that focus electromagnetic energy, and therefore heat, on the tumor. Temperature levels for treatments are monitored through small temperature sensors, and some of our systems can be interfaced with magnetic resonance imaging so that the treatment in progress can be observed, and temperatures can be monitored through images.

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

2

The BSD-500 has received FDA approval. In addition the system has gone through an extensive revision, and has obtained two FDA supplements to this approval to further refine its commercial presentation.

In October 2004, we entered into an agreement with Best Medical International, Inc. to act as our exclusive sales agent for the BSD-500 in the United States. Best Medical is a leading supplier of products in the target market for the BSD-500. In this sales launch, our first objective is to sell the BSD-500 to well known, progressive cancer treatment centers that can act as spokesmen and reference sites for our systems. We believe that these centers will be an important catalyst for broader, general sales of the BSD-500.

The list price for the BSD-500 varies from \$175 thousand to \$225 thousand, depending on the features of the system. Our target is to sell BSD-500 systems as companions for the over 1,500 installed brachytherapy systems (radiation systems using targeted radiation sources) that the BSD-500 was developed to complement. The BSD-500 increases the effectiveness of brachytherapy, a specialized form of radiation therapy.

The BSD-2000 does not currently have FDA approval except as an investigational device; however, the phase III clinical trial that we will use to apply for the FDA approval has been concluded and published in a major journal. We project that we will obtain FDA approval for the BSD-2000 in 2006. We are also seeking regulatory approval for the sale of the BSD-2000 in the People's Republic of China. We anticipate Chinese regulatory approval during 2005. However, the decision regarding the granting of regulatory approvals, together with their timing, is not in our control, and is the responsibility of those respective regulatory authorities.

The list price of the BSD-2000 ranges between \$350 thousand and \$1.3 million, depending on the features of the system. The target for the BSD-2000 is to sell companion BSD-2000 systems for the over 7,500 installed linear accelerators used for radiation therapy.

Nearly all of our sales of cancer therapy systems over recent past periods have been to cancer research institutions for use in conducting clinical trials with our equipment. As a company, we are now in the early stages of commercial selling of the BSD-500. Obtaining FDA approval for the BSD-2000 would

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

contribute to our sales efforts by providing the additional technology required for the treatment of solid tumors located virtually anywhere in the body.

Our business model for cancer systems is based on systems sales, a significant aftermarket revenue stream from service contracts and the sale of replacement components associated with the therapy. We intend to use the revenue from the sale of TherMatrx for commercializing our developed products, and for expanding into new markets.

Our Cancer Treatment Systems

Despite the massive attention given to cancer prevention and treatment, the American Cancer Society estimates that 1,368,030 new cancer cases will be diagnosed and that 563,700 Americans will die from cancer during 2004 (up from 556,500 cancer deaths in 2003). Exceeded only by heart disease, cancer, as a group of diseases, remains the second leading cause of death in the United States. 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.

3

The primary cancer therapies currently used include:

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

Because cancer remains a significant cause of death, these three cancer therapies are still grossly inadequate, and an enormous need for better treatment is obvious. Our therapy that produces heating of tissue (a condition called "hyperthermia") is an emerging cancer therapy that both kills cancer cells directly and has been shown to be a potent additive treatment in making certain of the major existing cancer therapies more effective for some cancers.

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

While sensitizing tumors for more effective treatment from radiation

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

and/or chemotherapy, hyperthermia also destroys cancer cells directly through damage to the plasma membrane, the cytoskeleton and the cell nucleus, and by disrupting the stability of cellular proteins. Tumors with poor blood supply systems lack the natural cooling capacity provided by efficient blood flow in normal tissues, making them selectively susceptible to the cancer-destructive effects of hyperthermia therapy. While temperatures between 40(degree)C and 45(degree)C are used to kill cancer cells in combination with radiation and chemotherapy, higher temperature treatments, called "thermal therapy" or "thermotherapy," are used when treatment of cancer is accomplished by heat alone.

Hyperthermia has other therapeutic uses. It can be used to shrink tumors prior to surgery, potentially making resection easier or even possible. Research has shown hyperthermia to be an activator for gene therapies by speeding gene production (heat mediated gene therapy). Hyperthermia may play a role in the development of new anti-tumor vaccines that are based on the production of heat shock proteins. Research has shown hyperthermia to be an angiogenesis inhibitor, which means it helps prevent cancer from inducing growth of new blood vessels to expand its blood supply. Hyperthermia could also become a follow-up therapy for other angiogenesis inhibitors, used in the final destruction of cancer cells depleted of blood by angiogenesis inhibitor therapy. Hyperthermia has been shown to improve a patient's quality of life. Even in situations where there is no hope for survival, hyperthermia may provide benefits through alleviation of such effects of cancer as bleeding, pain and infection.

Since 1978, we have been heavily involved in developing technological advances to expand the use of hyperthermia therapy for the treatment of cancer. Our efforts have included joint work with many notable cancer research centers in the United States and Europe. In past years, funding for our research efforts has been provided by such sources as the National Institutes of Health in the United States and major European government agencies. In recent years, we have focused our efforts in perfecting the technology required to precisely deliver deep, non-invasive hyperthermia therapy for the treatment of pelvic and other deep cancers and to demonstrate effective use of deep hyperthermia through clinical trials. We believe that our BSD-2000 system has emerged from this development effort as the world's most advanced system for deep hyperthermia therapy.

4

In the opening address at the April 21, 2001 annual meeting of the North American Hyperthermic Society (sponsored by the Radiological Society of North America), P. K. Sneed, M.D. of the University of California at San Francisco summarized the results of completed randomized clinical trials in which the effectiveness of radiation therapy combined with hyperthermia therapy were compared with the results of radiation therapy alone in cancer treatment. The summary of the report on these trials was that for melanoma, after two years, local control (local regression or disappearance of the tumor) was 28% for the control group of patients who received radiation therapy alone versus 46% local control for the patients who received both hyperthermia and radiation therapy. For recurrent breast cancer, the complete response rate (complete disappearance of the tumor) increased from 38% for those receiving radiation therapy alone to 60% for those patients who received both hyperthermia and radiation therapy. For glioblastoma (brain cancer), the two-year survival rate for patients who received radiation therapy alone was 15%, compared to 31% survival rate two years after treatment for those who received both hyperthermia and radiation therapy. For advanced cervical cancer, the complete response rate (disappearance of the tumor) rose from 57% for patients who received radiation treatments alone to 83% for patients receiving both hyperthermia and radiation therapy. The cervical cancer data was based on the condition of patients three

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

years after treatment.

Our Products and Services

We have developed the technology and products required to approach hyperthermia therapy through three different techniques, which collectively allow cancer to be treated virtually anywhere in the body:

- o 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.
- o Internal or interstitial hyperthermia treats tumors in combination with internal radiation therapy by inserting tiny microwave antennae that deliver hyperthermic microwave energy to tumors through the same catheters used to deliver radioactive materials, or "seeds," to tumors for radiation therapy. This technique can be employed in treating prostate cancer, breast cancer, head and neck cancer and a variety of other cancer sites.
- o Deep hyperthermia non-invasively treats tumors located deep within the body, including many problematic cancer sites located in the pelvis, abdomen and chest areas.

BSD-500 Systems. Our BSD-500 systems are used to deliver either superficial or interstitial hyperthermia therapy or both. There are four configurations of the BSD-500. The BSD-500i-4 and BSD-500i-8 provide interstitial hyperthermia treatment using four or eight channel generators, respectively. Each channel can control three interstitial applicators. The BSD-500c-4 and BSD-500c-8 provide both superficial and interstitial hyperthermia treatments using four or eight channel generators. These systems include a touch screen display monitor by which the operator controls the hyperthermia treatment, computer equipment and software that controls the delivery of microwave energy to the tumor, and a generator that creates the needed microwave energy for the treatment. Additionally, the systems include a variety of applicators, depending on each system configuration. Non-invasive superficial applicators are used for superficial hyperthermia treatments. For interstitial hyperthermia treatments, the system may include up to 24 tiny microwave heat-delivering antennae that are inserted into catheters used in the standard practice for internal radiation therapy (called brachytherapy).

5

In October 2003, we announced that we had received FDA approval for a new operating system, allowing us to commercially introduce this new family of four systems. Our FDA approval (described as a pre-market approval, or PMA, the standard FDA approval required to market Class III medical devices in the United States) for the BSD-500 family of systems is applicable to the marketing of all four configurations of the BSD-500 in the United States. We have also certified the BSD-500 systems for the CE Mark, which is required for export into some European countries. Obtaining FDA approval and CE Mark for the new BSD-500 operating systems were major milestones for us.

BSD-2000. The BSD-2000 family of products includes the BSD-2000, the BSD-2000/3D and the BSD-2000/3D/MR. These systems non-invasively deliver hyperthermic microwave energy to cancerous tumors, including those located deep within the body. These systems include a computer and software that control the delivery of microwave energy to the tumor, a microwave energy generator, an amplifier that boosts the microwave power, and a special applicator that delivers the microwave energy to the patient lying in a prone position on a

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

specially designed support table. The BSD-2000 systems are able to direct, focus and deliver microwave energy deep within the body by precisely "steering" the energy to the tumor from an array of cylindrical antennae. The basic BSD-2000 has eight microwave antennae enabling this electronic steering of energy within the patient's body. The BSD-2000/3D has 24 microwave antennae enabling additional electronic steering along the long axis of the body. The 3D steering is particularly useful when implemented with a magnetic resonance system that is capable of non-invasive 3D imaging showing the heated regions, thus permitting the 3D steering to more accurately target the energy to the tumor site.

The BSD-2000 systems have not yet received pre-market approval from the FDA for commercial marketing in the United States, but the BSD-2000 has obtained an investigational device exemption, or IDE, for sale in the United States for research purposes only. We have also certified the BSD-2000 family for the CE Mark required for export into certain European countries. We are engaged in the extensive and time consuming process of preparing an FDA submission requesting a PMA for the BSD-2000 based on clinical data we have already obtained. While we believe that this data has great merit and is worthy of submission, due to the inherent uncertainties of the FDA approval process there can be no assurance that FDA approval will be obtained through our submissions.

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

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

6

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

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

We installed and tested the first BSD-2000/3D/MR system at a leading

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

German oncological research institution, the Clinic of Medical Oncology of the Klinikum Gro(beta)hadern Medical School of Ludwigs-Maximilians-Universitat Munchen, in Munich, Germany. We installed a second BSD-2000/3D/MR system at the Department of Radiology of Charite University Medical School of Humboldt University in Berlin, Germany, as part of a collaborative effort with Siemens Medical Systems. The funding for purchase and development of these systems was provided by the German government and public foundation funds.

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

Sales, Marketing and Distribution

Our target market includes clinics, hospitals and institutes in which cancer is treated, whether in the Unites States or international markets.

In May 2002, we entered into an agreement with Nucletron B.V. under which Nucletron became our exclusive sales agent in most of the world for our BSD-500i interstitial hyperthermia therapy system. We sold only one BSD-500i through Nucletron. We have not felt that our relationship with Nucletron was successful, and our sales agreement with Nucletron wasterminated in March 2004.

In September 2004, we entered into an agreement with Dalian Orientech Co. LTD to seek regulatory approval for the sale of the BSD-2000 in the People's Republic of China, and thereafter to act as our exclusive distributor for the sale of the BSD-2000 in that country. The agreement has a five-year term, after which the agreement may be extended by mutual consent of the parties. Under the current agreement, Dalian Orientech will purchase the BSD-2000 systems from us and then resell them within the People's Republic of China. Dalian Orientech is compensated for its efforts by retaining the difference between the price it pays to purchase the products from us and the price it receives upon sale. Dalian Orientech is a leading distributor of hyperthermia systems in the People's Republic of China.

In October 2004, we entered into an agreement with Best Medical International, Inc. to act as our exclusive sales agent for our BSD-500 systems in the United States. The agreement has one-year term, prior to the conclusion of which we will negotiate the terms of any future relationship. If Best Medical meets certain sales milestones, it has a right of first refusal for a non-exclusive distribution agreement in the United States for our BSD-500 systems. Best Medical is entitled to sales commissions on the amounts we receive from its sales of our BSD-500 systems. Best Medical is a leading supplier of products in the target market for the BSD-500. In this sales launch, our first objective is to sell the BSD-500 to well known, progressive cancer treatment centers that can act as spokesmen and reference sites for our systems. We believe that these centers will be an important catalyst for broader, general sales of the BSD-500.

7

For our other products that deliver deep hyperthermia therapy, including the BSD-2000 and related products, we sell our equipment directly to end-users in the United States. We make international sales of these products through distributors located in various foreign countries.

Medizin Technik is our exclusive distributor of hyperthermia systems in Germany, Austria and Switzerland and to certain medical institutions in Belgium

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

and the Netherlands. Medizin Technik is required to use best efforts to sell our product within its territory. Due to the limited number of systems that are sold through this relationship, we do not have pre-negotiated price terms with Medizin Technik. If Medizin Technik identifies a potential customer, it will negotiate the price of a hyperthermia system with us, purchase the system, and resell the system to the customer on terms it negotiates with the customer. We generally do not provide our distributors with rights of return, price protection, discounts, credits, or other special terms or sale incentives. However, we did provide Medizin Technik with an extra applicator at no additional charge as a sales incentive in connection with the sale of a BSD-2000 system in fiscal 2004. Our distributorship agreement with Medizin Technik runs from year-to-year and may be terminated by either party by providing written notice to the other party before December 31 and automatically terminates upon the occurrence of certain events, including the retirement or death of Dr. Sennewald. Dr. Sennewald is a director and shareholder of BSD and of Medizin Technik.

Our sales and marketing strategy involves three main components:

- o promoting acceptance by the scientific community and cancer-treating healthcare professionals of hyperthermia therapy as a viable and effective therapy for treating cancer, either in combination with other therapies or as a stand alone therapy;
- o disseminating information about and marketing our hyperthermia therapy systems to the scientific community, cancer-treating healthcare professionals, cancer patients and the general public; and
- o working to continuously improve third-party reimbursement for medical services performed with our products.

We disseminate information about our company and our hyperthermia therapy systems by encouraging articles about hyperthermia therapy to be published in scientific journals, periodicals and other publications, and promoting dissemination of BSD information through television, radio and other media outlets. We post information about our products on our web site, www.bsdmc.com, and our materials are also posted on many other sites. We have developed promotional materials for our products, including product brochures, patient brochures and newsletters. We also participate actively in trade shows and scientific symposia, make public presentations delivered by our scientific staff and by scientists and researchers using our systems, and we actively participate in a variety of medical associations. We are co-sponsors of the annual international BSD Users' Conference in Europe.

Third-Party Reimbursement

We view obtaining adequate third-party reimbursement arrangements as essential to achieving commercial acceptance of our hyperthermia therapy products. Our products are purchased primarily by clinics, hospitals and other medical institutions that bill various third-party payers, such as Medicare, Medicaid, other government programs and private insurance plans, for the health care services provided to their patients using our products. Additionally,

managed care organizations and insurance companies directly pay for services provided to their patients. The Center for Medicare and Medicaid Services, or CMS, has established 23 billing codes that allow for third-party reimbursement and can be used for or in combination with the delivery of hyperthermia therapy,

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

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 or chemotherapy. Codes also have been established for providing deep hyperthermia therapy. Billing codes are available for both institutions and physicians.

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

General hyperthermia reimbursement has been approved in the United States, Germany, Holland, Switzerland and Japan. CMS has also provided billing codes for thermotherapy/thermal therapy treatment of BPH. These billing codes apply to TherMatrx's TMx-2000 system treatments of BPH.

Even though a new medical device may have been approved for commercial distribution, we may find limited demand for that product until reimbursement approval is obtained from governmental and commercial third party payors of health care. In addition, even after we receive reimbursement approval, or coverage, of a product, medical reimbursement rates are unpredictable. Both government and commercial third party payors of health care are seeking to limit the growth of health care costs. If clinics, hospitals, and other health care providers are not reimbursed adequately for our product, they may not purchase our product. We cannot project the extent to which our business may be affected by future legislative and regulatory developments, and private sector initiatives, to reduce health care costs. We cannot assure that future health care legislation or regulation will not have a material adverse effect on the coverage of our products, our business, financial condition and results of operations, or that reimbursement, existing or in the future, will be adequate to ensure that customers continue to purchase our products.

Competition

Competition in the medical products industry is intense. We believe that established product lines and cancer therapies, FDA approvals, know-how and reputation in the industry are key competitive factors. Currently, only a few companies besides BSD have received FDA approval to manufacture and sell hyperthermia therapy systems within the United States, including U.S. Labthermics and Celsion Corporation. Celsion is principally involved with clinical trials related to thermotherapy, hyperthermia and related fields. Labthermics produces ultrasound-based systems, which compete with our microwave hyperthermia systems. Several other companies have received IDEs in the United States or other international clearance for certain experimental hyperthermia systems designed to treat both malignant and benign diseases. Additionally, other companies, particularly established companies that currently manufacture and sell other cancer therapy systems, could potentially become competitors (in that they are also engaged in cancer treatment businesses), and they have significantly greater resources than we do.

We retain an interest in the BPH market because of our right to contingent payments from the sale of our ownership in TherMatrx based on future sales of TherMatrx's product. In the BPH market, competitive companies offering products similar to TherMatrx's products include Urologix and Dornier (which both have received pre-market approvals from the FDA for their treatment systems), VidaMed, a subsidiary of Medtronic (which has 510(k) clearance from the FDA) and other foreign manufacturers. In addition to thermotherapy equipment made by TherMatrx's competitors, there are other competitive treatments for BPH that are currently being developed, clinically investigated and/or actively

marketed.

9

Product Service

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

Generally, our distributors install and service systems sold to foreign customers and are responsible for managing their own warranty programs for their customers, including labor and travel expenses. We provide warranties for the replacement and/or repair of parts for 12 months for systems sold internationally through distributors and for 90 days for individual components. Spare parts are generally purchased by the distributors and stored at the distributors' maintenance facilities to allow prompt repair. Distributor service personnel are usually trained at customer sites and at our facilities in Salt Lake City, Utah.

Production

We manufacture and test our systems and products at our facilities in Salt Lake City, Utah. Our manufacturing facility is ISO 9001-1994 certified and follows FDA quality systems regulations. Some equipment components we purchase from suppliers are customized to our specifications. Key factors in our manufacturing process are assembly and testing. We purchase component parts and other materials from a variety of suppliers. We do not depend on a single supplier for any item, and believe we can acquire materials and parts from multiple sources on a timely basis.

Product Liability Exposure

The manufacturing and marketing of medical devices involves an inherent risk of product liability. Because our products are intended to be used in hospitals on patients who may be physiologically unstable and severely ill, we are exposed to potential product liability claims. We presently carry product liability insurance with coverage limits of \$1 million. However, we cannot assure you that our product liability insurance will provide adequate coverage against potential claims that might be made against us. No product liability claims are presently pending against us; however, we cannot assume that product liability claims will not be filed in the future or that such claims will not exceed our coverage limits.

Government Regulation

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

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Most of our hyperthermia treatment systems, including the BSD-500 and the BSD-2000 and related products, have required or require pre-market approval from the FDA instead of the simpler 510(k) approval, and we anticipate that our future systems will similarly require pre-market approval. Pre-market approval requires that we demonstrate that the medical device is safe and effective. To do this, we conduct either laboratory and/or clinical testing. The FDA will grant approval of the product if it determines there is reasonable assurance that the medical device is safe and effective. FDA approval must be obtained before commercial distribution of the product. We intend to continue to make improvements in and to our existing products. Significant product changes must be submitted to the FDA under investigational device exemptions, or IDEs, or pre-market approval supplements. As described in the Section entitled "Our Products and Services" above, we have obtained a PMA for our BSD-500 systems and IDE status for our BSD-2000 system.

10

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

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

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

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

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

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

11

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 emit 915 MHz for U.S. and some European installations and 433.92 MHz for some European installations, 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 six patents in the United States and two patents outside the United States. Four additional patents were assigned to TherMatrx, for which we obtained a license, and one patent license was obtained by us from University of California San Francisco and another license was obtained by us from the National Institutes of Health. A European patent for the BSD-2000/3D system has been issued. We believe that our patents represent the early pioneering and dominant patents in this field. These patents along with the advanced product development and leadership in the field are key elements for our current and future market position.

In July 1979, we entered into an exclusive worldwide license for a unique temperature probe called the Bowman Probe. The license will remain in effect as long as the technology does not become publicly known as a result of

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

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 October 21, 1999, we acquired from the University of California San Francisco (UCSF) the exclusive patent license (U.S. Patent 4,825,880) for small microwave antennae that can be inserted into cancerous tumors. This license required payment of 2.5% of sales on licensed products sold and payment of patent maintenance fees and other annual payments of \$4,000 to maintain the exclusive license. We terminated this patent license on September 24, 2004 because we did not believe that it had further application for use with our systems.

We also acquired on December 13, 2001 a patent license from the National Institutes of Health (NIH) for the U.S. Patent 5,284,114. This patent is for the combination of magnetic resonance integrated hyperthermia systems, including our BSD-2000/3D/MR system, and is based on a patent obtained by NIH in early research of the concept. The license agreement requires annual payment of \$1,000, \$4,000 per licensed product sold in the U.S., and \$1,000 per licensed product manufactured in the U.S. and sold outside the U.S. There is also to be a single payment of \$10,000 upon PMA or 510(k) FDA approval.

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

12

From time to time, we have had and may continue to have discussions with other companies, universities and private individuals concerning the possible granting of licenses covering technology and/or patents. There can be no assurance that such discussions will result in any agreements. In the past, we have granted non-exclusive practice licenses for a few selected patents to three companies. One of these companies is no longer in business.

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 2004 were \$656,857 compared to \$676,867 for fiscal 2003, a decrease of \$20,010, or 2.95%. Research and development expenses in fiscal 2004 related primarily to development of a commercial version of the BSD-2000/3D/MR hyperthermia system, enhancements to our BSD-500 systems and development of new products not yet announced. 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 risks and uncertainties that could adversely affect our projections, outlook and operating results.

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Company History

BSD was originally incorporated under the laws of the State of Utah on March 17, 1978. In July 1986, BSD was reincorporated in Delaware.

Employees

As of November 16, 2004, we had 26 employees; 22 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.

Risks Related to Our Business

Our future operating results are highly uncertain. Before deciding to invest in BSD Medical or to maintain or increase your investment, you should carefully consider the risks described below, in addition to the other information contained in this report. 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.

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

13

Since our inception in 1978, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of \$12,073,146 at August 31, 2004. In fiscal 2004, we recorded a net profit of \$8,412,961. Our net profit was primarily due to our sale of our ownership in TherMatrx, of which we owned approximately 25% at closing, to AMS. The sale included all of our TherMatrx shares. We received an initial cash payment, after the withholding of escrow funds and the payment of other initial obligations, of approximately \$9 million in connection with the closing. In fiscal 2003 we had a net loss of \$570,285 primarily due to a write-off of a significant receivable of approximately \$300,000 to bad debt expense, an increase to inventory reserve of \$90,000 and lower overall sales. We may continue to incur operating losses in the future as we continue to incur costs to develop our products, protect our intellectual property and expand our sales and marketing activities. To become profitable we will need to increase significantly the revenues we receive from sales of our hyperthermia therapy products to sustain and increase our profitability on a quarterly or annual basis. We may be unable to do so, and therefore may never achieve profitability.

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 yet to gain wide acceptance by cancer-treating physicians. We believe this is due in part to the lingering impression created by the inability of early hyperthermia therapy technologies to focus and control heat directed at specific tissue locations and 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 payers to make our products commercially viable, and we believe that reimbursement rates have not

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

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 sustain profitable operations.

While a substantial portion of our revenue in past periods has been derived from TherMatrx, revenue from this customer may decline to zero in future periods.

During the year ended August 31, 2004, our sales to TherMatrx declined to \$99,502, a decrease of \$1,355,441 from the year ended August 31, 2003. In fiscal 2004, TherMatrx represented approximately 6% of our net sales compared to approximately 57% of our net sales in fiscal 2003. In the past, we have manufactured, assembled and tested TherMatrx's TMx-2000 system, and also supplied equipment components and provided consulting services to TherMatrx. With the sale of our ownership in TherMatrx to AMS, we believe product sales to TherMatrx may decrease to zero in future fiscal years. TherMatrx is under no contractual obligation to obtain from us products or manufacturing, assembling, testing and other services. This projected decline in sales to TherMatrx will lead to a substantial decline in our revenue if we are unsuccessful in our efforts to generate an offsetting increase in sales of our hyperthermia cancer treatment systems.

We may not receive any contingent payments or significantly less in contingent payment than we have projected from the sale of our ownership in TherMatrx.

In connection with the sale of our ownership in TherMatrx to AMS, we received an initial payment of approximately \$9 million and the right to receive contingent payments based on the future sales of TherMatrx's DOT systems over the next 18 months. We may not receive any contingent payments. Any future payments are not guaranteed and are subject to uncertainties, and we cannot be sure that we will receive any contingent payments in addition to the initial payment of approximately \$9 million, which is the only amount guaranteed. Some of the factors that could cause us not to receive contingent payments, or to materially reduce contingent payments paid to us below our projections include, without limitation, the inability of AMS to successfully market and sell the DOT system at levels that we have assumed, the inability of AMS to pay the contingent payment obligation, the acquisition of AMS by another company that considers the DOT system to be a lower priority in its marketing efforts, the inability of AMS to obtain products to support the demand for DOT sales, a reported injury in which a patient claims harm from treatment by a DOT system, product recalls that could harm the ability to sell DOT products, failure of physicians to continue to endorse DOT products, or a reduction in the reimbursement amount paid by Medicare, Medicaid, and private insurance payors for DOT treatments.

Some of the medical institutions to which we have sold in the past have not been able to pay for their equipment, and some of our sales have therefore become substantial bad debts, a risk that could continue into the future.

Some of our customers have been developing clinics, and these customers have been particularly vulnerable to financial difficulties that can cause them to be unable to pay for equipment that they have purchased. For example, in the fourth quarter of fiscal 2003 we had a particularly high write off of over \$300,000 resulting from the default of a customer under contract. If we choose to accept higher risk sales opportunities to clinics in the future, we will be

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

subject to these customer credit risks that could lower future net sales due to bad-debt write offs, resulting in losses in future periods and potentially lowering the value of your stock. While we attempt to provide for foreseeable doubtful accounts, we cannot assure you that this provision will always be adequate to cover our credit risks.

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

We believe that the success of our efforts to increase sales of our hyperthermia systems in the future depends on our ability to successfully expand our sales distribution channels. Historically, we have sometimes failed in establishing successful new sales channels. In May 2002, we entered into an agreement with Nucletron B.V. under which Nucletron became our exclusive sales agent in most of the world for our BSD-500i interstitial hyperthermia therapy system. We sold only one BSD-500i through Nucletron. We have not felt that our relationship with Nucletron was successful, and our sales agreement with Nucletron was terminated in March 2004.

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

In addition, there can be no assurance that our channels of distribution that have been successful in the past will be successful in the future. We have derived most of our revenue from sales in Europe through our distributor Medizin-Technik, GmbH, which also purchases equipment components and parts from us. The loss or ineffectiveness of Medizin-Technik as a distributor and significant customer could result in lower revenue.

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

Our research and development efforts, pre-clinical tests and clinical trials, and the manufacturing, marketing, distribution and labeling of our products are subject to extensive regulation by the FDA and comparable international agencies. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive and our financial resources are limited.

We are currently enhancing our BSD 500 systems. These enhancements will require FDA pre-market approval supplements. In addition, we have not yet received pre-market approval for our BSD-2000 systems. Obtaining these pre-market approvals from the FDA are necessary for us to commercially market these systems in the United States. We may not be able to obtain these approvals on a timely basis, if at all, and such failure could harm our business prospects substantially. Further, even if we are able to obtain the approvals we seek from the FDA, the approvals granted may include significant limitations on the

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

indicated uses for which the products may be marketed, which restrictions could negatively impact our business.

We believe our technology may have application for other medical purposes. However, FDA or other regulatory approval for the use of our technology for these applications would be required. We may not be able to get these approvals, and if we do, obtaining these approvals would require significant time and expense.

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

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

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

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

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

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

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

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

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. Because our products are intended to be used in hospitals on patients who may be physiologically unstable and severely ill, we are exposed to potential product liability claims. We presently carry product liability insurance with coverage limits of \$1 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 you 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.

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

Our directors and executive officers own approximately 46% 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.

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

Our success will be largely dependent upon the efforts of Paul F. Turner, our Chairman and Senior Vice President, Hyrum A. Mead, our President, and Dixie T. Sells, our Vice President of Regulatory Affairs 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.

17

Because our common stock is traded on the OTC Bulletin Board, your ability to sell your shares in the secondary trading market may be limited.

Our common stock currently is traded on the over-the-counter market on the OTC Bulletin Board. Consequently, the liquidity of our common stock is impaired, not only in the number of shares that are bought and sold, but also through delays in the timing of transactions and lack of coverage by security analysts and the news media. As a result, prices for shares of our common stock may be lower than might otherwise prevail if our common stock were quoted on the Nasdaq Stock Market or traded on a national securities exchange, like the New York Stock Exchange or the American Stock Exchange.

Because our common stock is a "penny stock," you may have difficulty selling our shares in the secondary trading market.

Federal regulations under the Securities Exchange Act of 1934 regulate the trading of so-called "penny stocks," which are generally defined as any security not listed on a national securities exchange or Nasdaq, priced at less than \$5.00 per share and offered by an issuer with limited net tangible assets and revenues. Since our common stock currently trades on the OTC Bulletin Board at less than \$5.00 per share, our common stock is a "penny stock" and may not be traded unless a disclosure schedule explaining the penny stock market and the risks associated therewith is delivered to a potential purchaser prior to any trade.

In addition, because our common stock is not listed on Nasdaq or any national securities exchange and currently trades at less than \$5.00 per share, trading in our common stock is subject to Rule 15c-9 under the Exchange Act. Under this rule, broker-dealers must take certain steps prior to selling a "penny stock," which steps include:

- o obtaining financial and investment information from the investor;
- o obtaining a written suitability questionnaire and purchase agreement signed by the investor; and
- o providing the investor a written identification of the shares being offered and the quantity of the shares.

If these penny stock rules are not followed by the broker-dealer, the investor has no obligation to purchase the shares. The application of these comprehensive rules will make it more difficult for broker-dealers to sell our common stock and our stockholders, therefore, may have difficulty in selling their shares in the secondary trading market.

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:

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

- o announcements of new technological innovations;

18

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

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 2. PROPERTIES

Our office, production and research facilities are located in Salt Lake City, Utah. The complete headquarters and production facility occupies approximately 20,000 square feet. In November 2002, we renewed our lease for five years, which includes payments of approximately \$82,000 per year for five years adjusted annually for increases in the cost of living based on the Consumer Price Index for Urban Consumers. We have an option to purchase the building for \$1,000,000 upon 60 days notice for six years beginning December 1, 2002. Thereafter, the purchase price increases by \$50,000 each year, and the option expires at the end of the tenth year. The building lease is accounted for as an operating lease for financial statement purposes. The building is currently in good condition, is adequate for our needs, is suitable for all company functions and provides room for future expansion. We believe that we carry adequate insurance on the property.

ITEM 3. LEGAL PROCEEDINGS

There are no legal proceedings pending against or being taken by us.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

19

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock trades publicly on the OTC Bulletin Board under the

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

symbol "BSDM." The following table sets forth the high and low bid transactions, as provided by the OTC Bulletin Board, for the quarters in fiscal year 2003 and 2004. The amounts reflect inter-dealer prices, without retail mark-up, markdown or commission, and may not represent actual transactions.

Quarter Ended:	Bid	
	High	Low
November 30, 2002.....	.79	.42
February 28, 2003.....	.70	.40
May 31, 2003.....	.61	.45
August 31, 2003.....	.96	.45
November 30, 2003.....	2.00	.80
February 29, 2004.....	1.65	1.18
May 31, 2004.....	1.69	1.15
August 31, 2004.....	2.25	1.30

As of November 16, 2004, there were approximately 584 holders of record of our common stock. We have not paid any cash dividends on our common stock since our inception.

ITEM 6. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations and other parts of this report 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 subsections entitled "Forward-Looking Statements and Factors That May Affect Future Results and Financial Condition" below and the subsection entitled "Risk Factors" above. The following discussion should be read in conjunction with our consolidated financial statements and notes thereto included in this report. All information presented herein is based on our fiscal year ended August 31, 2004. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

General

We develop, manufacture, market and service systems that deliver focused electromagnetic energy for use in a variety of medical therapies and applications. Our objective is to commercialize our developed products and further expand the application of our technology into new markets. We pioneered the use of microwave thermal therapy for the treatment of the symptoms associated with enlarged prostate, and are responsible for much of the technology that has created a substantial medical industry using that therapy. Our longest-term development has been the application of focused electromagnetic energy for the treatment of cancer. In addition, although we have not entered these markets, we believe that our technology has application for numerous other medical purposes such as those described in the General section of this filing.

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

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

We determined early in our planning that we would treat our BPH development as a spin-off business with the intent of providing an asset that could help fund our other business plans. As a result, we introduced the opportunity to investment groups and subsequently on October 31, 1997 entered into an agreement with investors Oracle Strategic Partners, L.P. and Charles Manker. Together we established a new company, TherMatrx, which was independently managed.

On July 15, 2004, TherMatrx was sold to AMS. Our portion of the initial payment from this sale was nearly \$9 million, with additional payments contingent on the quarterly sales of TherMatrx through the fourth calendar quarter of 2005. We have estimated that our portion of the total payout from this sale will be approximately \$40 million. If TherMatrx sales exceed our projections, the maximum payout that we could receive from the sale is \$62.5 million. If TherMatrx sales fall under our projections, there is no guarantee of any further payment beyond the initial payment, which is non-refundable.

Since the inception of our company we have engineered systems designed to increase the effectiveness of cancer treatment through the use of focused electromagnetic energy. From this development our current BSD-500 and BSD-2000 systems have emerged. We have also developed enhancements to our BSD-2000 system including the BSD-2000/3D that is designed to allow three dimensional steering of deep focused energy and heat to targeted tumors and tissue and the BSD-2000/3D/MR that includes an interface for magnetic resonance imaging. These systems are sold with supporting software and may also be sold with support services.

Since inception, we have generated substantial operating losses and at August 31, 2004, had an accumulated deficit of \$12,073,146. We recorded net profit for fiscal 2004 of \$8,412,961. The primary reason for the net profit in fiscal 2004 was the income generated from the sale of our ownership in TherMatrx.

We recognize revenue from the sale of cancer treatment systems, the sale of parts and accessories related to the cancer treatment systems, the sale of software license rights, providing manufacturing services, training, and service support contracts. Product sales were \$1,494,311 and \$1,956,270 for the years ended August 31, 2004 and 2003, respectively. Service revenue was \$99,837 and \$277,912 for the years ended August 31, 2004 and 2003, respectively.

We derived \$1,012,192, or 62%, of our revenue in fiscal 2004 from sales to related parties. \$912,690 of such related party revenue was for the sale of two BSD-2000 systems and component parts sold to Medizin-Technik GmbH. Dr. Gerhard Sennewald, one of our directors, is a stockholder, executive officer and a director of Medizin-Technik GmbH. The remaining related party sale of \$99,502 was for probes, applicators and thermotherapy systems sold to TherMatrx. Since our ownership in TherMatrx has been sold they are no longer considered a related party and we don't expect any more sales from TherMatrx.

In fiscal 2004, we derived \$581,956, or 36%, of our revenue from sales to unrelated parties. These revenues consisted of the sale of three BSD 500 systems for \$471,725, billable labor of \$18,053, service contracts of \$72,437,

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

and sales of consumable devices used with our hyperthermia systems of \$19,741.

Cost of sales for the year ended August 31, 2004, included raw material and labor costs. Research and development expenses include expenditures for new product development and development of enhancements to existing products.

Critical Accounting Policies and Estimates

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

Revenue Recognition. Revenue from the sale of cancer treatment systems is recognized when a purchase order has been received, the system has been shipped, the selling price is fixed or determinable, and collection is reasonably assured. Most system sales are F.O.B. shipping point, therefore shipment is deemed to have occurred when the product is delivered to the transportation carrier. Most system sales do not include installation. If installation is included as part of the contract, revenue is not recognized until installation has occurred, or until any remaining installation obligation is deemed to be perfunctory. Some sales of cancer treatment 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 guaranteed by BSD. We provide a reserve allowance for estimated returns. To date, returns have not been significant.

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

Our revenue recognition policy is the same for sales to both related parties and non-related parties. We provide the same products and services under the same terms for non-related parties as with related parties. Sales to distributors are recognized in the same manner as sales to end-user customers. Deferred revenue and customer deposits payable include amounts from service contracts as well as cash received for the sales of products, which have not been shipped.

Inventory Reserves. As of August 31, 2004, we had recorded a reserve for potential inventory impairment of \$80,000. During fiscal 2004, we reduced our inventory reserve from \$140,000 to \$80,000. In addition to the reduction of inventory reserve we also wrote off \$154,814 in obsolete inventory. We periodically review our inventory levels and usage, paying particular attention to slower-moving items. If projected sales for fiscal 2005 do not materialize or if our hyperthermia systems do not receive increased market acceptance, we may be required to increase the reserve for inventory in future periods. We have projected no orders to be placed with us for TherMatrx systems, and do not project a requirement for any inventory impairment based on this decline. In the past we have purchased inventory only after receiving orders for TherMatrx systems, and only in quantities sufficient to fulfill those orders. We have no inventory for TherMatrx systems that is currently at risk, whether or not future orders are placed with us for TherMatrx systems.

Product Warranty. We provide product warranties on our BSD-500 and BSD-2000 systems. These warranties vary from contract to contract, but generally consist of parts and labor warranties for one year from the date of sale. 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 provide our customers with payment terms that vary from contract to contract. Our allowance for doubtful accounts at August 31, 2004 was \$0. Bad debt expense for the fiscal year ended August 31, 2004 was approximately \$15,000. We perform ongoing credit evaluations of our customers and maintain allowances for possible losses which, when realized, have been within the range of management's expectations with exception of the bad debt expense of approximately \$300,000 recorded in fiscal 2003 as discussed below. This resulted from a sale of BSD-2000 that was recorded in fiscal year 2002 to a customer that was determined to be uncollectible in the fourth quarter of fiscal 2003. Allowance estimates are recorded on a customer-by-customer basis and are determined based on the age of the receivable, compliance with payment terms, and prior history with existing clients. To date, actual results have not differed materially from management's estimates, with the exception of the above-mentioned bad debt. The non-payment of a receivable related to the sale of a BSD-500 or BSD-2000 could have a material adverse impact on our results of operations.

Results of Operations: Comparison of Fiscal Years ended August 31, 2004 and 2003

Revenue. Revenue for fiscal 2004 was \$1,630,648 compared to \$2,572,682 for fiscal 2003, a decrease of \$942,034, or approximately 36.6%. The decrease in total revenue was primarily due to a decrease in sales during fiscal 2004 to TherMatrx of approximately \$1,291,941 and a decrease in royalty revenue of \$302,000 partially offset by an increase in sales to Medizin-Technik of \$396,548. We expect no sales to TherMatrx in fiscal 2005. We also expect royalty revenue to decline to \$0 in fiscal 2005. Sales to Medizin-Technik may fluctuate significantly depending on Medizin-Technik's anticipated sales and ability to place orders in Europe. Our revenue can fluctuate significantly from period to period because we have historically sold relatively few BSD-2000 and BSD-500 systems as these systems are expensive. Sales of very few systems can cause a large change in the revenue from period to period as noted in the increase in sales to Medizin-Technik from 2003 to 2004. Product sales decreased to \$1,494,311 in fiscal 2004 from \$1,956,270 in fiscal 2003, a decrease of \$461,959, or 24%.

Related Party Revenue. We derived \$1,012,192, or 62% of our revenue in fiscal 2004 from sales to related parties as compared to \$1,907,585, or 74%, in fiscal 2003. \$99,502 of such related party revenue in fiscal 2004 was from the sales of thermotherapy systems, component products and contract services to TherMatrx. We also received a royalty payment of \$36,500 paid to us by TherMatrx that is included in other revenue. We believe that we provided less than 1% of the inventory and related manufacturing services purchased by TherMatrx in fiscal 2004 as compared to approximately 38% in fiscal 2003. This decline in sales to TherMatrx in fiscal 2004 was due to increased use of other suppliers in providing products and services. Because of the sale of our ownership in TherMatrx in July 2004, TherMatrx is no longer considered a related party. The remaining related party revenue of approximately \$912,690 in fiscal 2004 was for two BSD-2000 system and various component parts sold to Medizin-Technik. The significant increase in sales to Medizin-Technik in fiscal 2004 was due to the sale of two BSD-2000 systems compared to one in fiscal 2003. Sales to

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Medizin-Technik may fluctuate significantly from period to period due to the high cost of a BSD-2000 or BSD-500 system. Sales increases of one or two systems can have a material effect on our revenue.

Non-related Party Revenue. In fiscal 2004, we derived approximately \$581,956, or 36%, of our total revenue as compared to approximately \$326,597, or 13%, in fiscal 2003 from non-related party sales. Our fiscal 2004 non-related party revenue consisted of sales of three BSD-500 systems for approximately \$471,725. The balance of our non-related party revenue consisted of consumable devices of \$19,741, service contracts of \$72,437, and billable labor of \$18,053

23

Cost of Sales. Cost of sales for fiscal 2004 was \$1,116,781 compared to \$1,227,377 for fiscal 2003, a decrease of \$110,596 or approximately 9%. This decrease resulted primarily from lower sales in fiscal 2004. Cost of sales to related parties in fiscal 2004 decreased to \$668,619 from \$1,132,758 in fiscal 2003 primarily due to the decrease in related party sales and the change in product mix sold to related parties from \$1,907,585 of systems, component products and services in fiscal 2003 to \$1,012,192 of systems, component products and services in fiscal 2004. During fiscal 2004, approximately \$491,768, or 88%, of the related party cost of sales were attributable to sales to Medizin-Technik and approximately \$67,318, or 12%, were attributable to TherMatrx.

Gross Profit. Gross profit for the fiscal year ending August 31, 2004 was \$477,367, or 30%, as compared to \$1,006,805, or 45%, of total product sales for the fiscal year ending August 31, 2003. The decline in gross profit margin was primarily due to the cost of excess production employees resulting from the decrease in sales. Also, we made an adjustment to inventory to reflect the lower of cost or market, which resulted in an increase in cost of sales of approximately \$154,814. In addition, we had sales of higher margin hyperthermia system products accompanied by production efficiencies obtained from a higher volume of hyperthermia system sales in the period ending August 31, 2003.

Research and Development Expenses. Research and development expenses for fiscal 2004 were \$656,857 compared to \$676,867 for fiscal 2003, a decrease of \$20,010, or 2.95%. Research and development expenses in fiscal 2004 related primarily to development of a commercial version of the BSD-2000/3D/MR hyperthermia system and enhancements to our BSD-500 systems.

Inventory Impairment Expense. As of August 31, 2004, we had recorded a reserve for potential inventory impairment of \$80,000. During fiscal 2004, we reduced our inventory reserve from \$140,000 to \$80,000. In addition to the reduction of inventory reserve we also wrote off \$154,814 in obsolete inventory. We periodically review our inventory levels and usage, paying particular attention to slower-moving items. We recorded an inventory impairment charge in fiscal 2003 of \$90,000 increasing our total inventory reserve at August 31, 2003 to \$140,000. On at least an annual basis, we attempt to identify inventory items that have shown relatively no movement or very slow movement. Generally, if an item has shown little or no movement for over a year, it is examined for obsolescence. If it is determined that recoverability of the item is impaired, a reserve is established for that item. In addition, if we identify products that have become obsolete due to product upgrades or enhancements, a reserve is established for such products.

Selling, General and Administrative Expenses. Selling, general and administrative expenses for fiscal 2004 were \$1,147,628 compared to \$1,297,438 fiscal 2003, a decrease of \$149,810, or approximately 12%. This decrease was primarily due to decreases in bad debt and consulting expense of approximately \$342,492 in fiscal 2004 as compared to fiscal 2003. This decrease was partially

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

offset by increases in sales and marketing expenses of approximately \$105,575 and increases in board compensation and legal fees of \$36,986.

We recorded a bad debt expense of \$300,394 in fiscal 2003 as a result of a receivable write-off due to our inability to collect payment relating to the sale of a BSD-2000 system in fiscal 2002. The sale in fiscal 2002 was to a non-related party. At the time the sale was made, we were led to believe that the customer had secured payment for the system. After our efforts to collect the receivable failed, we determined to seek return of the system and write off the receivable. Accordingly, during the fourth quarter of fiscal 2003, we recorded a bad debt expense of \$300,394. This bad debt expense was the net result of a receivable write-off of approximately \$346,000 and the value of returned inventory of approximately \$46,000. We believe this is an isolated case and not indicative of a trend. Historically, our bad debt expense has been substantially lower than fiscal 2003 levels. Generally, we require a significant deposit on the sales of our BSD systems, which reduces the likelihood of bad debt expense.

24

Interest income. Interest income increased to \$18,500 in fiscal 2004 as compared to \$2,838 in fiscal 2003 due to higher levels of investments resulting from greater cash generated from the sale of TherMatrx.

Other Income. Other income for fiscal 2004 was \$9,142,570 compared to \$58,715 in fiscal 2003. This increase resulted almost entirely from a gain recognized on the sale of TherMatrx.

Net Profit/ Loss. In fiscal 2004 we had a net profit of \$8,412,961 as compared to a net loss in fiscal 2003 of \$570,285. The net profit related to the sale of our ownership in TherMatrx.

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 for thermotherapy systems and component parts supplied by us to TherMatrx, market acceptance of our BSD hyperthermia systems, changes in the medical capital equipment market, changes in order mix and product order configurations, competition, regulatory developments and other matters. Operating expenses may fluctuate as a result of the timing of sales and marketing activities, research and development and clinical trial expenses, 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.

Liquidity and Capital Resources

Since inception, we have generated an accumulated deficit of \$12,073,146. We have historically financed our operations through cash from operations, licensing of technological assets and issuance of common stock.

We generated \$7,491,538 in cash from operating activities in fiscal 2004 compared to cash used of \$227,298 in fiscal 2003. This was primarily a result of our sale of our TherMatrx shares for approximately \$9 million, offset by an increase in the deferred tax asset of \$829,000. In addition, accounts receivable decreased by \$129,849, and accounts payable decreased by \$180,937. Accrued expenses decreased by \$190,555 primarily as a result of a decrease in customer deposits as orders were shipped and the write-off of the accrued loss in equity affiliate that was associated with the sale of our TherMatrx shares.

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Our investing activities resulted in net cash used of \$42,389 relating to the purchase of certain property and equipment. Cash provided by financing activities totaled \$2,112,002 reflecting proceeds from the issuance of common stock in connection with the exercise of outstanding stock options and the private placement of 2,059,600 shares to investors at \$1.10 per share in November and December 2003. Total cash increased from \$136,003 at August 31, 2003 to \$9,697,154 at August 31, 2004, as a result of the sale of our TherMatrx shares and the November and December 2003 private placement.

We expect to use the payments from the sale of our TherMatrx shares, including any contingent payments, for general corporate purposes, including the sales and marketing effort for our FDA approved cancer therapy products, supporting the FDA application for our cancer therapy products under investigational status, and the development of future products used in medical therapy.

We expect to incur additional expenses related to the commercial introduction of our BSD-500 systems, which will precede any revenue from the sale of such systems. Due to additional participation at trade shows, expenditures on publicity, additional travel, higher sales commissions and other related expenses, we project that our sales and marketing expenses will be

25

approximately \$500,000 higher in fiscal 2005 than in the prior year to support the commercial introduction of the BSD-500 systems. In addition, we anticipate that we will incur expenses of approximately \$200,000 related to governmental and regulatory, including FDA, approvals during fiscal 2005 in excess of fiscal 2004. We are making these investments in sales and marketing and on government and regulatory activities to increase our revenue from sales of our BSD-500 system and, upon receipt of FDA approval, from the sale of our BSD-2000 system in the United States. These increased marketing and regulatory expenses are an investment in generating offsetting revenue against the decline in TherMatrx sales that we have projected, and to provide future revenue growth over the long term. We also project that we will incur approximately \$250,000 in additional new development expenses associated with developments for the treatment of non-cancerous diseases and medical conditions.

We believe any cash shortfall during fiscal 2005 that results from this decrease in revenues and increase in expenses can be covered through the cash raised in our November and December 2003 private placements and with the cash from the sale of TherMatrx shares. We believe we can cover any cash shortfall with cost cutting or available cash. If we cannot cover any such cash shortfall with cost cutting or available cash, we would need to obtain additional financing. We cannot be certain that any financing will be available when needed or will be available on terms acceptable to us. 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.

FORWARD-LOOKING STATEMENTS

With the exception of historical facts, the statements contained in sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" 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:

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

- o our anticipated financial performance and business plan;
- o our expectations regarding the commercial introduction of the BSD-500 system;
- o our expectations and efforts regarding receipt of FDA and Chinese regulatory approvals relating to the BSD-2000 system;
- o our technological developments to the BSD-500 and BSD-2000 systems;
- o our ability to successfully develop our technology for new applications and the expense of such developments;
- o our development or acquisition of new technologies;
- o our expectation that sales to TherMatrx may decline to zero in future periods;
- o the amount of expenses we will incur for the commercial introduction of the BSD-500 system;
- o the amount of expenses we will incur for governmental and regulatory, including FDA, approvals;
- o our expectation that related party revenue will continue to be a significant portion of our total revenue;
- o our belief that sales of BSD-500 and BSD-2000 systems will increase through our future sales and marketing efforts;
- o our belief that our current working capital and cash from operations will be sufficient to fund our anticipated operations for fiscal 2005
- o our assumption that we will receive contingent payments, and the amount of such payments, in connection with the sale of our ownership in TherMatrx to AMS; and
- o our anticipated use of proceeds from the sale of our ownership in TherMatrx to AMS;

26

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 the section entitled "Risk Factors" included elsewhere in this report. 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 7. FINANCIAL STATEMENTS

BSD MEDICAL CORPORATION
Financial Statements
August 31, 2004 and 2003

BSD MEDICAL CORPORATION
Index to Financial Statements

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

	Page

Report of Independent Registered Public Accounting Firm	F-1
Balance Sheet	F-2
Statement of Operations	F-3
Statement of Stockholders' Equity	F-4
Statement of Cash Flows	F-5
Notes to Financial Statements	F-6

REPORT OF INDEPENDENT REGISTERED
PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
of BSD Medical Corporation

We have audited the balance sheet of BSD Medical Corporation (the Company) as of August 31, 2004, and the related statements of operations, stockholders' equity, and cash flows for the years ended August 31, 2004 and 2003. 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, 2004, and the results of its operations and its cash flows for the years ended August 31, 2004 and 2003 in conformity with accounting principles generally accepted in the United States of America.

/s/Tanner + Co.

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Salt Lake City, Utah
October 7, 2004

F-1

BSD MEDICAL CORPORATION
Balance Sheet

August 31, 2004

Assets	

Current assets:	
Cash and cash equivalents	\$ 9,697,154
Receivables, net	43,904
Related party receivables	215,400
Inventories, net	740,416
Deferred tax asset	829,000
Other current assets	51,066

Total current assets	11,576,940
Property and equipment, net	139,100
Patent, net of amortization of \$6,921	25,007

	\$ 11,741,047

Liabilities and Stockholders' Equity	

Current liabilities:	
Accounts payable	\$ 99,131
Accrued expenses	423,915
Deferred revenue	47,223

Total current liabilities	570,269

Deferred tax liability	51,000
Commitments and contingencies	-
Stockholders' equity:	
Preferred stock, \$.001 par value; 10,000,000 authorized, no shares issued and outstanding	-
Common stock, \$.001 par value; authorized 40,000,000 shares; issued 19,945,982 shares and	

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

outstanding 19,921,651 shares	19,946
Additional paid-in capital	23,201,020
Deferred compensation	(27,808)
Accumulated deficit	(12,073,146)
Treasury stock, at cost	(234)

Total stockholders' equity	11,119,778

	\$ 11,741,047

See accompanying notes to financial statements.

F-2

BSD MEDICAL CORPORATION
Statement of Operations

Years Ended August 31,

	2004	2003
	-----	-----
Revenues:		
Sales	\$ 581,956	\$ 326,597
Sales to related parties, net	1,012,192	1,907,585
Revenue from royalties in arrears	-	275,000
Other revenue - related party	36,500	63,500
	-----	-----
	1,630,648	2,572,682
	-----	-----
Costs and expenses:		
Cost of sales	448,162	94,619
Cost of sales to related parties	668,619	1,132,758
Research and development	656,857	676,867
Selling, general, and administrative	1,147,628	1,297,438
	-----	-----
	2,921,266	3,201,682
	-----	-----
Operating loss	(1,290,618)	(629,000)
	-----	-----
Other income (expense):		
Gain on sale of equity interest	9,111,211	-
Interest income	18,500	2,838
Interest expense	(491)	-
Other	31,359	55,877
	-----	-----
	9,160,579	58,715
	-----	-----

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Income (loss) before income taxes	7,869,961	(570,285)
Income tax benefit	543,000	-
Net income (loss)	\$ 8,412,961	\$ (570,285)
Income (loss) per common share - basic	\$ 0.43	\$ (0.03)
Income (loss) per common share - diluted	\$ 0.41	\$ (0.03)
Weighted average shares - basic	19,397,000	17,805,000
Weighted average shares - diluted	20,331,000	17,805,000

See accompanying notes to financial statements.

F-3

	Common Stock		Additional	Deferred	Accumulated	
	Shares	Amount	Paid-in Capital	Compen- sation	Deficit	Sh
Balance September 1, 2002	17,756,328	\$ 17,757	\$ 21,037,457	\$ (26,274)	\$ (19,915,822)	24,
Common stock issued for:						
Cash	20,000	20	1,980	-	-	
Services	38,106	38	23,962	-	-	
Warrants	25,199	25	(25)	-	-	
Amortization of deferred compensation	-	-	-	6,358	-	
Deferred compensation	-	-	7,500	(7,500)	-	
Net loss	-	-	-	-	(570,285)	
Balance August 31, 2003	17,839,633	17,840	21,070,874	(27,416)	(20,486,107)	24,
Common stock issued for:						
Cash	2,090,350	2,090	2,109,912	-	-	
Services	15,999	16	11,984	-	-	

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Amortization of deferred compensation	-	-	-	7,858	-
Deferred compensation	-	-	8,250	(8,250)	-
Net income	-	-	-	-	8,412,961

Balance August 31, 2004	19,945,982	\$ 19,946	\$ 23,201,020	\$ (27,808)	\$ (12,073,146) 24,

See accompanying notes to financial statements

BSD MEDICAL CORPORATION
Statement of Cash Flows

Years Ended August 31,

	2004	2003
	-----	-----
Cash flows from operating activities:		
Net income (loss)	\$ 8,412,961	\$ (570,285)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
(Recovery of) provision for doubtful accounts	14,569	284,393
Increase in inventory reserve and write off of inventory	154,814	90,000
Depreciation and amortization	46,461	48,678
Recognition of deferred gain on sale of building	-	(15,275)
Amortization of deferred compensation	7,858	6,358
Stock compensation expense	12,000	24,000
Decrease (Increase) in:		
Receivables	129,849	9,614
Inventories	(92,757)	(85,743)
Deferred tax asset	(829,000)	-
Other current assets	(7,828)	(24,901)
Increase (decrease) in:		
Accounts payable	(180,937)	217,447
Accrued expenses	(190,555)	(133,066)
Deferred revenue	(36,897)	(78,518)
Deferred tax liability	51,000	-
	-----	-----
Net cash provided by (used in) operating activities	7,491,538	(227,298)
	-----	-----
Cash flows from investing activities-		
purchase of property and equipment	(42,389)	(60,599)
	-----	-----
Cash flows from financing activities-		

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

proceeds from issuance of common stock	2,112,002	2,000

Increase (decrease) in cash and cash equivalents	9,561,151	(285,897)
Cash and cash equivalents, beginning of year	136,003	421,900

Cash and cash equivalents, end of year	\$ 9,697,154	\$ 136,003

See accompanying notes to financial statements

F-5

BSD MEDICAL CORPORATION
Notes to Financial Statements

August 31, 2004 and 2003

1. Organization and Significant Accounting Policies

Organization

BSD Medical Corporation (the Company) was incorporated in the State of Delaware on July 3, 1986. The Company develops, produces, markets, and services systems used for the treatment of cancer and other diseases. These systems are sold worldwide. In addition, the Company held an approximate 30% interest in TherMatrix until July 15, 2004. On July 15, 2004, American Medical Systems Holdings, Inc., or AMS, acquired TherMatrix, Inc. for \$40 million in cash plus future payments contingent upon the combined entity's future sales of TherMatrix's DOT systems. The sale included all of the Company's TherMatrix shares, which were reduced at closing to approximately 25% of the total outstanding TherMatrix shares because of the exercise of outstanding options to acquire common stock of TherMatrix. The Company received an initial cash payment, after the withholding of escrow funds and the payment of other initial obligations, of approximately \$9 million in connection with the closing.

Cash and Cash Equivalents

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

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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization are determined using the straight-line method over the

estimated useful lives of the assets. 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.

F-6

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

1. Organization and Significant Accounting Policies Continued

Investment in Joint Venture

The Company had an approximate 30% ownership in TherMatrx, a corporate joint venture that is engaged in the manufacture and sale of medical devices. The investment was accounted for on the equity method of accounting. Because the Company's percent share of accumulated losses in TherMatrx had exceeded its original investment no asset was recorded on the balance sheet. On July 15, 2004, American Medical Systems Holdings, Inc., or AMS, acquired TherMatrx, Inc. for \$40 million in cash plus future payments contingent upon the combined entity's future sales of TherMatrx's DOT systems. The sale included all of the Company's TherMatrx shares, which were reduced at closing to approximately 25% of the total outstanding TherMatrx shares because of the exercise of outstanding options to acquire common stock of TherMatrx. The Company received an initial cash payment, after the withholding of escrow funds and the payment of other initial obligations, of approximately \$9 million in connection with the closing.

Patents

Patents are carried at cost and are being amortized over 17 years.

Warranty Reserve

The Company provides limited warranties to its customers for products sold. Estimated future warranty obligations are accrued each period. As of August 31, 2004, the accrued warranty reserve was approximately \$6,900. During the fiscal years ended August 31, 2004 and 2003, total warranty expense was \$28,148 and \$11,502, respectively.

Income Taxes

The Company accounts 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

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

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.

F-7

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

-
1. Organization and Significant Accounting Policies Continued
- 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 2,437,533 shares and 1,275,303 shares of common stock at prices ranging from \$.10 to \$1.80 per share were outstanding at August 31, 2004 and 2003, respectively. Options outstanding during the fiscal year ended August 31, 2003 were not included in the calculation of diluted earnings per share because their effect was anti-dilutive.
- The shares used in the computation of the Company's basic and diluted income (loss) per share are reconciled as follows:

	2004	2003
	-----	-----
Weighted average number of shares outstanding - basic	19,397,000	17,805,000
Dilutive effect of stock options	934,000	-
	-----	-----
Weighted average number of shares outstanding, assuming dilution	20,331,000	17,805,000
	-----	-----

F-8

BSD MEDICAL CORPORATION

1. Organization and Significant Accounting Policies Continued

Stock-Based Compensation

The Company accounts for stock options granted to employees under the recognition and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations, and has adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, "Accounting for Stock-Based Compensation". Accordingly, no compensation cost has been recognized in the financial statements, as all options granted under those plans had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant. Had the Company's options been determined based on the fair value method, the results of operations would have been reduced to the pro forma amounts indicated below:

	Years Ended August 31,	
	2004	2003
Net income (loss) - as reported	\$ 8,412,961	\$ (570,285)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	-	-
Deduct: total stock based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(101,597)	(123,770)
Net income (loss) - pro forma	\$ 8,311,364	\$ (694,055)
Earnings per share:		
Basic - as reported	\$.43	\$ (.03)
Basic - pro forma	\$.43	\$ (.04)
Diluted - as reported	\$.41	\$ (.03)
Diluted - pro forma	\$.41	\$ (.04)

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

-
1. Organization and Significant Accounting Policies Continued

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	2004	2003
Expected dividend yield	\$ -	\$ -
Expected stock price volatility	113%	122%
Risk-free interest rate	4.3%	4.3%
Expected life of options	5 years	5 years

The weighted average fair value of options granted during the years ended August 31, 2004 and 2003 were \$1.01 and \$.57, respectively.

Revenue Recognition

The Company recognizes revenue from the sale of cancer treatment systems, the sale of parts and accessories related to the cancer treatment systems, the sale of software license rights, providing manufacturing services, providing training, and service support contracts. Product sales were \$1,494,311 and \$1,956,270 for the years ended August 31, 2004 and 2003, respectively. Service revenue was \$99,837 and \$277,912 for the years ended August 31, 2004 and 2003, respectively.

Revenue from the sale of cancer treatment systems is recognized when a purchase order has been received, the system has been shipped, the selling price is fixed or determinable, and collection is reasonably assured. Most system sales are F.O.B. shipping point, therefore shipment is deemed to have occurred when the product is delivered to the transportation carrier. Most system sales do not include installation. If installation is included as part of the contract, revenue is not recognized until installation has occurred, or until any remaining installation obligation is deemed to be perfunctory. Some sales of cancer treatment 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 the Company's 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 guaranteed by the Company. The Company provides a reserve allowance for estimated returns. To date, returns have not been significant.

1. Organization and Significant Accounting Policies Continued

Revenue Recognition Continued

Revenue from the sale of software license rights is recognized when a valid purchase order has been received, the software license has been delivered to the customer, the selling price is fixed or determinable, and collection is reasonably assured. Delivery is deemed to have occurred if diskettes have been shipped, or if the software has been delivered electronically by email. To date, the sale of software license rights has not been material.

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

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.

The Company's revenue recognition policy is the same for sales to both related parties and non-related parties. The Company provides the same products and services under the same terms for non-related parties as with related parties.

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

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

F-11

1. Organization and

Concentration of Credit Risk

Financial instruments that potentially subject the

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Significant
Accounting
Policies
Continued

Company to concentration of credit risk consists primarily of trade receivables. In the normal course of business, the Company provides credit terms to its customers. Accordingly, the Company performs ongoing credit evaluations of its customers and maintains allowances for possible losses. During the year ended August 31, 2003, the Company wrote off a receivable of approximately \$346,000. This receivable was recorded as a sale in fiscal year 2002 and resulted in a significant write-off in the fourth quarter of 2003.

The Company has cash in bank and short-term investments that, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and short-term investments.

Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Reclassifications

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

F-12

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

2. Detail of
Certain
Balance
Sheet
Accounts

Details of certain balance sheet accounts as of August 31, 2004, are as follows:

Receivables:	
Trade receivables	\$ 259,304
Less allowance for doubtful accounts	-

	\$ 259,304

Inventories:	
Parts and supplies	\$ 351,019
Work-in-process	469,397
Reserve for obsolete inventory	(80,000)

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

		\$ 740,416

	Accrued expenses:	
	Accrued vacation	\$ 102,353
	Accrued payroll and taxes	32,174
	Income taxes payable	250,000

	Other accrued expenses	423,915

		\$ 849,915

3. Property and Equipment	Property and equipment consists of the following:	
	Equipment	\$ 706,621
	Furniture and fixtures	297,741

		1,004,362
	Less accumulated depreciation	(865,262)

		\$ 139,100

4. Operating Lease	During the year ended August 31, 2003, the Company renewed its building lease for five years, which includes payments of approximately \$82,000 per year, adjusted annually for increases in the cost of living based on the Consumer Price Index for Urban Consumers.	

F-13

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

4. Operating Lease Continued	Future minimum payments at August 31, 2004, are as follows:	
	Years Ending August 31,	Amount
	-----	-----
	2005	\$ 82,320
	2006	82,320
	2007	82,320
	2008	82,320
	2009	-

		\$ 329,280

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Annual rent expense on this operating lease for the years ended August 31, 2004 and 2003 amounted to \$83,735 and \$67,000, respectively.

5. Deferred Revenue The Company has entered into certain service contracts for which it has received payment in advance. The Company is recognizing these service revenues over the life of the service agreements.

6. Income Taxes The components of the income tax (expense) benefit for the year ended August 31, 2004 is as follows:

Current:		
Federal		\$ (130,000)
State		(105,000)

		(235,000)

Deferred:		
Federal		778,000

		\$ 543,000

F-14

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

6. Income Taxes Continued The income tax benefit (expense) differs from the amount computed at federal statutory rates as follows:

	Years Ended August 31,	
	2004	2003
	-----	-----
Income tax benefit (expense) at statutory rate	\$ (2,935,000)	\$ 198,000
Change in estimate of use of net operating loss carryforwards	990,000	-
Change in estimate of research and development tax credits	347,000	-
Alternative minimum tax	(73,000)	-
Expiration of net operating loss carryforwards	-	(19,000)
Other	9,000	-
Change in valuation allowance	2,205,000	(179,000)
	-----	-----

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

\$ 543,000 \$ -

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

Net operating loss carryforward	\$	174,000
Accrued expenses		35,000
Deferred revenue		16,000
Inventory reserve		27,000
Warranty reserve		3,000
Depreciation		(42,000)
Deferred compensation expense		(9,000)
Research and development tax credits		517,000
Alternative minimum tax credits		57,000

	\$	778,000

F-15

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

7. Stock Options and Warrants

Stock Options

The Company's 1987 Employee Stock Option Plan authorizes the granting of incentive options to certain key employees of the Company and nonqualified stock options to certain key employees, non-employee directors, or individuals who provide services to the Company. The Plan, as amended, provides for the granting of options for an aggregate of 950,000 shares. The options vest according to a set schedule over a five-year period and expire upon the employee's termination or after ten years from the date of grant.

The Company's 1998 Employee Stock Option Plan authorizes the granting of incentive stock options to certain key employees and non-employees who provide services to the Company. The Plan provides for the granting of options for an aggregate of 2,000,000 shares. The options vest subject to management's discretion.

The Company's 1998 Director Stock Plan was revised to provide an annual compensation of \$20,000 to each non-employee director. The annual compensation plan calls for payment to be made twice a year with each payment consisting of \$5,000 cash and \$5,000 in common stock, with the number of shares issued calculated by dividing the unpaid compensation by a daily average of the preceding twenty day closing price of the Company's common stock. The Plan also grants each non-employee outside director

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

25,000 options each year at an exercise price of 85% of the fair market value of the common stock at the date the option is granted. The Plan allows for an aggregate of 1,000,000 shares to be 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. For certain options issued under this plan, the Company has recorded as deferred compensation the excess of the market value of common stock at the date of grant over the exercise price.

F-16

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

7. Stock Options and Warrants Continued A schedule of the options and warrants is as follows:

	Options	Warrants	Price Per Share
Outstanding at September 1, 2002	1,258,901	-	\$.10 to 1.76
Granted	75,000	-	.73
Exercised	(58,598)	-	.10 to .37
Forfeitures	-	-	-
Outstanding at August 31, 2003	1,275,303	-	.10 to 1.76
Granted	1,090,000	102,980	1.2 to 1.80
Exercised	(30,750)	-	.10 to .45
Forfeitures	-	-	-
Outstanding at August 31, 2004	2,334,553	102,980	\$.10 to 1.80

The following table summarizes information about stock options and warrants outstanding at August 31, 2004:

Options and Warrants Outstanding			Options and Warrants Outstanding		
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

\$.10-.25	425,953	1.33	\$.13	425,953	\$.13
	.37-1.11	843,600	6.00		.62	679,230		.60
	1.20-1.80	1,167,980	8.80		1.28	278,295		1.51

\$.10-1.80	2,437,533	6.52	\$.85	1,383,478	\$.64
----	----------	-----------	------	----	-----	-----------	----	-----

8. Foreign Customer and Major Customer During the years ended August 31, 2004 and 2003, the Company had sales of \$99,502 and \$1,391,443 (including \$63,500 in royalty revenues), respectively, to TherMatrx, a previously unconsolidated affiliate of which it owned approximately 30%. This related party relationship ended on July 15, 2004 when TherMatrx was sold to AMS (see note 11). During the years ended August 31, 2004 and 2003, the Company had sales to a European entity controlled by a significant stockholder and member of the Board of Directors of the Company of approximately \$912,690 and \$518,000 respectively.

F-17

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

9. Related Party Transactions Not otherwise disclosed At August 31, 2004, accounts receivable includes approximately \$215,400, due from an entity controlled by a significant stockholder and member of the Board of Directors.

10. Supplemental Cash Flow Information Actual amounts paid for interest and income taxes are as follows:

	Years Ended August 31,	
	2004	2003
Interest expense	\$ 491	\$ -
Income taxes	\$ -	\$ -

11. Significant Unconsolidated Affiliate The Company had an approximate 30% interest in an unconsolidated affiliate (TherMatrx) at August 31, 2003.

On July 15, 2004, American Medical Systems Holdings, Inc., or AMS, acquired TherMatrx, Inc. for \$40 million in cash plus future payments contingent upon the combined entity's future sales of TherMatrx's DOT systems. The sale included all of our TherMatrx shares, which were reduced at closing to approximately 25% of the total outstanding TherMatrx shares because of the exercise of outstanding options to acquire common stock

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

of TherMatrx. The Company received an initial cash payment, after the withholding of escrow funds and the payment of other initial obligations, of approximately \$9 million in connection with the closing.

F-18

BSD MEDICAL CORPORATION
Notes to Financial Statements
Continued

-
11. Significant Unconsolidated Affiliate Continued Summarized financial information of an unconsolidated affiliate of the Company, as of and for the year ended September 30, 2003 (the affiliate's fiscal year ended September 30) is as follows:

	2003

Result for year:	
Gross revenue	\$ 13,298,422
Gross profit	\$ 9,589,803
Net income (loss)	\$ 1,520,190
Year-end financial position	
Current assets	\$ 6,313,746
Non-current assets	\$ 2,335,232
Current liabilities	\$ 1,913,453
Non-current liabilities	\$ 474,748

12. Commitments and Contingencies
- The Company has an employment agreement with the President of the Company. The agreement provides that the President's salary will be based upon a reasonable mutual agreement. Additionally, in the case of non-voluntary termination, the acting president will receive severance pay for a six-month period, which includes an extension of all employee rights, privileges, and benefits, including medical insurance. The six-month severance pay would be the salary at the highest rate paid to the president prior to such a non-voluntary termination. The agreement also requires the Company to pay the acting president for any accrued unused vacation and bonuses.

The Company has an exclusive worldwide license for a unique temperature probe. The license has no determinable life. The Company pays royalties based upon its sales of this probe. There were no Royalties accrued as of August 31, 2004 and \$1,000 was accrued at August 31, 2003. Royalty expense amounted to approximately \$5,000 for the years ended August 31, 2004 and 2003.

F-19

-
13. Fair Value of Financial Instruments None of the Company's financial instruments are held for trading purposes. The Company estimates that the fair value of all financial instruments at August 31, 2004 and 2003 does not differ materially from the aggregate carrying values of its financial instruments recorded in the accompanying balance sheet. The estimated fair value amounts have been determined by the Company using available market information and appropriate valuation methodologies. Considerable judgment is necessarily required in interpreting market data to develop the estimates of fair value, and, accordingly, the estimates are not necessarily indicative of the amounts that the Company could realize in a current market exchange.
14. Recent Accounting Pronouncements In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" (FIN No. 46), which addresses consolidation by business enterprises of variable interest entities. FIN No. 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements", to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN No. 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The Company does not expect to identify any variable interest entities that must be consolidated. In the event a variable interest entity is identified, the Company does not expect the requirements of FIN No. 46 to have a material impact on its financial condition or results of operations.

F-20

-
14. Recent Accounting Pronouncements In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This new statement changes the accounting for certain financial instruments

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Continued

that, under previous guidance, issuers could account for as equity or classifications between liabilities and equity in a section that has been known as "mezzanine capital." It requires that those certain instruments be classified as liabilities in balance sheets. Most of the guidance in SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003. Management anticipates that the adoption of SFAS No. 150 may have a material impact on the Company's consolidated financial statements if in the future the Company issues mandatorily redeemable preferred stock. Such mandatorily redeemable preferred stock, previously included as "mezzanine capital", would be included as a liability in accordance with SFAS 150.

F-21

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 8A. CONTROLS AND PROCEDURES

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based upon that evaluation, the principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective and adequately designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms.

During the fourth fiscal quarter, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B. OTHER INFORMATION

None.

27

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

Information with respect to this item is set forth under "Election of Directors" and "Directors and Executive Officers" appearing in the definitive

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

proxy statement to be delivered to stockholders in connection with the 2005 Annual Meeting of Stockholders (the "Proxy Statement"). Such information is incorporated herein by reference.

ITEM 10. EXECUTIVE COMPENSATION

Information with respect to this item is set forth under "Executive Compensation" in the Proxy Statement. Such information is incorporated herein by reference.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Information with respect to this item is set forth under "Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement. Such information is incorporated herein by reference.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Information with respect to this item is set forth under "Certain Relationships and Related Transactions" in the Proxy Statement. Such information is incorporated herein by reference.

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

The following exhibits are incorporated herein by reference as indicated:

Exhibit -----	Description -----
3.1	Amended and Restated Certificate of Incorporation. Incorporated by reference to Exhibit 3.1 of the BSD Medical Corporation Form 10-KSB, filed December 1, 2003.
3.2	Bylaws. Incorporated by reference to Exhibit 3.2 of the BSD Medical Corporation Registration Statement on Form S-1, filed October 16, 1986.
4.1	Specimen Common Stock Certificate. Incorporated by reference to Exhibit 4 of the BSD Medical Corporation Registration Statement on Form S-1, filed October 16, 1986.
4.2	Securities Purchase Agreement dated December 10, 2003 among BSD Medical Corporation and the purchasers identified therein. Incorporated by reference to Exhibit 4.2 of the BSD Medical Corporation Form 10-KSB, filed December 1, 2003.
4.2	Amendment No. 1 to Securities Purchase Agreement dated December 10, 2003 among BSD Medical Corporation and the purchasers identified therein. Incorporated by reference to Exhibit 99.1 of the BSD Medical Corporation Form 8-K, filed December 22, 2003.
4.3	Warrant to Purchase 42,980 Shares of Common Stock dated December 10, 2003 issued by BSD Medical Corporation to T.R. Winston & Company, LLC. Incorporated by reference to Exhibit 99.2 of the BSD Medical Corporation Form 8-K, filed December 22, 2003.

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

- 4.4 Warrant to Purchase 60,000 Shares of Common Stock dated December 10, 2003 issued by BSD Medical Corporation to The Runnel Family Trust Dated 1/11/2000. Incorporated by reference to Exhibit 99.3 of the BSD Medical Corporation Form 8-K, filed December 22, 2003.
- 10.1 Transfer of Trade Secrets Agreement dated December 7, 1979, among BSD Medical Corporation, Vitek, Incorporated and Ronald R. Bowman. Incorporated by reference to Exhibit 10.6 of the BSD Medical Corporation Registration Statement on Form S-1, filed October 16, 1986.
- 10.2 Second Addendum to Exclusive Transfer of Trade Secrets Agreement dated April 2, 1987. Incorporated by reference to Exhibit 10 of the BSD Medical Corporation Form 10-KSB, filed April 8, 1988.
- 10.3 BSD Medical Corporation 1998 Director Stock Plan. Incorporated by reference to Exhibit A of the BSD Medical Corporation Schedule 14A, filed July 27, 1998.
- 10.4 BSD Medical Corporation 1998 Stock Incentive Plan. Incorporated by reference to Exhibit B of the BSD Medical Corporation Schedule 14B, filed July 27, 1998.
- 10.5 Lease Agreement dated December 5, 1997, between BSD Medical Corporation and Alcoh Development, Inc., Alan S. Cohen, Orlene H. Cohen, and Reelman Investments, L.C. Incorporated by reference to Exhibit 10.5 to BSD Medical Corporation's Registration Statement on Form SB-2 filed January 27, 2004.
- 10.6 Lease Extension Agreement and Contract to Purchase dated November 1, 2002 between BSD Medical Corporation and Alcoh Development, Inc., Alan S. Cohen, Orlene H. Cohen, and Reelman Investments, L.C. Incorporated by reference to Exhibit 10.6 to BSD Medical Corporation's Registration Statement on Form SB-2 filed January 27, 2004.
- 10.7 Employment Agreement dated August 10, 1999 between BSD Medical Corporation and Hyrum A. Mead. Incorporated by reference to Exhibit 10.7 to BSD Medical Corporation's Registration Statement on Form SB-2 filed January 27, 2004.
- 10.8 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.
- 10.9 Agreement dated May 27, 1994 between BSD Medical Corporation and Medizin Technik GmbH. Incorporated by reference to Exhibit 10.9 to BSD Medical Corporation's Registration Statement on Form SB-2 filed January 27, 2004.
- 10.10 Agreement and Plan of Merger dated June 15, 2004 by and among American Medical Systems, Inc., Leio Acquisition Corp., TherMatrx, Inc., TherMatrx Investment Holdings, LLC and BSD Medical Corporation. Incorporated by reference to Exhibit 10.11 to BSD Medical Corporation's Amendment No. 2 to Registration Statement on Form SB-2 filed July 15, 2004.

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

- 21 Subsidiary List. Incorporated by reference to Exhibit 21 of the BSD Medical Corporation Form 10-K, filed December 1, 2003.
- 31.1 Certification of Chief Executive Officer of BSD pursuant to Rule 13a-14.
- 31.2 Certification of Chief Financial Officer of BSD pursuant to Rule 13a-14.
- 32.1 Certification of Chief Executive Officer attached pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
- 32.2 Certification of the Chief Financial Officer of BSD pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information with respect to this item is set forth under "Principal Accountant Fees and Services" in the Proxy Statement. Such information is incorporated herein by reference.

30

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 29, 2004

By: /s/ Hyrum A. Mead

Hyrum A. Mead
President and Member of the Board of
Directors
(principal executive officer)

Date: November 29, 2004

By: /s/ Dennis Bradley

Dennis Bradley
Controller
(principal financial and accounting
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 29, 2004

By: /s/ Paul F. Turner

Edgar Filing: BSD MEDICAL CORP - Form 10KSB

Paul F. Turner
Chairman of the Board, Senior Vice
President and Chief Technology
Officer

Date: November 29, 2004

By: /s/ Hyrum A. Mead

Hyrum A. Mead
President and Member of the Board of
Directors
(principal executive officer)

Date: November 29, 2004

By: /s/ Gerhard W. Sennewald

Dr. Gerhard W. Sennewald
Member of the Board of Directors

Date: November 29, 2004

By: /s/ J. Gordon Short

Dr. J. Gordon Short
Member of the Board of Directors

Date: November 29, 2004

By: /s/ Michael Nobel

Dr. Michael Nobel
Member of the Board of Directors