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BSD MEDICAL CORP  
Form SB-2/A  
July 22, 2004

As filed with the Securities and Exchange Commission on July 21, 2004  
Registration No. 333-112240

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U.S. SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

AMENDMENT NO. 3  
FORM SB-2  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933  
BSD MEDICAL CORPORATION  
(Exact name of Registrant as specified in its charter)

Delaware	3845	75-1590407
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2188 West 2200 South  
Salt Lake City, Utah 84119  
(801) 972-5555  
(Address, including zip code, and telephone number, including  
area code, of Registrant's principal executive offices)

-----  
Hyrum A. Mead  
President  
BSD Medical Corporation  
2188 West 2200 South  
Salt Lake City, Utah 84119  
(801) 972-5555  
(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

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Copy to:  
Nolan S. Taylor, Esq.  
Dorsey & Whitney LLP  
170 South Main Street, Suite 900  
Salt Lake City, Utah 84101  
(801) 933-7360

Approximate date of commencement of proposed sale to the public:  
from time to time after the effective date of  
this registration statement.

If any of the securities being registered on this Form are to be offered on a  
delayed or continuous basis pursuant to Rule 415 under the Securities Act of  
1933, other than securities offered only in connection with dividend or interest  
reinvestment plans, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant  
to Rule 462(b) under the Securities Act, please check the following box and list  
the Securities Act registration statement number of the earlier effective  
registration statement for the same offering. ☐

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

☐ If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ☐

### ----- CALCULATION OF REGISTRATION FEE

Title of Shares to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price per Share(2)	Proposed Aggre Offering
Common stock, \$0.001 par value per share	2,162,580	\$1.25	\$2,70

- (1) The amount to be registered consists of 2,162,580 shares of common stock to be sold by the selling stockholders identified in this registration statement. Of the 2,162,580 shares of common stock, 2,059,600 are currently outstanding and beneficially owned by the selling stockholders and 102,980 are issuable upon the exercise of warrants by the selling stockholders.
- (2) Estimated based upon the average of the bid and asked price of the Registrant's common stock on January 23, 2004, as reported by the OTC Bulletin Board, pursuant to Rule 457(c) promulgated under the Securities Act of 1933, as amended.
- (3) Registration fee was previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders named herein may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

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(Subject to completion: Dated JULY 21, 2004)

2,162,580 Shares  
BSD MEDICAL CORPORATION

## Common Stock

This prospectus relates to the public offering, which is not being underwritten, of a total of 2,162,580 shares of the common stock of BSD Medical Corporation by the selling stockholders described herein. The price at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the sale of these shares.

Our common stock is quoted on the OTC Bulletin Board under the symbol "BSDM." On July 19, 2004, the last reported sale price for our common stock on the OTC Bulletin Board was \$1.75 per share.

You should carefully consider the risk factors beginning on page 2 of this prospectus before purchasing any of the common stock offered by this prospectus.

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Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July \_\_, 2004.

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You should rely only on information contained in this prospectus. We have not authorized any person to make a statement that differs from what is in this prospectus. If any person does make a statement that differs from what is in this prospectus, you should not rely on it. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state in which the offer or sale is not permitted. The information in this prospectus is complete and accurate as of its date, but the information may change after that date.

In this prospectus, the terms "BSD" "company," "we," "us," and "our" refer to BSD Medical Corporation.

### PROSPECTUS SUMMARY

The following summary should be read in conjunction with, and is qualified in its entirety by, the more detailed information and financial statements appearing elsewhere in this prospectus.

#### Company Overview

BSD Medical Corporation develops, manufactures, markets and services hyperthermia microwave systems used to treat cancer, the second leading cause of death in the United States according to the National Cancer Society. Our treatment systems are designed to precisely deliver microwave energy to elevate the temperature of cancerous tumors, directly killing cancerous cells and enhancing the effectiveness of certain other cancer therapies.

The focus of our cancer therapy business is to develop and commercialize systems that provide hyperthermia treatment for cancerous tumors that occur anywhere in the body. To accomplish this, we have developed systems capable of treating both superficial tumors, or tumors near the body's surface, and deep tumors. These systems consist of two families of products: the BSD-500 and the BSD-2000.

In October 2003, we announced that we had received FDA approval for a new operating system, allowing us to commercially introduce in the United States a new family of four systems, including the BSD-500i-4, BSD-500c-4, BSD-500i-8 and BSD-500c-8. These new systems enable us to treat cancers near the surface of the body using heat created from focused microwave energy, known as superficial hyperthermia, and also to treat cancers deeper in the body or in natural orifices like the esophagus using microwave antennae, known as interstitial hyperthermia. In addition to treating melanoma, recurring breast cancer and other cancers requiring superficial hyperthermia therapy, these new systems are used as companions to interstitial radiation systems, called brachytherapy systems, that treat cancer with radioactive seeds. We believe that over 1,500 brachytherapy systems have been installed, providing a target customer base for our systems. We have also obtained the CE Mark certification required to export these systems to Europe. The new BSD-500 systems are compact, portable and ergonomically engineered for use in a demanding hospital environment.

Our BSD-2000 family of systems employs an array of microwave antennae used to focus on and treat tumors located deep in the body. The BSD-2000 system has not been submitted for FDA pre-market approval, or PMA. Accordingly, we do not have authority to distribute the BSD-2000 system for sale in the United

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States, except as an investigational device. The phase III clinical trial through which we intend to seek a PMA for this system has already been completed, and we are underway in developing the commercial version of the BSD-2000 that we intend to use as the basis of the FDA submission.

In planning for the anticipated pre-market approval of the BSD-2000, including the commercial upgrades required before market introduction, we estimated that it would be faster to obtain FDA approvals for the commercial upgrades if those approvals are received while the BSD-2000 was classified by the FDA as an investigational device. Three independent investigational device approvals are required to complete these commercial upgrades. First, a new commercial amplifier system for the BSD-2000 has been submitted and approved by the FDA under an investigational device status. Second, we recently received FDA investigational device approval for a new commercial patient treatment applicator. Third, we have submitted an application for investigational device approval of new commercial software for the BSD-2000. The software submission was completed in May 2004. The FDA has 30 days to respond once a submission has been made for investigational device approval. Further work and delays can then follow. All of these investigational device upgrades are an integral part of the BSD-2000 system and will not therefore be submitted individually for pre-market approval.

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Once the anticipated investigational device upgrade approvals have been obtained, it becomes considerably more difficult to estimate the time frame until a potential pre-market approval can be obtained for the BSD-2000. The timing of a FDA decision depends on the workload of the FDA and the extent of the review process required. While the response time for submissions can vary greatly, the average response time between submission and pre-market approval was 364 days in fiscal year 2003 as reported by the FDA.

In July 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 includes 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 \$8,975,000 in connection with the closing. Our approximate 30% ownership of TherMatrx was reduced to approximately 25% because of the exercise of outstanding options to acquire common stock of TherMatrx at the closing. 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 \$8,975,000. 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 \$8,975,000. 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 \$8,975,000, which is the only amount guaranteed. We expect to use the payments from the sale of our TherMatrx shares, including any contingent payments, for general

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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.

Our principal sources of revenue include the sale of our BSD-500 and BSD-2000 series hyperthermia systems and the sale of thermotherapy systems, component parts and contract manufacturing services to TherMatrx. During the nine months ended May 31, 2004, total sales of \$1,541,397 consisted of \$881,738, or 57%, from the sale of a two BSD-2000 systems and miscellaneous equipment to a related party; \$471,724, or 31%, from the sale of three BSD-500 systems to non-related parties; \$99,503, or 6%, from the sale of thermotherapy systems, component products and contract services to TherMatrx; and \$88,432, or 6%, for service contracts, billable labor, and other miscellaneous items to non-related parties. During the fiscal year ended August 31, 2003, total sales of \$2,572,682 consisted of \$1,391,443, or 54%, from the sale of thermotherapy systems, component products and contract service to TherMatrx; \$63,500, or 2% from royalties paid to us by TherMatrx; \$516,142, or 20%, from the sale of a BSD-2000 systems and various component parts to a related party; \$203,386, or 8%, from the sale of two BSD-500 systems to non-related parties; \$123,211, or 5%, for service contracts, billable labor, and other miscellaneous items to non-related parties; and \$275,000, or 11%, from royalties paid by non-related parties.

Our principal executive offices are located at 2188 West 2200 South, Salt Lake City, Utah 84101, and our telephone number is (801) 972-5555.

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### The Offering

The selling stockholders identified in this prospectus are selling up to 2,162,580 shares of our common stock, which they acquired from us in private placements on November 28, 2003 and December 10, 2003 or will be issued upon the exercise of warrants issued to a broker-dealer in connection with the private placements. We will not receive any proceeds from the sale of the shares by the selling stockholders.

### RISK FACTORS

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 prospectus. 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.

Since our inception in 1978, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of \$21,077,431 at May 31, 2004. In fiscal 2003, we recorded a net loss of \$570,285. Our net loss was 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. For the nine months ended May 31, 2004, we recorded a net loss of \$591,324. 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

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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 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 recent periods has been derived from TherMatrx, we expect revenue from this customer to decline in the current and future periods.

For the year ended August 31, 2003, TherMatrx accounted for \$1,454,943, or approximately 57% of our net sales and was our largest customer. We manufacture, assemble and test TherMatrx's TMx-2000 system, and also supply equipment components and provide consulting services to TherMatrx. During the nine months ended May 31, 2004 our sales to TherMatrx declined to \$99,503, a decrease of \$816,410 from the nine months ended May 31, 2003. We anticipate revenue from TherMatrx to be substantially less in the fourth quarter of fiscal 2004 than it was in the fourth quarter of fiscal 2003. In addition, we currently

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expect revenue from TherMatrx to be significantly less in fiscal 2004 than it was in fiscal 2003. With the sale of our TherMatrx shares 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. TherMatrx now purchases most of its products from other sources. 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 TherMatrx.

In connection with the closing of the sale of TherMatrx to AMS, we received an initial payment of approximately \$8,975,000 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 \$8,975,000, 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,

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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 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 believe our relationship with Nucletron was unsuccessful. Our sales agreement with Nucletron was terminated in March 2004.

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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. Medizin-Technik sold none of our hyperthermia therapy systems in Europe in fiscal 2003 and has sold two of our hyperthermia therapy systems in fiscal 2004. The loss or ineffectiveness of Medizin-Technik as a distributor and



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

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

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.

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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

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property rights to stay competitive.

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

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

A product liability settlement could exceed our ability to pay.

The manufacturing and marketing of medical devices involves an inherent risk of product liability. 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.

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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.

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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.

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:

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- 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

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common stock and our stockholders, therefore, may have difficulty in selling their shares in the secondary trading market.

Sales of a substantial number of shares of our common stock in the public market, including the shares offered under this prospectus, could lower our stock price and impair our ability to raise funds in new stock offerings.

Future sales of a substantial number of shares of our common stock in the public market, including the shares offered under this prospectus, or the perception that such sales could occur, could adversely affect the prevailing market price of our common stock and could make it more difficult for us to raise additional capital through the sale of equity securities. This prospectus relates to the sale or distribution of up to 2,162,580 shares of common stock by the selling stockholders. The shares subject to this prospectus represent approximately 11% of our issued and outstanding common stock as of June 30, 2004. We filed this registration statement pursuant to an agreement with the holders of the common stock and warrants purchased in our November and December 2003 private placements. We are required under this agreement to use our reasonable best efforts to cause this registration statement to remain effective until the earlier of (1) the sale of all the shares of our common stock covered by this registration statement; or (2) such time as the selling stockholders named in this registration statement become eligible to resell the shares of our common stock pursuant to Rule 144(k) under the Securities Act.

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. For example, on February 4, 2004 there were zero shares of our stock traded and the closing price remained at \$1.35 per share (the closing price for the prior trading day). Only eight trading days later, following a news release involving an FDA approval, there were 175,082 shares of our stock traded at a closing price of \$1.57. Over the four month period beginning November 2003 and ending at the February 2004 stock market close, the average daily trading volume for our stock was 26,014 shares. In November 2003, however, the average daily volume was 46,728 shares or 80% above the four month daily average. Conversely, in December 2003 the average daily volume was 14,298 shares or 45% below the four month daily average. The average daily trading volume was over three times greater in November 2003 than it was in December 2003. The following factors could impact the market for our stock and cause further volatility in our stock price:

- o announcements of new technological innovations;
- o FDA and other regulatory developments;

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- 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.

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If we sell shares of our common stock at a per share price of less than \$1.10 to raise additional capital, we will have to issue additional shares to the investors in our November and December private placement, which will dilute our other stockholders' ownership.

To execute our business plan, and in particular to market our recently FDA approved products, we may need to raise additional capital. We agreed with the investors in our November and December private placement transactions that we would issue them additional shares of our common stock if we sold shares of common stock within one year of their investment at a per share price of less than the price they paid, which was \$1.10 per share. The anti-dilution protection provided to these investors, commonly referred to as ratchet anti-dilution, would require us to issue to these investors additional shares equal to the difference between the number of shares that they would have been issued if the per share price they paid equaled the lowest price at which we issued shares to raise capital within one year of their investment, regardless of the number that we issue, and the number of shares they were issued. If this anti-dilution protection were triggered, the investors would not be required to pay any additional consideration for the additional shares issued to them, and our other stockholders' ownership would be diluted by the issuance. Because of the significant dilution that could occur if this anti-dilution protection were triggered, we may choose to not raise additional capital if we cannot raise it at a per share price that would avoid triggering the anti-dilution protection. This could delay the execution of our business plan.

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.

### USE OF PROCEEDS

The shares of common stock offered by this prospectus will be sold by the selling stockholders, and the selling stockholders will receive all of the proceeds from sales of such shares. We will not receive any proceeds from the sale of the shares offered by this prospectus.

### BUSINESS

#### Overview

We develop, manufacture, market and service hyperthermia microwave systems used to treat cancer, the second leading cause of death in the United States according to the National Cancer Society. Our treatment systems are designed to precisely deliver microwave energy to elevate the temperature of cancerous tumors, directly killing cancerous cells and enhancing the effectiveness of certain other cancer therapies.

The focus of our cancer therapy business is to develop and commercialize systems that can provide hyperthermia treatment for cancerous tumors that occur anywhere in the body. To accomplish this, we have developed systems capable of treating both superficial tumors, or tumors near the body's

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surface, and deep tumors. These systems consist of two families of products: the BSD-500 and the BSD-2000.

In October 2003, we announced that we had received FDA approval for a new operating system, allowing us to launch the commercial market introduction in the United States of a new family of four systems, including the BSD-500i-4, BSD-500c-4, BSD-500i-8 and BSD-500c-8. These new systems enable us to treat cancers near the surface of the body using heat created with focused microwave energy, known as superficial hyperthermia, and also to treat cancers deeper in the body or in natural orifices like the esophagus using microwave antennae, known as interstitial hyperthermia. In addition to treating melanoma, recurring breast cancer and other cancers requiring superficial hyperthermia therapy, these new systems are used as companions to interstitial radiation systems, called brachytherapy systems, that treat cancer with radioactive seeds. We believe that over 1,500 brachytherapy systems have been installed, providing a target customer base for our systems. We have also obtained the CE Mark certification required to export these systems to Europe. The new BSD-500 systems are compact, portable and ergonomically engineered for use in a demanding hospital environment.

Our BSD-2000 family of systems employs an array of microwave antennae used to focus on and treat tumors located deep in the body. The BSD-2000 system has not been submitted for FDA pre-market approval, or PMA. Accordingly, we do not have authority to distribute the BSD-2000 system for sale in the United States, except as an investigational device. The phase III clinical trial through which we intend to seek a PMA for this system has already been completed, and we are underway in developing the commercial version of the BSD-2000 that we intend to use as the basis of the FDA submission.

In July 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 includes 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 \$8,975,000 in connection with the closing. Our approximate 30% ownership of TherMatrx was reduced to approximately 25% because of the exercise of outstanding options to acquire common stock of TherMatrx at the closing. 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 \$8,975,000. 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 \$8,975,000. 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 \$8,975,000, which is the only amount guaranteed. 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.

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

#### Cancer and Hyperthermia Therapy

Despite the massive attention given to cancer prevention and treatment, the American Cancer Society estimates that 1,334,100 new cancer cases were diagnosed and that 556,500 Americans died from cancer during 2003 (up from 555,500 cancer deaths in 2002). 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.

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. 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 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.

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 years after treatment.

#### Our Products and Services

We have developed the technology and products required to approach



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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.

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- 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).

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 six 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 six 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 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

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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.

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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, Tubingen University Medical School, Essen University Hospital, Charite 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.

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 German oncological research institution, the Clinic of Medical Oncology of the Klinikum Gro(bet)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

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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.

Other Products and Services. In addition to our hyperthermia therapy systems, we manufacture for, and supply treatment systems and related equipment components to, other medical device companies, as described below.

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TherMatrx, Inc. We manufacture, assemble and test for TherMatrx its FDA-approved TMx-2000 thermotherapy system that treats benign prostatic hyperplasia, or BPH, a condition associated with an enlarged prostate that commonly affects men over age 50. We also supply TherMatrx with equipment components used for its TMx-2000 system, including probes, applicators and temperature components. We also have provided regulatory compliance and other consulting services to TherMatrx.

In November 1997, we entered into an agreement with Oracle Strategic Partners and Charles Manker to form TherMatrx as a jointly-owned private company. In return for an equity interest in TherMatrx, we transferred to TherMatrx four patents related to the thermal treatment of BPH. As described more fully elsewhere in this prospectus, in July 2004, AMS acquired TherMatrx, including all of our TherMatrx shares.

TherMatrx's TMx-2000 system is a non-surgical, catheter-based therapy that has been shown to provide safe and effective relief from BPH symptoms. The treatment can be performed in a clinic or physician's office. The therapy avoids the side effects and complications of surgery. TherMatrx obtained FDA approval to begin marketing its products in July of 2001 and began marketing the TMx-2000 shortly after receiving FDA approval.

In manufacturing, assembling and testing the TMx-2000 system and supplying equipment components and providing consulting services to TherMatrx, TherMatrx has been our largest customer. For the year ended August 31, 2003, TherMatrx accounted for \$1,454,943, or approximately 57% of our revenue. Our product sales to TherMatrx dropped significantly during the first nine months of fiscal 2004 compared to first nine months of fiscal 2003 because of TherMatrx's existing excess inventory. TherMatrx is under no contractual obligation to obtain from us products or manufacturing, assembling, testing or other services, and is free to obtain such products and services from another source at any time. We believe TherMatrx purchases the majority of its products from other sources. With the sale of our TherMatrx shares to AMS, we believe product sales to TherMatrx may decrease to zero in future fiscal years.

Medizin-Technik GmbH. Additionally, we supply equipment components to Medizin-Technik located in Munich, Germany, which is a significant distributor of our hyperthermia therapy systems in Europe. Medizin-Technik purchases equipment and components to service our hyperthermia therapy systems that it sells to its customers in Europe. The President and Chief Executive Officer of Medizin-Technik is Dr. Gerhard W. Sennewald, one of our directors and significant stockholders. Medizin-Technik was a significant customer for us in fiscal 2003 with sales of \$517,979 or 20% of our revenue. Medizin-Technik has been a significant customer in prior years and we anticipate that it will be a significant customer for us in the future. The loss of Medizin-Technik as a distributor and significant customer would have a material adverse effect on our business. The distribution rights of Medizin-Technik have been in place since

the early 1980s.

#### Sales, Marketing and Distribution

In the United States, our target market includes clinics, hospitals and institutes in which cancer is treated. In the international market we similarly target cancer treatment centers in clinics, hospitals and institutes.

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.

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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 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](http://www.bsdmc.com), and our materials are also posted on many other sites. We have

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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 payors, such as Medicare, Medicaid, other government programs and private insurance plans for the health care services provided to their patients using our products. Additionally, managed care organizations and insurance companies directly pay for services provided to their patients. The Center for Medicare and Medicaid Services, or

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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, depending on the circumstances of the treatment. Codes have been established for 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.

Effective November 1995, HCFA, the predecessor agency to CMS, authorized Medicare reimbursement for certain investigational devices and certain related services 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

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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.

### 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.

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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

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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.

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.

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

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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

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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.

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

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

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

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

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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



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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 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 to destroy them from the inside. The innovative microwave antenna design enables the therapeutic heating length to be tailored to match the tumor size. This license requires 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 remain current on these payments.

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 only a one-time cash payment with no continuing costs.

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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

During the fiscal years ended August 31, 2003, and August 31, 2002, we expended \$676,867 and \$603,137 respectively for research and development, representing 26% and 23% of total revenues. Research and development expenditures increased in fiscal 2003 due to costs associated with the

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development of the BSD-2000/3D/MR system, the continued enhancements of our BSD-500 systems and the 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.

### Employees

As of May 31, 2004, BSD had 24 employees; 22 of whom were full-time employees. None of our employees is 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.

### 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. We have leased the building for an annual rental expense of approximately \$78,000. 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.

### Legal Proceedings

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

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### MANAGEMENT

The following table sets forth certain information concerning our directors, executive officers and key employees. The directors have served in their respective capacities since their election and/or appointment and will serve until the next annual stockholders' meeting or until their successors are duly elected and qualified. The executive officers serve at the pleasure of the Board of Directors. There are no family relationships among any of our directors or officers.

Name	Age	Position
Paul F. Turner, MSEE*	56	Chairman of the Board, Senior Vice President, and Chief Technology Officer
Hyrum A. Mead, MBA*	56	President and Director

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Gerhard W. Sennewald, Ph.D.	67	Director
J. Gordon Short, M.D.	72	Director
Michael Nobel, Ph.D.	63	Director
Dixie Toolson Sells	53	Vice President of Regulatory Affairs
Ray Lauritzen	53	Vice President of Field Service

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\*Executive officers of BSD.

Paul F. Turner, MSEE, has served as a director of BSD since 1994 and currently serves as Chairman of the Board of Directors. Mr. Turner also has served as the Senior Vice President and Chief Technology Officer of BSD since August 1999. From October 1995 to August 1999, Mr. Turner served as the Acting President of BSD. From 1986 to October 1995, Mr. Turner served in various capacities with BSD, including Staff Scientist, Senior Scientist, Vice President of Research, and Senior Vice President of Research. Mr. Turner has led the design of microwave treatment systems for tumors, including the development of external phased array antennae technology to focus radiated microwave energy deep into the central area of the body to treat deep tumors. He has also integrated this technology with magnetic resonance imaging to non-invasively monitor treatments within the patient's body.

Hyrum A. Mead, MBA, has served as President and a director of BSD since August 1999. Previously, he served five years as Vice President of Business Development at ZERO Enclosures, a leading manufacturer in the telecommunications, computer and aerospace enclosures industry and seven years as President of Electro Controls, a manufacturer of computer controlled power systems. Mr. Mead began his career in marketing with IBM where he was involved with the introduction of many new products.

Gerhard W. Sennewald, Ph.D., has served as a director of BSD since 1994. Dr. Sennewald has served as the President and Chief Executive Officer of Medizin-Technik GmbH, of Munich, Germany, a firm which is engaged in the business of distributing hyperthermia equipment and diagnostic imaging equipment and services, from April 1985 to the present. In connection with his service to Medizin-Technik GmbH, Dr. Sennewald has been BSD's key European representative and distributor for 17 years and has been instrumental in obtaining the majority of BSD's foreign sales.

J. Gordon Short, M.D., has served as a director of BSD since 1994. From 1978 to 2000, Dr. Short served as President of Brevis Corporation, a privately-held medical products company that specializes in consumable specialty

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supplies and in hand hygiene products, and from 1978 to the present, Dr. Short has served as the Vice President and Chairman of the Board of Brevis Corporation. From 1978 to 1982, Dr. Short served BSD as a Medical Director. In that capacity, he participated in the initial development and establishment of certain of BSD's products. He also previously served on BSD's Medical Advisory Board.

Michael Nobel, Ph.D., has served as a director of BSD since January 1998. From 1991 to the present, Dr. Nobel has served as the Executive Chairman of the MRAB Group, a privately-held company which provides diagnostic imaging services. From 1995 to the present, Dr. Nobel has served as the Chairman of the

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Board of the Nobel Family Society. From 1995 to the present, he also has served as Chairman of the American Non-Violence Project Inc., and has served as a consultant to UNESCO in Paris and the United Nations Social Affairs Division in Geneva. Dr. Nobel participated in the introduction of magnetic resonance imaging as European Vice President for Fonar Corp.

Dixie Toolson Sells has served as Vice President of Regulatory Affairs of BSD since December 1994. Ms. Sells served as Administrative Director of BSD from 1978 to 1984, as Director of Regulatory Affairs from 1984 to September 1987, and as Vice President of Regulatory Affairs from September 1987 to October 1993. She served as Director of Regulatory Affairs from October 1993 to December 1994. Ms. Sells has served as Vice President of Regulatory Affairs since 1994. She served as Corporate Secretary from 1994 to 2002. Ms. Sells also serves on the Board of Directors of the Intermountain Biomedical Association.

Ray Lauritzen served as Field Service Manager of BSD from 1982 to January 1988 and has served as Vice President of Field Service Operations from January 1988 to the present.

### Audit Committee

We have established an audit committee, which consists of Mr. Sennewald, Mr. Short and Mr. Nobel. The audit committee is responsible for reviewing and monitoring our financial statements and internal accounting procedures, recommending the selection of independent auditors by our board, evaluating the scope of the annual audit, reviewing audit results, consulting with management and our independent auditor prior to presentation of financial statements to stockholders and, as appropriate, initiating inquiries into aspects of our internal accounting controls and financial affairs. We currently do not have an audit committee financial expert because of our relatively small size and our limited resources to attract such an expert.

### EXECUTIVE COMPENSATION

The following table sets forth certain information regarding all compensation earned by Paul Turner, our Senior Vice President and Chief Technology Officer, and Hyrum Mead, our President, for services rendered to us during fiscal 2003, 2002 and 2001. No other executive officer received total salary and bonus compensation in excess of \$100,000 for the fiscal year ended August 31, 2003.

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Summary Compensation Table

Name and Principal Position	Year	Annual Compensation		Com
		Salary (\$)	Bonus (\$)	
=====	=====	=====	=====	=====
Paul Turner,	2003	\$145,000	\$400	
Chairman of the Board, Senior Vice	2002	\$145,000	\$400	
President, Chief Technology Officer	2001	\$145,000	\$400	
Hyrum A. Mead,				

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President, Director	2003	\$125,000	\$400
	2002	\$125,000	\$30,000
	2001	\$125,000	\$400

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(1) Represents options to purchase shares of TherMatrx common stock we owned on the date of grant. These options were granted by us in July 2002 and were exercised in the fourth quarter of fiscal 2002 at an exercise price per share of \$0.001. We recognized a compensation expense related to these TherMatrx options computed using a value of \$4.00 per share. The \$4.00 per share value is based solely on the price per share for common stock sold by TherMatrx to existing TherMatrx stockholders in December 2001.

The following table summarizes the exercise of stock options during fiscal 2003 by Messrs. Turner and Mead, and the fiscal year-end value of unexercised stock options held by each of them. None of these executive officers exercised stock options during fiscal 2003.

## AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR-END OPTION VALUES

Name and Position	Number of Securities Underlying Unexercised Options at FY-end (#)		Value of Unexercised In-the-Money Options at FY-end (\$) (1)	
	Exercisable	Unexercisable	Exercisable	Unexercisable
=====	=====	=====	=====	=====
Hyrum A. Mead, President	200,000	120,000	\$33,600	\$16,800
Paul F. Turner, Sr. VP and Chief Technology Officer	180,953	0	\$124,858	0

(1) Value based on the difference between the fair market value of one share of our common stock at August 31, 2003, \$0.79, and the exercise price of the options ranging from \$0.10 to \$0.81 per share. Options are in-the-money if the market price of the shares exceeds the option exercise price.

## Compensation of Directors

We provide annual compensation in the amount of \$12,000 to each non-employee director. Of this amount, \$4,000 is to be paid in cash and the balance is to be paid in the form of restricted shares of our common stock under our 1998 Director Stock Option Plan. In addition to the annual compensation to directors, each non-employee director will receive an annual option to purchase 25,000 restricted shares of our common stock at a purchase price of 85% of the fair market value at the date the option is granted. The options vest ratably over 5 years and expire in 10 years.

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Paul F. Turner and Hyrum A. Mead are the only members of the Board of Directors who are employed by us. Messrs. Turner and Mead do not receive any separate compensation for services performed as directors.

### Employment Contracts

We entered into an employment agreement with Mr. Mead dated August 10, 1999. This agreement provides that Mr. Mead shall receive an annual base salary of \$125,000, which shall be reviewed annually by the Board of Directors. The agreement provides that if Mr. Mead is involuntarily terminated, Mr. Mead will receive severance compensation for a period of six months, including an extension of all benefits and perquisites. The severance amount shall include six months of salary at the highest rate paid to Mr. Mead prior to termination and an additional amount equal to all bonuses received by Mr. Mead during the 12-month period preceding termination (excluding any signing bonus received during such period). The agreement also requires us to vest any options granted to Mr. Mead for the purchase of our common stock, allowing a 90-day period for Mr. Mead to exercise those options. Mr. Mead's agreement includes a non-competition covenant prohibiting him from competing with us for one year following his termination.

We entered into an employment agreement with Mr. Turner dated November 2, 1988. The agreement provides that Mr. Turner's salary will be based upon a reasonable mutual agreement. The agreement provides that if Mr. Turner's employment is involuntarily terminated, he will receive severance pay for a one-year period, which pay includes an extension of all of his rights, privileges and benefits as an employee (including medical insurance). The one year severance pay shall be equal to Mr. Turner's regular salary for the 12-month period immediately prior to the termination. The agreement also requires us to pay Mr. Turner for any accrued, unused vacation at the time of termination. We are also obligated to pay Mr. Turner \$1,000 (or the equivalent value in stock options) for each newly issued patent obtained by us as a result of Mr. Turner's efforts (Mr. Turner receives only \$500 if multiple inventors are involved). Mr. Turner's agreement includes a non-competition covenant prohibiting him from competing with us for one year following his termination. We may continue the non-competition period for up to four additional years by notifying Mr. Turner in writing and by continuing the severance payments for the additional years during which the non-competition period is extended.

### SELLING STOCKHOLDERS

The following table sets forth the number of shares of our common stock beneficially owned by the selling stockholders as of June 30, 2004, based on the selling stockholders' representations regarding their ownership. The percentages shown in the table are based on 19,913,651 shares of common stock outstanding on that date. We cannot estimate the number of shares that will be held by the selling stockholders after completion of this offering because the selling stockholders may sell all or some of the shares and because there currently are no agreements, arrangements or understandings with respect to the sale of any of the shares. The term "selling stockholder" or "selling stockholders" includes the stockholders listed below and their transferees, assignees, pledgees, donees or other successors. Each selling stockholder reserves the right to accept or reject, in whole or in part, any proposed sale of shares. Each selling stockholder also may offer and sell less than the number of shares indicated. No selling stockholder is making any representation that any shares covered by this prospectus will or will not be offered for sale. Except as indicated in this section, we are not aware of any material relationship between us and a selling stockholder within the past three years other than as a result of a selling stockholder's beneficial ownership of our common stock.

Unless otherwise indicated in the table below, the shares being offered

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in this prospectus were issued to seven accredited investors pursuant to that certain Securities Purchase Agreement dated as of November 28, 2003, and as

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amended on December 10, 2003 (the "Purchase Agreement"), between us and these investors. In accordance with the terms and conditions of the Purchase Agreement, we issued an aggregate of 2,059,600 shares of common stock. We also issued a three-year, immediately exercisable warrant to purchase up to 102,980 shares of common stock at an exercise price of \$1.80 per share (the "Warrant") to a broker-dealer in connection with the Purchase Agreement. The shares to be issued upon exercise of the Warrant are also being offered in this prospectus.

Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Before the Offering	Shares of common Stock Being Offered in the Offering	Number of Share of Common Stock Beneficially Owned After the Offering
JMG Capital Partners, L.P (1)	455,000	455,000	--
JMG Triton Offshore Fund, Ltd (2)	455,000	455,000	--
J. Steven Emerson IRA R/O II (3)	1,127,787	910,000	217,787
Emerson Partners, Ltd. (4)	135,000	135,000	--
High Tide, LLC (5)	45,500	45,500	--
Kenneth R. Malkes	13,600	13,600	--
The Runnels Family Trust (6)	105,500	105,500	--
T.R. Winston & Company, LLC (7)	42,980	42,980	--

\* Represents beneficial ownership of less than 1.0% of the outstanding shares of common stock.

- (1) JMG Capital Partners, L.P. ("JMG Partners") is a California limited partnership. Its general partner is JMG Capital Management, LLC (the "Manager"), a Delaware limited liability company and an investment adviser registered with the Securities and Exchange Commission. The Manager has voting and dispositive power over JMG Partners' investments, including these shares. The equity interests of the Manager are owned by JMG Capital Management, Inc., ("JMG Capital") a Delaware corporation, and Asset Alliance Holding Corp., a Delaware corporation. Jonathan M. Glaser is the Executive Officer and Director of JMG Capital and has sole investment discretion over JMG Partners' portfolio holdings.
- (2) JMG Triton Offshore Fund, Ltd. (the "Fund") is an international business company under the laws of the British Virgin Islands. The Fund's investment manager is Pacific Assets Management LLC, a Delaware limited liability company (the "Manager"). The Manager is an investment adviser registered with the Securities and Exchange Commission and has voting and dispositive power over the Fund's investments, including

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- these shares. The equity interests of the Manager are owned by Pacific Capital Management, Inc., a Delaware company ("Pacific") and Asset Alliance Holding Corp., a Delaware company. The equity interests of Pacific are owned by Messrs. Roger Richter, Jonathan M. Glaser and Daniel A. David. Messrs. Glaser and Richter have sole investment discretion over the Fund's portfolio holdings.
- (3) J. Stevens Emerson, the sole beneficiary of J. Steven Emerson IRA R/O II, has voting and investment control over these shares.
  - (4) J. Stevens Emerson, a manager of Emerson Partners, Ltd., has voting and investment control over these shares.
  - (5) G. Tyler Runnels, manager of High Tide, LLC ("High Tide"), has voting and investment control over these shares. High Tide, an affiliate of T.R. Winston & Company, LLC, has represented to us that the shares held by it were purchased in the ordinary course of business, and that at the time of issuance it did not have any agreements or understandings, directly or indirectly, with any person to distribute the shares.
  - (6) The shares being offered in this prospectus include 60,000 shares issuable upon exercise of warrants. These warrants were issued to The Runnels Family Trust ("Runnels Trust") at the direction of T.R. Winston & Company, LLC ("TR Winston") in connection with placement services relating to the Purchase Agreement provided by TR Winston, and we agreed to register for resale the shares issuable upon exercise of the warrants. With respect to the remaining 45,500 shares, the Runnels Trust has represented to us that shares were purchased in the ordinary course of business, and that at the time of issuance it did not have any agreements or understandings, directly or indirectly, with any person to distribute the shares. G. Tyler Runnels, trustee of the Runnels Trust, has voting and investment control over these shares.
  - (7) The shares being offered in this prospectus include 42,980 shares issuable upon exercise of warrants. These warrants were issued to T.R. Winston & Company, LLC ("TR Winston") in connection with placement services relating to the Purchase Agreement, and we agreed to register for resale the shares issuable upon exercise of the warrants. G. Tyler Runnels, Chairman, and John W. Galuchie, Jr., President of TR Winston, have voting and investment control over these shares. TR Winston is a registered broker-dealer and all of the securities issued to it were issued as compensation for placement services.

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We have agreed to prepare and file any amendments and supplements to the registration statement relating to these shares as may be necessary to keep the registration statement effective until such time as all of the shares covered by this prospectus have been sold or until all of such shares may be sold without registration or restriction pursuant to Rule 144(k) under the Securities Act.

This prospectus also covers any additional shares of our common stock which become issuable in connection with the shares being registered by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration which results in an increase in the number of our outstanding shares of common stock.

### PLAN OF DISTRIBUTION

We have registered the 2,162,580 shares of our common stock offered in this prospectus on behalf of the selling stockholders. We will pay all expenses of this registration, other than fees and expenses, if any, of counsel or other advisors to the selling stockholders. The selling stockholders are responsible for paying any commissions, discounts, or other brokerage fees incurred in connection with their sale of any of the shares.



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The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market prices, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected at various times in one or more of the following transactions, or in other kinds of transactions:

- o in the over-the-counter market;
- o in private transactions and transactions otherwise than on exchanges or systems or in the over-the-counter market;
- o in connection with short sales of the shares;
- o by pledge to secure debt and other obligations;
- o through the writing of options, whether the options are listed on an options exchange or otherwise;
- o in connection with the writing of non-traded and exchange-traded call options, in hedge transactions and in settlement of other transactions in standardized or over-the-counter options; or
- o through a combination of any of the above transactions.

The selling stockholder and its successors, including its transferees, pledgees or donees or their successors, may sell the common stock directly to purchasers or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholder or the purchasers. These discounts, concessions or commissions as to any particular underwriter, broker-dealer or agent may be in excess of those customary in the types of transactions involved.

We have agreed to indemnify the selling stockholders, and each director, officer or controlling person of each selling stockholder within the meaning of Section 15 of the Securities Act of 1933 against all losses, claims,

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damages, liabilities and expenses, (or action in respect thereof) including any of the foregoing incurred in settlement of any litigation, commenced or threatened, arising out of or based on (i) any untrue statement or alleged untrue statement of a material fact contained in, or information incorporated by reference into, any registration statement or prospectus (or any amendment or supplement thereto) or any preliminary prospectus prepared in connection with the registration contemplated by the Purchase Agreement, (ii) any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, (iii) any failure by us to fulfill and perform any agreement, covenant or undertaking pursuant to the Purchase Agreement, or (iv) any failure or breach of our representations and warranties as set forth in the Purchase Agreement.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance on Rule 144 under the Securities Act of 1933, if they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in the sale of shares may be "underwriters" within the meaning of the Securities Act of 1933. Any commissions received by broker-dealers or agents on the sales and any profit on the resale of shares purchased by broker-dealers or agents may be deemed to be underwriting

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commissions or discounts under the Securities Act of 1933.

Under the rules of the SEC, any person engaged in the distribution of our common stock may not simultaneously buy, bid for or attempt to induce any other person to buy or bid for our common stock in the open market for a period of two business days prior to the beginning of the distribution. The rules and regulations under the Securities Exchange Act of 1934 may also limit the timing of purchases and sales of shares of our common stock by the selling stockholders. We have notified the selling stockholders they should not begin any distribution of common stock unless they have stopped purchasing and bidding for common stock in the open market as provided in applicable securities regulations, including Regulation M promulgated under the Securities Exchange Act of 1934.

We have informed the selling stockholders that the anti-manipulation provisions of Regulation M may apply to the sales of their shares. We have advised the selling stockholders of the requirement for delivery of this prospectus in connection with any sale of the common stock.

### MANAGEMENT'S 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 prospectus 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 prospectus. All information presented herein is based on our fiscal year ended August 31, 2003 and the nine months ended May 31, 2004. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

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#### General

We develop, manufacture and market microwave systems used in the treatment of cancer. Our microwave systems are used in cancer treating therapies that elevate the temperature of tumors or other targeted tissue to conditions classified as either hyperthermia or thermal therapy, also called thermotherapy, through precisely delivered microwave energy.

Since our inception, we have been engaged in the development and improvement of technology that can better accomplish cancer treatment through hyperthermia therapy. From our predecessor hyperthermia systems, our current BSD-500 and BSD-2000 hyperthermia 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. Our hyperthermia 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, 2003, had an accumulated deficit of \$20,486,107. We recorded net loss

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for fiscal 2003 of \$570,285.

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 \$1,956,270 and \$1,866,192 for the years ended August 31, 2003 and 2002, respectively. Service revenue was \$212,181 and \$716,240 for the years ended August 31, 2003 and 2002, respectively

We derived \$1,907,585, or 74% of our revenue in fiscal 2003 from sales to related parties. Approximately \$1,391,443 of such related party revenue was from manufacturing, assembling and testing thermotherapy systems for TherMatrx and selling probes, applicators and temperature sensors and other components and contract services to TherMatrx. We also realized \$63,500 of royalty revenue from TherMatrx, which is included in other revenue. The remaining related party revenue of approximately \$516,142 was for one BSD-2000 system 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.

In fiscal 2003, we derived \$326,597, or 13% of our revenue from sales to unrelated parties. These revenues consisted of the sale of two BSD 500 systems for \$203,386, billable labor of \$20,863, service contracts of \$65,731, and sales of consumable devices used with our hyperthermia systems of \$36,617. During the fiscal year ended August 31, 2003, we also recognized revenue of \$275,000 for royalties in arrears that were collected from a legal settlement. Such royalties were owing pursuant to a 1996 agreement in which we granted a license to use our patented technology related to benign prostatic hyperplasia, or BPH. This payment from the licensee was for settlement in full of all royalty obligations on the part of the licensee and such royalties will not continue in future periods.

Cost of sales for the year ended August 31, 2003, included raw material and labor costs. Research and development expenses include expenditures for new product development and development of enhancements to existing products.

As described more fully elsewhere in this prospectus, in July 2004, AMS acquired TherMatrx, including all of our TherMatrx shares. Having sold our TherMatrx shares, any future product sales to TherMatrx are uncertain and could decrease to zero in future fiscal periods. While TherMatrx may purchase products from us in the future, we have not included any TherMatrx sales in our business planning. It has never been our intent to focus our business on contract manufacturing. We historically provided manufacturing services to TherMatrx to help it develop its business.

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We project that in fiscal year 2004 the significant decline of TherMatrx sales will create a significant decline in our total revenue as compared to fiscal 2003, and that we will incur a greater loss in fiscal 2004 than in 2003.

We intend to use the cash generated from the sale of our TherMatrx shares to aggressively pursue our business plan and diversify our revenue base away from related party revenue. Our plan includes increasing support for sales and marketing of our FDA approved products and the pursuit of pre-marketing approval for the BSD-2000 in an effort to complete our objective of providing treatment for solid tumors located throughout the body. Our plan also anticipates th