BSD MEDICAL CORP Form 10-Q January 14, 2010

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

FORM	10-Q
(Mark	One)
ý	Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the	quarterly period ended November 30, 2009
0	Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the	transition period from to
	Commission File No. 001-32526

BSD Medical Corporation (Exact Name of Registrant as Specified in Its Charter)

Delaware (State or other jurisdiction of incorporation or organization) 75-1590407 (I.R.S. Employer Identification No.)

2188 West 2200 South Salt Lake City, Utah 84119 (Address of principal executive offices, including zip code)

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

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

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

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

Large accelerated filer o Accelerated filer o

Non-accelerated filer o Smaller reporting company

ý

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No  $\acute{y}$ 

As of January 14, 2010, there were 22,039,301 shares of the Registrant's common stock, \$0.001 par value per share, outstanding.

# BSD MEDICAL CORPORATION FORM 10-Q

# FOR THE QUARTER ENDED NOVEMBER 30, 2009

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## PART I - FINANCIAL INFORMATION

## Item 1. Financial Statements

# BSD MEDICAL CORPORATION Condensed Balance Sheets (Unaudited)

ASSETS Current assets:	November 30, 2009	August 31, 2009
Cash and cash equivalents	\$5,933,675	\$7,791,938
Accounts receivable, net of allowance for doubtful accounts of \$20,000	135,800	289,617
Related party trade accounts receivable	152,560	41,016
Income tax receivable	1,415,758	1,415,758
Inventories, net	2,042,627	1,794,476
Other current assets	143,157	94,536
Total current assets	9,823,577	11,427,341
	2,0-2,017	,,
Property and equipment, net	1,335,259	1,352,384
Patents, net	72,163	77,633
	,	,
	\$11,230,999	\$12,857,358
LIABILITIES AND STOCKHOLDERS' EQUITY  Current liabilities:		
Accounts payable	\$367,575	\$226,905
Accrued liabilities	393,696	548,079
Deferred revenue – current portion	57,039	67,851
Total current liabilities	818,310	842,835
Deferred revenue – net of current portion	120,694	73,534
Total liabilities	939,004	916,369
Commitments and contingencies  Stockholders' equity:		
Preferred stock, \$.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock; \$.001 par value, 40,000,000 shares authorized, 22,039,301 shares		
issued	22,040	22,040
Additional paid-in capital	28,890,884	28,593,305
Treasury stock, 24,331 shares at cost	(234)	(234)
Accumulated deficit	(18,620,695)	(16,674,122)
Total stockholders' equity	10,291,995	11,940,989
	\$11,230,999	\$12,857,358

See accompanying notes to condensed financial statements

# BSD MEDICAL CORPORATION Condensed Statements of Operations (Unaudited)

		Three Months Ended November 30,			
		2009		2008	
Revenues:	4		•	1 200 206	
Sales	\$	272,895	\$	1,208,396	
Sales to related parties		153,308		23,168	
Total revenues		426,203		1,231,564	
Operating costs and expenses:					
Cost of sales		226,520		600,480	
Cost of related party sales		150,847		22,172	
Research and development		543,427		507,223	
Selling, general and administrative		1,459,395		1,510,307	
Total operating costs and expenses		2,380,189		2,640,182	
Loss from operations		(1,953,986	)	(1,408,618	)
Other income (expense):					
Interest and investment income		3,209		258,732	
Other income (expense)		4,204		(34,259	)
Total other income (expense)		7,413		224,473	
Loss before income taxes		(1,946,573	)	(1,184,145	)
Income tax provision		-		(249,000	)
Net loss		(1,946,573	)	(1,433,145	)
		, , ,	,		
Other comprehensive loss - increase in unrealized					
loss on investments, net of income tax		-		(4,391,565	)
Net comprehensive loss	\$	(1,946,573	) \$	(5,824,710	)
Net loss per common share:					
Basic	\$	(0.09	) \$	(0.07	)
Diluted	\$	(0.09	) \$	(0.07	)
Weighted average number of shares outstanding:					
Basic		22,039,000		21,769,000	)
Diluted		22,039,000		21,769,000	)

See accompanying notes to condensed financial statements

# BSD MEDICAL CORPORATION Condensed Statements of Cash Flows (Unaudited)

Three Months Ended November 30. 2009 2008 Cash flows from operating activities: Net loss \$ (1,946,573)\$ (1,433,145)Adjustments to reconcile net loss to net cash used in operating activities: Depreciation and amortization 35,774 33,276 Stock-based compensation 297,579 273,173 Stock issued for services 37,500 Decrease (increase) in: Receivables 42,273 40,712 Income tax receivable 249,000 Inventories (236, 241)(248, 151)Other current assets (48,621 ) 24,506 Increase (decrease) in: 140,670 309,068 Accounts payable Accrued liabilities (86,433 (154,383 ) Customer deposits (119,729)Deferred revenue 36,348 (8,307)Net cash used in operating activities (1,845,084)(916,620 ) Cash flows from investing activities: Purchase of property and equipment (13,179)(18,185)Purchase of investments (216,638 Net cash used in investing activities (13,179)(234,823 Cash flows from financing activities (1,151,443) Net decrease in cash and cash equivalents (1,858,263)Cash and cash equivalents, beginning of period 7,791,938 1,394,652

See accompanying notes to condensed financial statements

\$

5,933,675

\$

243,209

5

Cash and cash equivalents, end of period

#### **BSD MEDICAL CORPORATION**

Notes to Condensed Financial Statements (Unaudited)

#### Note 1. Basis of Presentation

The interim financial information of BSD Medical Corporation (the "Company") as of November 30, 2009 and for the three months ended November 30, 2009 and 2008 is unaudited, and the condensed balance sheet as of August 31, 2009 is derived from audited financial statements. The accompanying unaudited condensed balance sheets of the Company as of November 30, 2009 and August 31, 2009, the related unaudited condensed statements of operations and of cash flows for the three months ended November 30, 2009 and 2008 have been prepared in accordance with U.S. generally accepted accounting principles for interim financial reporting and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). The condensed financial statements do not include all of the information and notes required by U.S. generally accepted accounting principles for complete financial statements. These condensed financial statements should be read in conjunction with the notes thereto, and the financial statements and notes thereto included in our annual report on Form 10-K for the year ended August 31, 2009.

All adjustments (consisting only of normal recurring adjustments) necessary for the fair presentation of our financial position as of November 30, 2009 and August 31, 2009, and our results of operations and our cash flows for the three months ended November 30, 2009 and 2008 have been included. The results of operations for the three months ended November 30, 2009 may not be indicative of the results for our fiscal year ending August 31, 2010.

#### Note 2. Net Loss Per Common Share

The computation of basic earnings per common share is based on the weighted average number of shares outstanding during the period. The computation of diluted earnings per common share is based on the weighted average number of shares outstanding during the period plus the weighted average common stock equivalents which would arise from the exercise of stock options outstanding using the treasury stock method and the average market price per share during the period.

The shares used in the computation of the Company's basic and diluted earnings per share are reconciled as follows:

	Three Months Ended November 30,			
	2009 2008			
Weighted average number of shares outstanding – basic Dilutive effect of stock options	22,039,000	21,769,000		
Weighted average number of shares outstanding – diluted	22,039,000	21,769,000		

No stock options are included in the computation of diluted weighted average number of shares for the three months ended November 30, 2009 and 2008 because the effect would be anti-dilutive. As of November 30, 2009, the Company had outstanding options to purchase a total of 2,362,287 common shares of the Company that could have a future dilutive effect on the calculation of earnings per share.

#### Note 3. Fair Value of Financial Instruments

Our financial instruments currently consist primarily of cash and cash equivalents, accounts receivable and accounts payable. We estimate that the fair value of our cash, accounts receivable and accounts payable at November 30, 2009 and August 31, 2009 does not differ materially from their aggregate carrying values due to the short-term nature of these financial instruments.

Included in our cash equivalents at November 30, 2009 and August 31, 2009 are money market funds of \$5,751,590 and \$7,672,673, respectively, which are highly liquid and have a maturity of three months or less.

In accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification<sup>TM</sup> (ASC) Topic 820, Fair Value Measurements and Disclosure, we categorize our financial assets and liabilities that we measure on a recurring basis into a three-level fair value hierarchy as defined in the standard. Our money market funds are the only financial instruments that we currently measure on a recurring basis. The following table summarizes our financial assets measured on a recurring basis as of November 30, 2009 and August 31, 2009:

Description	Ac	uoted Prices in tive Markets for ical Assets (Level 1)	Ol	gnificant Other oservable uts (Level 2)	Unc	gnificant observable uts (Level 3)
November 30, 2009 Money Market Funds	\$	5,751,590	\$	-	\$	-
August 31, 2009 Money Market Funds	\$	7,672,673	\$	_	\$	_

Note 4. Inventories

Inventories consisted of the following:

	November 30, 2009		August 31, 2009	
Parts and supplies	\$	1,093,821	\$	1,041,355
Work-in-process		841,126		555,584
Finished goods		167,680		257,537
Reserve for obsolete inventory		(60,000 )		(60,000 )
Inventories, net	\$	2,042,627	\$	1,794,476

Note 5. Property and Equipment

Property and equipment consisted of the following:

	ľ	November 30, 2009	August 31, 2009
Equipment	\$	1,072,643	\$ 1,074,364
Furniture and fixtures		298,576	298,576
Leasehold improvements		24,220	24,220
Building		956,000	956,000
Land		244,000	244,000
		2,595,439	2,597,160
Less accumulated depreciation		(1,260,180)	(1,244,776)
Property and equipment, net	\$	1,335,259	\$ 1,352,384

Note 6. Related Party Transactions

During the three months ended November 30, 2009 and 2008, we had sales of \$153,308 and \$23,168, respectively, to entities controlled by a significant stockholder and member of the Board of Directors. These related party transactions represent approximately 36% and 2% of total sales for each respective three-month period.

As of November 30, 2009 and August 31, 2009, receivables included \$152,560 and \$41,016, respectively, from these related parties.

#### Note 7. Stock-Based Compensation

We have both an employee and director stock incentive plan, which are described more fully in Note 10 in our 2009 Annual Report on Form 10-K. As of November 30, 2009, we had approximately 559,000 shares of common stock reserved for future issuance under the stock incentive plans.

The Company accounts for stock-based compensation in accordance with ASC Topic 718, Compensation – Stock Compensation. Under the fair value recognition provisions of this standard, stock-based compensation cost is measured at the grant date based on the value of the award granted using the Black-Scholes option pricing model, and recognized over the period in which the award vests. The stock-based compensation expense has been allocated to the various categories of operating costs and expenses in a manner similar to the allocation of payroll expense as follows:

	Three Months Ended November 30,		
	2009 2008		
Cost of sales	\$ 16,365	\$	18,429
Research and development	45,859		42,329
Selling, general and administrative	235,355		212,415
Total	\$ 297,579	\$	273,173

During the three months ended November 30, 2009, we granted no stock options.

Unrecognized stock-based compensation expense expected to be recognized over the estimated weighted-average amortization period of 2.86 years is approximately \$2,762,000 as of November 30, 2009.

A summary of the time-based stock option awards as of November 30, 2009, and changes during the three months then ended, is as follows:

	Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contract Term (Years)	Aggregate Intrinsic Value
Outstanding at August 31,				
2009	2,379,087	\$ 3.54		
Granted	-			
Exercised	-			
Forfeited or expired	(16,800 )	5.47		
Outstanding at November				
30, 2009	2,362,287	\$ 3.53	7.88	
Exercisable at November	1.057.240	Φ 2.65	( (0	Φ <b>257</b> 050
30, 2009	1,057,240	\$ 3.65	6.68	\$257,958

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value, based on the Company's closing stock price of \$1.98 as of November 30, 2009, which would have been received by the holders of in-the-money options had the option holders exercised their options as of that date.

#### Note 8. Income Taxes

The income tax (provision) benefit consisted of the following:

	Three Months Ended November 30,		
	2009		2008
Current Deferred	\$ -	\$	(20,000 ) (229,000)
Total	\$ -	\$	(249,000)

The deferred income tax provision of \$229,000 in the three months ended November 30, 2008 resulted from our recording a valuation allowance against our deferred tax assets. In recording the valuation allowance, we were unable to conclude that it is more likely than not that our deferred tax assets, including portions of our taxable loss and tax credit carry forwards, will be realized. In reaching this determination, we evaluated factors such as prior earnings

history, expected future earnings and our ability to carry back reversing items to offset income taxes paid.

#### Note 9. Supplemental Cash Flow Information

The Company paid no amounts for interest expense during the three months ended November 30, 2009 and 2008. The Company paid no amounts for income taxes during the three months ended November 30, 2009 and 2008.

During the three months ended November 30, 2009, the Company had no non-cash financing and investing activities.

During the three months ended November 30, 2008, the Company had the following non-cash financing and investing activities:

- Increased other comprehensive loss and decreased investments by \$4,391,565.
- Increased common stock and decreased additional paid-in capital by \$450.
- Decreased income tax receivable and additional paid-in capital by \$159,558.

#### Note 10. Recent Accounting Pronouncements

Effective July 1, 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 168, The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles – a Replacement of FASB Statement No. 162. The FASB Codification became the source of authoritative U.S. generally accounting principles (GAAP) recognized by the FASB to be applied to nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of this Statement, the Codification superseded all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification became nonauthoritative. This statement was effective for financial statements issued for interim and annual periods ending after September 15, 2009, or our quarter ended November 30, 2009. Accounting Standards Updates (ASU) are now issued for changes to the FASB Codification for new GAAP promulgated by the FASB, amendments to the SEC content in the FASB Codification, as well as for editorial changes.

ASU 2009-13, Revenue Recognition (Topic 605) – Multiple-Deliverable Revenue Arrangements – a Consensus of the FASB Emerging Issues Task Force, was issued in October 2009. This ASU establishes a selling price hierarchy for allocating the sales price of a multiple element arrangement and eliminates the residual method of allocation. The ASU will require that a vendor determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. The ASU significantly expands the disclosures related to a vendor's multiple-deliverable revenue arrangements. The guidance will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. We currently are unable to determine what impact the future application of this pronouncement may have on our financial statements.

ASU 2009-14, Software (Topic 985) – Certain Revenue Arrangements That Include Software Elements – a Consensus of the FASB Emerging Issues Task Force, was issued in October 2009. This ASU provides guidance on allocating and measuring revenue when vendors sell or lease tangible products in an arrangement that contains software that is more than incidental to the tangible product as a whole. The ASU requires that hardware components of a tangible product would be excluded from the scope of the software revenue guidance and clarifies that if the software contained in the tangible product is essential to the tangible product's functionality, the software is excluded from the scope of the software revenue guidance. The guidance will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, or our fiscal year beginning September 1,

2010. Early adoption is permitted. We currently are unable to determine what impact the future application of this pronouncement may have on our financial statements.

## Note 11. Subsequent Events

We have evaluated events occurring after the date of our accompanying balance sheets through January 14, 2010, the date of the filing of this Quarterly Report on Form 10-Q. We did not identify any material subsequent events requiring adjustment to our accompanying condensed financial statement.

#### Item 2. 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 report contain forward-looking statements that involve risks and uncertainties. Forward-looking statements can also be identified by words such as "anticipates," "expects," "believes," "plans," "predicts," and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to those discussed in the subsection entitled "Forward-Looking Statements" below. The following discussion should be read in conjunction with our financial statements and notes thereto included in this report. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

#### General

BSD Medical Corporation (Company) develops, manufactures, markets and services medical systems that deliver precision-focused radio frequency (RF) or microwave energy into diseased sites of the body, heating them to specified temperatures as required by a variety of medical therapies. Our business objectives are to commercialize our products developed for the treatment of cancer and to further expand our systems to treat other diseases and medical conditions. Our product line for cancer therapy has been created to offer hospitals and clinics a complete solution for thermal treatment of cancer as provided through microwave/RF systems.

While our primary developments to date have been cancer treatment systems, we also pioneered the use of microwave thermal therapy for the treatment of symptoms associated with enlarged prostate, and we are responsible for technology that has contributed to a new medical industry addressing the needs of men's health. In accordance with our strategic plan, we subsequently sold our interest in TherMatrx, Inc., the company established to commercialize our technology to treat enlarged prostate symptoms, to provide substantial funding that we can utilize for commercializing our systems used in the treatment of cancer and in achieving other business objectives.

In spite of the advances in cancer treatment technology, nearly 40% of cancer patients continue to die from the disease in the United States. Our product line includes systems that have been strategically designed to offer a range of thermal treatment systems for the treatment of cancer, including both hyperthermia and ablation treatment systems. Studies have shown that both hyperthermia and ablation treatments kill cancer but they have different clinical applications.

Our hyperthermia cancer treatment systems are used to treat cancer with heat (hyperthermia) while boosting the effectiveness of radiation through a number of biological mechanisms. Hyperthermia is usually used to increase the effectiveness of other therapies; e.g., radiation therapy and chemotherapy for the treatment of locally advanced cancers. Hyperthermia usually refers to treatments delivered at temperatures of 40-49°C for one hour.

Our microwave ablation system is to be used to ablate (remove or vaporize) soft tissue with heat alone. Thermal ablation usually refers to heat treatments delivered at temperatures above 55°C for short periods of time. Thermal ablation is used to destroy local tumors using a short intense focus of heat on a specific area, which is usually small, similar to surgical removal of the tumor.

Commercialization of our systems that are used to treat cancer is our most immediate business objective. Current and future cancer treatment sites for our systems may include cancers of the prostate, breast, head, neck, bladder, cervix, colon/rectum, ovarian, esophagus, liver, kidney, brain, bone, stomach and lung. Our cancer treatment systems have been used to treat thousands of patients throughout the world and have received many awards, including the Frost & Sullivan "Technology Innovation of the Year Award" for cancer therapy devices awarded for the development of the BSD-2000.

Although we have not entered most of these markets, we also believe that our technology has application for a number of other medical purposes in addition to cancer.

#### Our Products and Services

We have developed technology and products for thermal ablation and hyperthermia cancer therapy through multiple techniques, which collectively allow cancer to be treated virtually anywhere in the body:

- Thermal ablation ablates (removes or vaporizes) soft tissues at high temperatures through focused microwave energy.
- Superficial hyperthermia non-invasively treats cancerous tumors located within a few centimeters of the surface of the body, such as melanoma and recurrent breast cancer.
- Internal or interstitial hyperthermia treats tumors in combination with internal radiation therapy by inserting tiny microwave antennae that deliver hyperthermic microwave energy to tumors through the same catheters used to deliver radioactive materials, or "seeds," to tumors for radiation therapy. This technique can be employed in treating prostate cancer, breast cancer, head and neck cancer and a variety of other cancer sites.
- Deep hyperthermia non-invasively treats tumors located deep within the body, including many problematic cancer sites located in the pelvis.

MTX-180. Our MTX-180 has been developed to employ precision-guided microwave energy to ablate soft tissue. The MTX-180 is a compact, mobile system that includes a state-of-the-art computer, a microwave generator, single-patient-use disposable applicators and a proprietary thermistor-based temperature monitoring system. The delivery of microwave energy is controlled by time and power parameters set by the operator utilizing an interactive touch-screen monitor that allows the operator to quickly and easily control the treatment. The MTX-180 provides minimally invasive access to the target tissue and can be used in open surgical as well as in percutaneous ablation procedures, which will allow the MTX-180 to be used by both surgeons and interventional radiologists. The MTX-180 was developed to provide treatments as a stand-alone therapy, rather than only in combination with other therapies.

The MTX-180 represents a major part of our business plan moving forward. It introduces into our product line a disposable applicator used in each treatment, which we believe represents the potential for a significant ongoing revenue stream after the sale of the system. Our sales force is experienced in marketing to interventional radiologists and surgeons, the users of thermal ablation systems. Internationally, we expect sales will be conducted through established and new distributors located primarily in Europe and Asia.

In September 2008, the FDA granted us a 510(k) clearance to market the Phase I MTX-100, which authorizes the commercial sale of the device in the United States. At the same time that we received the 510(k) clearance for the MTX-100 System, we had already started design of a more advanced Phase II ablation system that would provide a wider range of clinical applications and improved ease of use as well as additional revenue streams. Since receipt of FDA clearance to market the MTX-100, we have devoted significant efforts to optimizing the design of the system to improve its ease of use and its medical applications. Following clinical evaluations of Phase I, we decided to postpone market entry until completion of the optimized Phase II MTX-180 design. We believe this will allow us to enter this market with an optimized system that will have a wider range of clinical applications and increased revenue streams.

Additional time will be required to complete the market-ready Phase II design, apply for applicable regulatory approvals, and finalize the manufacturing processes for the MTX-180 and the applicators. Also, final marketing and sales strategies must be completed prior to market introduction. We currently are unable to predict when these efforts will be completed and when revenues from the sale of the MTX-180 and related applicators will begin. We do not believe, however, that these revenues will begin until at least the second quarter of calendar year 2010, and we cannot be sure that these revenues will be consistent with our expectations.

BSD-500. Our BSD-500 systems are used to deliver either superficial hyperthermia therapy, which is non-invasive and delivered externally using antennae placed over the tumor, or interstitial hyperthermia therapy, which is delivered using antennae that are inserted into the tumor, or both. These systems include a touch screen display monitor by which the operator controls the hyperthermia treatment, computer equipment and software that controls the delivery of microwave energy to the tumor, and a generator that creates the needed microwave energy for the treatment. Additionally, the systems include a variety of applicator (radiating antennae) configurations, depending on the system. Various configurations of non-invasive applicators (antennae) are used for superficial hyperthermia treatments. For interstitial hyperthermia treatments, the system may include up to 24 small microwave heat-delivering antennae that are inserted into catheters used for internal radiation therapy (called brachytherapy).

Our primary FDA approval (described as a pre-market approval, or PMA, which is the standard FDA approval required to market Class III medical devices in the United States) for the BSD-500 is for the use of hyperthermia and radiation therapy to treat certain tumors using the BSD-500 Hyperthermia System. There are some clinical studies that have been published that show the effectiveness and safety for the use of hyperthermia and certain chemotherapy drugs for the treatment of some cancers. We do not currently have FDA approval for the use of hyperthermia in conjunction with chemotherapy, but physicians are allowed to utilize medical devices that have been approved or cleared by the FDA, including the BSD-500 Hyperthermia System, for off label indications (indications for use that are not included in the FDA approval or clearance).

We have received FDA approval through FDA supplements for implementation of a new operating system and a new power generation system and other commercial upgrades for the BSD-500 configurations. We have also certified the BSD-500 systems for the CE Mark, which is required for export into some European and non-European countries.

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 localized therapeutic heating (hyperthermia) to solid tumors by applying radiofrequency (RF) energy to certain cancerous tumors, including those located deep within the body. These systems consist of four major subsystems: an RF power generator delivery subsystem; a proprietary, thermistor-based, thermometry subsystem; a computerized monitoring and control subsystem; and an applicator subsystem that includes an applicator and patient support system; as well as various accessories. The BSD-2000 delivers energy to a patient using a power source and an array of multiple antennae that surround the patient's body. The BSD-2000 systems create a central focusing of energy that can be adjusted to target the 3-dimensional shape, size, and location of the tumor, thus providing dynamic control of the heating delivered to the tumor region. The basic BSD-2000 has eight microwave antennae enabling this electronic steering of energy within the patient's body. The BSD-2000/3D has 24 microwave antennae enabling additional electronic steering along the long axis of the body. The 3D steering is particularly useful when implemented with a magnetic resonance system that is capable of non-invasive 3D imaging showing the heated regions, thus permitting the 3D steering to more accurately target the energy to the tumor site.

The BSD-2000 system has not yet received PMA from the FDA for commercial marketing in the United States, but the BSD-2000 has obtained an investigational device exemption, or IDE, for placement 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 and non-European countries and have obtained regulatory approval for the sale of the BSD-2000 in the People's Republic of China.

We have been engaged over the past three years in the extensive process of supporting an FDA submission requesting PMA for the BSD-2000 that was filed on March 28, 2006. During the PMA review process, we continued to work closely with the FDA to determine an appropriate pathway to obtain a marketing approval for the BSD-2000 utilizing the clinical data that was available to us to support a marketing approval. During this process, we submitted multiple amendments and held multiple face-to-face meetings with the FDA. As a result of the process, the FDA suggested that the Humanitarian Device Exemption (HDE) marketing approval process might be the most expeditious pathway for us to obtain a marketing approval. Due to the length of time that the submission had already been under review by the FDA, the significant amount of additional time required to continue to pursue the PMA, and our desire to bring the BSD-2000 to market as quickly as possible, we followed the FDA's suggestion.

On May 18, 2009, the FDA granted HUD designation for our BSD-2000 for use in conjunction with radiation therapy for the treatment of cervical carcinoma patients who are ineligible for chemotherapy. This is the first of the two steps required to obtain HDE marketing approval. Subsequent to the FDA granting the HUD for the BSD-2000, which confirms that the intended use population is fewer than 4,000 patients per year, we filed an HDE submission with the FDA. The FDA generally has 75 days from the date of receipt of the HDE submission to grant or deny an HDE application. This period includes a 30-day filing period during which the FDA determines whether the HDE application is sufficiently complete to permit substantive review. During this review, the FDA may refine the indications for use which received HUD designation to finalize the indications for use for which HDE approval will be granted. This decision will be based on the data that is available to support the device's HDE application. We believe that the data previously submitted to the FDA and reviewed by the agency in our PMA application can be used to support the HDE approval. As of the date of filing this report, the FDA continues its review of our HDE marketing submission for the BSD-2000. Although we remain optimistic that HDE marketing approval will be granted, we are unable to predict when the review process will be completed and its ultimate outcome. If we are unable to receive HDE marketing approval, or if the FDA requires us to undergo extensive testing in order to grant HDE marketing approval, our business could be adversely affected.

The PMA was placed on hold until the HUD designation was granted by the FDA. Once the HUD designation was granted and the HDE was filed, per FDA regulations, we withdrew the PMA submission. We can decide to pursue PMA for the BSD-2000 at a future date.

The HDE approval of the BSD-2000 Hyperthermia System will authorize the commercial sale of the BSD-2000 in the United States. However, there are some differences between the HDE marketing approval and PMA approval, as well as some limitations on the HDE approved devices. The HDE approval demonstrates safety and probable benefit, is intended for use in the treatment of a disease that affects fewer than 4,000 individuals in the United States per year, is only granted when no comparable device has been approved to treat the same disease population, and requires approval from an Institutional Review Board before being used in a facility. In addition, we cannot charge an amount for an HDE approved device that exceeds the costs of research and development, fabrication, and distribution. A device can have both PMA and an HDE approval as long as the approvals are for different indications for use. In addition, a product can have multiple HDE approvals for different applications, and we may decide to pursue additional HDE approvals for the BSD-2000 in the future.

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

BSD-2000/3D. Through research funded by the National Cancer Institute in the United States and supportive efforts by other domestic and international research institutions, we enhanced the BSD-2000 to create the 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 of the tumor. As part of our international collaborative research efforts, sophisticated treatment planning software for the BSD-2000/3D has also been developed.

We have not yet submitted to the FDA a PMA 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 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 Großhadern Medical School of Ludwigs-Maximilians-Universität München, in Munich, Germany. We have since installed BSD-2000/3D/MR systems at multiple other locations.

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

#### Marketing and Distribution

Our target customers include clinics, hospitals and institutions in which cancer is treated, located either in the United States or international markets.

To support our sales and marketing efforts in the United States, we maintain a sales and marketing organization currently consisting of eight persons. Our vice president of international sales directs our international sales and marketing efforts, which consist of relationships with distributors and other agents as well as our own direct sales efforts.

We are currently concentrating on expanding our business into international markets, which we consider to represent our greatest business opportunities.

We entered into an agreement with Dalian Orientech Co. LTD, a privately owned company, to assist us in obtaining regulatory approval for the sale of the BSD-2000 in the People's Republic of China, and thereafter to act as our distributor for the sale of the BSD-2000 in that country. We subsequently obtained Chinese regulatory approval, allowing the distributor to begin to market and sell the BSD-2000 system to hospitals in China. We believe the prospects for increased sales of our systems in China represent one of our greatest business opportunities.

Historically, a significant portion of our revenues have been derived from sales to Medizin-Technik GmbH located in Munich, Germany, which is our exclusive distributor of hyperthermia systems in Germany, Austria and Switzerland, and to certain medical institutions in Belgium and the Netherlands. Medizin Technik is owned by Dr. Gerhard W. Sennewald, one of our directors and a significant stockholder. We have also sold systems in Poland and Italy, and have conducted our own direct sales and marketing efforts in other countries in Europe, India, and Asia. We recently announced the selection of a distributor in India, the world's second most populated country, and have appointed a sales manager for Latin America whose focus will be the medical markets in Mexico, Brazil, Argentina and Chile, as well as other Latin American countries.

#### Critical Accounting Policies and Estimates

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

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

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

Revenue from manufacturing services is recorded when an agreement with the customer exists for such services, the services have been provided, and collection is reasonably assured. Revenue from training services is recorded when an agreement with the customer exists for such training, the training services have been provided, and collection is reasonably assured. Revenue from service support contracts is recognized on a straight-line basis over the term of the contract.

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

Investments: Investments with scheduled maturities greater than three months, but not greater than one year, are recorded as short-term investments. As of November 30, 2009 and August 31, 2009, we had no investments, but had cash and cash equivalents comprised primarily of money market funds. Prior to the liquidation of all our mutual funds in March and May 2009, our investments consisted primarily of a highly liquid, managed portfolio of mutual funds, and were all considered available-for-sale securities. The investments were carried at fair value based on quoted market prices, with net unrealized gains and losses reported as other comprehensive income (loss) in stockholders' equity in our balance sheets. Realized gains and losses are included in our statements of operations.

Inventory Reserves: We periodically review our inventory levels and usage, paying particular attention to slower-moving items. If projected sales do not materialize, or if our hyperthermia systems do not receive increased market acceptance, we may be required to increase the reserve for inventory impairment in future periods.

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

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

Stock-based Compensation: We account for stock-based compensation in accordance with ASC Topic 718, which requires us to measure the compensation cost of stock options and other stock-based awards to employees and directors at fair value at the grant date and recognize compensation expense over the requisite service period for awards expected to vest. The grant date fair value of stock options is computed using the Black-Scholes valuation model, which model utilizes inputs that are subject to change over time, including the volatility of the market price of our common stock, risk free interest rates, requisite service periods and assumptions made by us regarding the assumed life and vesting of stock options and stock-based awards. As new options or stock-based awards are granted, additional non-cash compensation expense will be recorded by us.

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

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

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

#### **Results of Operations**

#### Revenues

We recognize revenue from the sale of our hyperthermia cancer treatment systems and related parts and accessories (collectively, product sales), the sale of consumable devices used with certain of our systems, training, service support contracts and other miscellaneous revenues. Our revenues can fluctuate significantly from period to period because our sales, to date, have been based upon a relatively small number of hyperthermia systems, the sales price of each being substantial enough to greatly impact revenue levels in the periods in which they occur. Sales of a few systems, particularly BSD-2000/3D/MR systems, can cause a large change in our revenues from period to period and the sales cycle for our systems generally extends over multiple financial reporting periods. In addition, differences in the configuration of the systems sold, pricing, and other factors can result in significant differences in the sales price per system and in the total revenues reported in a given period. As a result, there may be quarterly financial reporting periods where we may report no or minimal revenues from the sale of hyperthermia systems. Through November 30, 2009, we have not had any sales of our MTX-180 system.

To date, hyperthermia therapy has not gained wide acceptance by cancer-treating physicians. We believe this is due in part to the lingering impression created by the inability of early hyperthermia therapy technologies to focus and control heat directed at specific tissue locations and conclusions drawn in early scientific studies that hyperthermia was only marginally effective. Additionally, we do not believe that reimbursement rates from third-party payors have been adequate to promote hyperthermia therapy acceptance in the medical community.

We also believe the worldwide economic downturn has made it difficult for many of our customers to obtain approval for the purchase of our hyperthermia systems and to arrange related financing. As a result, we have not experienced significant growth in the number of our systems sold. We believe these difficulties may continue to negatively impact our operating results. To the extent that adverse economic conditions continue, we believe our sales of hyperthermia systems will continue to be negatively impacted and possibly decrease in fiscal year 2010 as compared to fiscal year 2009.

The following table summarizes the number of our systems sold for the respective reporting periods:

		Three Months Ended November 30,		
	2009	2008		
BSD-500	1	3		
BSD-2000	-	2		
BSD-2000/3D	-	-		
BSD-2000/3D/MR	-	-		
Total	1	5		

We have historically derived a substantial portion of our revenues from sales to related parties. All of the related party revenue was for the sale of hyperthermia systems and related component parts and services sold to Medizin-Technik GmbH and Dr. Gerhard Sennewald. Dr. Sennewald, one of our directors and significant stockholders, is a stockholder, executive officer and a director of Medizin-Technik GmbH. We derived \$153,308, or approximately 36%, of our total revenue in the three months ended November 30, 2009 from sales to related parties, as compared to \$23,168 or approximately 2%, in the three months ended November 30, 2008.

In the three months ended November 30, 2009, we derived \$272,895, or approximately 64%, of our total revenue from non-related parties, as compared to \$1,208,396, or approximately 98%, in the three months ended November 30, 2008.

The following tables summarize the sources of our revenues for the respective reporting periods:

	Three Months Ended November 30,		
Non-Related Parties	2009		2008
Product sales	\$ 245,000	\$	1,179,040
Consumable devices	-		2,402
Service contracts	23,585		15,641
Other	4,310		11,313
Total	\$ 272,895	\$	1,208,396
	Three Months Ended November 30,		
Related Parties	2009		2008
Product sales	\$ 110,175	\$	_
Consumable devices	8,250		19,463
Service contracts	-		-
Other	34,883		3,705
Total	\$ 153,308	\$	23,168

Total revenues for the three months ended November 30, 2009 were \$426,203 compared to \$1,231,564 for the three months ended November 30, 2008, a decrease of \$805,361, or 65%. The overall decrease in revenues in the first quarter of the current fiscal year is due primarily to a significant decrease in non-related party sales, partially offset by an increase in related party sales. We sold only one hyperthermia system in the three months ended November 30, 2009 to non-related parties compared to five hyperthermia systems in the three months ended November 30, 2008. We had no sales of hyperthermia systems to related parties in the three months ended November 30, 2009 and 2008.

#### **Gross Profit**

Our gross profit and gross profit percentage will fluctuate from period to period depending on the mix of revenues reported for the period and the type and configuration of the hyperthermia systems sold during the period. Our total gross profit was \$48,836, or 11% of total sales, for the three months ended November 30, 2009, and \$608,912, or 49%, for the three months ended November 30, 2008. The decrease in gross profit in the current fiscal year primarily resulted from the decrease in product sales, for which our gross profit is higher than our other sources of revenue. In addition, as our sales volume decreases, we believe we are unable to fully absorb certain fixed manufacturing costs that are included in cost of sales, thus decreasing our gross profit percentage.

#### Operating Costs and Expenses:

Cost of Sales – Cost of sales include raw material, labor and allocated overhead costs. We calculate and report separately cost of sales for both non-related and related party sales, which are sales to Medizin-Technik and Dr. Sennewald. Cost of sales as a percentage of sales will fluctuate from period to period depending on the mix of sales for the period and the type and configuration of the hyperthermia systems sold during the period. Total cost of sales for the three months ended November 30, 2009 was \$377,367 compared to \$622,652 for the three months ended November 30, 2008, a decrease of \$245,285, or 39%. This decrease resulted primarily from fewer product sales in the current fiscal year. As discussed above, in total, we sold four fewer hyperthermia systems in the three months ended November 30, 2009 than we did in the three months ended November 30, 2008.

Research and Development Expenses – Research and development expenses include expenditures for new product development and development of enhancements to existing products. Research and development expenses were \$543,427 for the three months ended November 30, 2009 compared to \$507,223, for the three months ended November 30, 2008, an increase of \$36,204, or approximately 7%. The increase in research and development expenses in the current fiscal year is due to our continuing efforts to develop an advanced generation of the microwave ablation system, software improvements to enhance the utility of the BSD-500 and BSD-2000 systems, possible market expansion of our current products into other cancer and non-cancerous indications, and other enhancements to our current products and the development of new products.

Selling, General and Administrative Expenses – Our selling, general and administrative expenses remained fairly constant in the first quarter of the current fiscal year compared to the first quarter of last fiscal year. Selling, general and administrative expenses were \$1,459,395 for the three months ended November 30, 2009 compared to \$1,510,307 for the three months ended November 30, 2008, a decrease of \$50,912, or approximately 3%.

#### Other Income (Expense) and Income Tax Provision

Interest and Investment Income: Interest and investment income was \$3,209 for the three months ended November 30, 2009 compared to \$258,732 for the three months ended November 30, 2008. The decrease in interest and investment income in the current fiscal year resulted primarily from lower levels of cash and investments compared to the prior fiscal years. The proceeds from the sale of our mutual funds in March and May 2009 have been deposited in money market funds. Therefore, we anticipate that our interest and investment income for the foreseeable future will be substantially less than previously earned on our mutual funds, but we believe we have significantly reduced the exposure to our funds of market fluctuations.

Income Tax Provision: We recorded no income tax provision or benefit for income taxes during the three months ended November 30, 2009. The income tax provision for the three months ended November 30, 2008 was \$249,000 comprised of a current provision of \$20,000 and a deferred tax provision of \$229,000. The deferred tax provision of \$229,000 in the three months ended November 30, 2008 resulted from our recording a valuation allowance against our deferred tax assets. In recording the valuation allowance, we were unable to conclude that it is more likely than not that our deferred tax assets, including portions of our taxable loss and tax credit carry forwards, will be realized. In reaching this determination, we evaluated factors such as prior earnings history, expected future earnings and our ability to carry back reversing items to offset income taxes paid.

#### Fluctuation in Operating Results

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

#### Liquidity and Capital Resources

Since inception through November 30, 2009, we have generated an accumulated deficit of \$18,620,695 where generally our operating revenues have been insufficient to cover our operating expenses. We have historically financed our operations through cash from operations, research grants, licensing of technological assets, issuance of common stock and sale of investments in spinoff operations. As of November 30, 2009, we had cash and cash equivalents of \$5,933,675, comprised primarily of money market funds.

During the three months ended November 30, 2009, we used cash of \$1,845,084 in operating activities, primarily as a result of our net loss of \$1,946,573, decreased by non cash expenses totaling \$333,353, including depreciation and amortization, and stock-based compensation. Net cash used in operating activities also included an increase in inventories of \$248,151, an increase in other current assets of \$48,621 and a decrease in accrued liabilities of \$154,383, partially offset by a decrease in receivables of \$42,273, increase in accounts payable of \$140,670 and increase in deferred revenue of \$36,348.

By comparison, net cash used in operating activities was \$916,620 during the three months ended November 30, 2008, primarily as a result of our net loss of \$1,433,145 decreased by non cash expenses totaling \$343,949, including depreciation and amortization, stock-based compensation, and stock issued for services. Net cash used in operating activities also included an increase in inventories of \$236,241, decrease in customer deposits of \$119,729, and decrease in deferred revenue of \$8,307, partially offset by a decrease in receivables of \$40,712, decrease in income tax receivable of \$249,000, decrease in other current assets of \$24,506, and an increase in accounts payable of \$309,068.

Net cash used in investing activities for the three months ended November 30, 2009 was \$13,179, resulting from the purchase of property and equipment. For the three months ended November 30, 2008, net cash used by investing activities was \$234,823, resulting from the purchase of property and equipment of \$18,185 and the purchase of investments of \$216,638.

No net cash was provided by or used in financing activities for the three months ended November 30, 2009 and 2008.

We expect to incur additional expenses related to the commercial introduction of our systems, research and development, trade shows, expenditures on publicity, travel, increased salaries and commissions and other related expenses. In addition, we anticipate that we will continue to incur expenses related to seeking governmental and regulatory approvals for our products and for corporate governance and compliance with the Sarbanes-Oxley Act of 2002.

We believe that our current cash and cash equivalents, income tax refunds receivable and projected sales will be sufficient to fund our operations for the next twelve months.

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

On October 1, 2009, our universal shelf registration statement was declared effective by the SEC for the issuance of common stock, preferred stock, warrants, senior debt, subordinated debt and units up to an aggregate amount of \$50.0 million. However, the amount of securities which we may offer pursuant to this shelf registration statement during any twelve-month period shall be limited to one-third of the aggregate market value of the common equity of BSD Medical held by our non-affiliates since our public float is not in excess of \$75.0 million. We may periodically offer one or more of these securities in amounts, prices and on terms to be announced when and if the securities are offered. At the time any of the securities covered by the registration statement are offered for sale, a prospectus supplement will be prepared and filed with the SEC containing specific information about the terms of any such offering.

As of November 30, 2009, we had no significant commitments for the purchase of property and equipment.

We had no off balance sheet arrangements as of November 30, 2009.

#### Recent Accounting Pronouncements

Effective July 1, 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 168, The FASB Accounting Standards Codification<sup>TM</sup> and the Hierarchy of Generally Accepted Accounting Principles – a Replacement of FASB Statement No. 162. The FASB Codification became the source of authoritative U.S. generally accounting principles (GAAP) recognized by the FASB to be applied to nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. On the effective date of this Statement, the Codification superseded all then-existing non-SEC accounting and reporting standards. All other non-grandfathered non-SEC accounting literature not included in the Codification became nonauthoritative. This statement was effective for financial statements issued for interim and annual periods ending after September 15, 2009, or our quarter ended November 30, 2009. Accounting Standards Updates (ASU) are now issued for changes to the FASB Codification for new GAAP promulgated by the FASB, amendments to the SEC content in the FASB Codification, as well as for editorial changes.

ASU 2009-13, Revenue Recognition (Topic 605) – Multiple-Deliverable Revenue Arrangements – a Consensus of the FASB Emerging Issues Task Force, was issued in October 2009. This ASU establishes a selling price hierarchy for allocating the sales price of a multiple element arrangement and eliminates the residual method of allocation. The ASU will require that a vendor determine its best estimate of selling price in a manner that is consistent with that used to determine the price to sell the deliverable on a standalone basis. The ASU significantly expands the disclosures related to a vendor's multiple-deliverable revenue arrangements. The guidance will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Early adoption is permitted. We currently are unable to determine what impact the future application of this pronouncement may have on our financial statements.

ASU 2009-14, Software (Topic 985) – Certain Revenue Arrangements That Include Software Elements – a Consensus of the FASB Emerging Issues Task Force, was issued in October 2009. This ASU provides guidance on allocating and measuring revenue when vendors sell or lease tangible products in an arrangement that contains software that is more than incidental to the tangible product as a whole. The ASU requires that hardware components of a tangible product would be excluded from the scope of the software revenue guidance and clarifies that if the software contained in the tangible product is essential to the tangible product's functionality, the software is excluded from the scope of the software revenue guidance. The guidance will be effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, or our fiscal year beginning September 1, 2010. Early adoption is permitted. We currently are unable to determine what impact the future application of this pronouncement may have on our financial statements.

#### FORWARD-LOOKING STATEMENTS

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

- · our belief about the market opportunities for our products;
- · our anticipated financial performance and business plan;
- our expectations regarding the commercialization of, and the potential revenue from, the BSD-2000, BSD 500 and MTX-180 systems;
- our expectations to further expand our developments to treat other forms of cancer and other diseases and medical conditions:
- our expectations about the impact on our financial statements resulting from the implementation of recent accounting pronouncements;
- · our belief that expanding our business into international markets represents a significant business opportunity;
- · our belief that the prospects for increased sales in China represents one of our greatest business opportunities;
- our expectations that our international sales of the MTX-180 will be conducted through established and new distributors located primarily in Europe and Asia;
- our expectations that our interest and investment income for the foreseeable future will be substantially less than previously earned on our mutual funds.
- our expectations that we will continue to incur expenses related to seeking governmental and regulatory approvals for our products;
- our belief that postponing market entry of the MTX-180 until completion of the Phase II design will allow us to enter the market with an optimized system that will have a wider range of applications and increased revenue streams;
- our expectations about when the MTX-180 will be ready to market and when revenues from the sale of the MTX-180 and related applicators will begin;
- our expectations that the disposable applicator to be used in conjunction with the MTX-180 represents a significant ongoing revenue stream;
- · our expectations regarding FDA approvals relating to the BSD-2000 system;
- our belief that as sales volume increases (decreases) we will increase (decrease) our gross profits percentage because certain fixed manufacturing costs are included in our cost of

sales;

our intentions to continue to devote substantial sums to research and development;