

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2011

or

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

For the transition period from _____ to _____

Commission File Number: 000-54361

BioDrain Medical, Inc.

(Exact name of registrant as specified in its charter)

Minnesota

(State or other jurisdiction of
incorporation or organization)

33-1007393

(I.R.S. Employer
Identification No.)

2060 Centre Pointe Blvd., Suite 7,
(Address of principal executive offices)

Mendota Heights, MN 55120
(Zip Code)

651-389-4800

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 No

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 No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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.

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

APPLICABLE ONLY TO CORPORATE ISSUERS:

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date. As of November 1, 2011, the registrant had 30,427,328 shares of common stock, par value \$.01 per share, outstanding.

BIODRAIN MEDICAL, INC.

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PART 1. FINANCIAL INFORMATION
Item 1. Condensed Financial Statements

BIODRAIN MEDICAL, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED BALANCE SHEETS
(Unaudited)

	<u>September 30,</u> <u>2011</u>	<u>December 31,</u> <u>2010</u>
<u>ASSETS</u>		
Current Assets:		
Cash	\$ 77,728	\$ 9,383
Accounts receivable	19,277	-
Prepaid expense and other assets	30,649	8,126
Total Current Assets	<u>127,654</u>	<u>17,509</u>
Fixed assets, net	5,009	6,831
Intangibles, net	141,532	141,532
Total Assets	<u>\$ 274,195</u>	<u>\$ 165,872</u>
<u>LIABILITIES AND SHAREHOLDERS' DEFICIT</u>		
Current Liabilities:		
Current portion of long term debt (See Note 7)	\$ -	\$ 10,267
Current portion of convertible debt, net of discounts of \$32,513 and \$0	683,987	56,000
Accounts payable	719,969	768,720
Accrued expenses	551,896	498,707
Total Current Liabilities	<u>1,955,852</u>	<u>1,333,694</u>
Long term debt and convertible debt, net of discounts of \$39,807 and \$109,310 (See Notes 6 and 7)	705,593	1,006,789
Liability for equity-linked financial instruments (See Note 9)	87,533	14,946
Stockholders Deficit:		
Common stock, \$.01 par value, 200,000,000 authorized, 29,139,828 and 14,002,290 outstanding	291,398	140,023
Additional paid-in capital	6,134,829	5,052,497
Deficit accumulated during development stage	(8,901,010)	(7,382,077)
Total Shareholder' Deficit	<u>(2,474,783)</u>	<u>(2,189,557)</u>
Total Liabilities and Shareholders' Deficit	<u>\$ 274,195</u>	<u>\$ 165,872</u>

See Notes to Condensed Financial Statements

BIODRAIN MEDICAL, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>		<u>Period From</u>
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>	<u>April 23, 2002</u>
					<u>(Inception)</u>
					<u>To September 30,</u>
					<u>2011</u>
Revenue	\$ 20,264	\$ -	\$ 22,638	\$ 288	\$ 38,663
Cost of goods sold	11,161	-	12,981	140	20,121
Gross margin	9,103	-	9,657	148	18,542
General and administrative expense	428,843	381,053	1,014,667	1,531,669	6,917,559
Operations expense	135,358	55,649	402,479	165,308	1,580,351
Sales and marketing expense	60,989	36,415	149,247	177,065	805,016
Interest expense	61,033	33,873	176,118	107,580	612,851
Loss (gain) on valuation of equity-linked financial instruments	(23,006)	(348,880)	(213,921)	(1,025,294)	(996,225)
Total expense	663,217	158,110	1,528,590	956,328	8,919,552
Net income (loss) available to common shareholders	\$ (654,114)	\$ (158,110)	\$ (1,518,933)	\$ (956,180)	\$ (8,901,010)
Loss per common share basic and diluted	\$ (0.02)	\$ (0.01)	\$ (0.07)	\$ (0.08)	\$ (1.73)
Weighted average shares used in computation, basic and diluted	27,236,303	13,159,639	22,193,681	12,428,401	5,136,012

See Notes to Condensed Financial Statements

BIODRAIN MEDICAL, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENT OF STOCKHOLDERS' DEFICIT
PERIOD FROM APRIL 23, 2002 (INCEPTION)
TO SEPTEMBER 30, 2011

	Shares	Amount	Paid in Capital	Deficit	Total
Issuance of common stock 9/1/02, \$.0167 (1)	598,549	\$ 5,985	\$ 4,015	\$ -	\$ 10,000
Issuance of common 10/23/02, \$1.67/share	2,993	30	4,970		5,000
Net loss				(51,057)	(51,057)
Balance 12/31/02	601,542	\$ 6,015	\$ 8,985	\$ (51,057)	\$ (36,057)
Issuance of common 2/12/03, \$.0167 (2)	23,942	239	161		400
Issuance of common 6/11&12,\$1.67 (3)	21,548	216	34,784		35,000
Net Loss				(90,461)	(90,461)
Balance 12/31/03	647,032	\$ 6,470	\$ 43,930	\$ (141,518)	\$ (91,118)
Issuance of common 5/25/04, \$.0167 (4)	6,567	66	44		110
Net Loss				(90,353)	(90,353)
Balance 12/31/04	653,599	\$ 6,536	\$ 43,974	\$ (231,871)	\$ (181,361)
Issuance of common 12/14/05, \$.0167 (5)	14,964	150	100		250
Vested stock options and warrants			2,793		2,793
Net Loss				(123,852)	(123,852)
Balance 12/31/05	668,563	\$ 6,686	\$ 46,867	\$ (355,723)	\$ (302,170)
Issuance of common 5/16 & 8/8, \$.0167 (6)	86,869	869	582		1,451
Issuance of common 10/19 & 23, \$.0167 (7)	38,906	389	261		650
Issuance of common 12/01, \$1.67 (8)	28,739	287	44,523		44,810
Vested stock options and warrants			13,644		13,644
Net Loss				(273,026)	(273,026)
Balance 12/31/06	823,077	\$ 8,231	\$ 105,877	\$ (628,749)	\$ (514,641)
Issuance of common 1/30/07 @ 1.67 (9)	599	6	994		1,000
Value of equity instruments issued with debt			132,938		132,938
Capital contributions resulting from waivers of debt			346,714		346,714
Vested stock options and warrants			73,907		73,907
Net loss				(752,415)	(752,415)
Balance 12/31/07	823,676	\$ 8,237	\$ 660,430	\$ (1,381,164)	\$ (712,497)
Issuance of common 6/11 to 9/30, \$.35 (10)	4,552,862	45,528	1,547,974		1,593,502
Shares issued to finders, agents	2,012,690	20,127	(20,127)		-
Shares issued to pay direct legal fees	285,714	2,857	(2,857)		-
Issuance of common due to antidilution provisions	205,899	2,059	(2,059)		-
Shares issued to pay investor relations services 6/23/08, \$.35	250,000	2,500	85,000		87,500
Vested stock options and warrants			354,994		354,994
Capital contributions resulting from waivers of debt			129,684		129,684
Net loss				(1,762,628)	(1,762,628)
Balance 12/31/08	8,130,841	\$ 81,308	\$ 2,753,039	\$ (3,143,792)	\$ (309,445)
Cumulative effect of adoption of EITF 07-5			(486,564)	6,654	(479,910)
Vested stock options and warrants			111,835		111,835
Shares issued 3/20/09 to pay for fund raising	125,000	1,250	(1,250)		-
Shares issued under PMM in April 2009, \$.50	700,000	7,000	343,000		350,000
Shares issued under PPM in May 2009, \$.50	220,000	2,200	107,800		110,000
Shares issued under PPM in June 2009, \$.50	50,000	500	24,500		25,000
Shares issued under PPM in August 2009, \$.50	80,000	800	39,200		40,000
Shares issued under PPM in September 2009, \$.50	150,000	1,500	73,500		75,000
Shares issued to directors, management and consultant in August 2009, \$.50	797,810	7,978	390,927		398,905
Shares issued to finder in September 2009, \$.50	100,000	1,000	49,000		50,000
Capital contributions resulting from waivers of debt			84,600		84,600
Value of equity-linked financial instruments issued in connection with PPMs			(222,296)		(222,296)
Value of equity instruments issued with debt			30,150		30,150
Shares issued to consultant for fund raising	30,000	300	(300)		-
Shares issued under PPM in November 2009, \$.50	50,000	500	24,500		25,000
Shares issued upon conversion of debt and interest, \$.27	935,446	9,354	247,100		256,454
Shares issued upon conversion of shareholder note, \$.35	14,024	140	4,766		4,906
Net Loss				(2,892,230)	(2,892,230)
Balance 12/31/09	11,383,121	113,830	3,573,507	(6,029,368)	(2,342,030)

Shares issued in March 2010 under PPM, \$.50	174,550	1,746	85,529	87,275
Shares issued to consultants for IR and consulting, \$.50	374,090	3,741	183,304	187,045
Vested stock options and warrants			11,382	11,382
Value of equity instruments issued for consulting services			354,602	354,602
Value of equity-linked financial instruments issued in connection with PPM in first quarter			(25,553)	(25,553)
Shares issued in April 2010 under PPM, \$.50	180,000	1,800	88,200	90,000
Shares issued in May 2010 to consultant, \$.50	12,850	129	6,296	6,425
Shares issued in May 2010 to 2008 investors as a penalty for late registration of 4,552,862 shares, \$.50	710,248	7,102	348,022	355,124
Value of equity instruments issued with debt in second quarter			96,613	96,613
Value of equity-linked financial instruments issued in connection with PPM in second quarter			(31,332)	(31,332)
Value of equity-linked financial instruments issued in connection with PPM in third quarter			(31,506)	(31,506)
Value of equity instruments issued with debt in third quarter			15,553	15,553
Shares issued in September 2010 under PPM, \$.10	250,000	2,500	22,500	25,000
Shares issued to consultants in third quarter at \$.22 per share	488,860	4,889	102,660	107,549
Shares issued, November 2010, upon exercise of warrants at \$.135 per share	128,571	1,286	16,071	17,357
Shares issued to directors as compensation at \$.15 per share	300,000	3,000	42,000	45,000
Value of equity instruments issued with debt in fourth quarter			7,308	7,308
Vested stock options in fourth quarter			161,107	161,107
Equity instruments issued to consultants in fourth quarter			26,234	26,234
Net Loss				(1,352,709)
Balance 12/31/2010	14,002,290	\$ 140,023	\$ 5,052,497	\$ (7,382,077)
Value of equity instruments issued with debt in first quarter			47,908	47,908
Value of equity-linked financial instruments issued in connection with stock in first quarter			(265,815)	(265,815)
Shares issued in first quarter at \$.075 per share under PPM	5,333,334	53,334	346,666	400,000
Shares issued in first quarter at \$.085 per share under PPM	1,294,117	12,941	97,059	110,000
Shares issued in first quarter at \$.09 per share under PPM	200,000	2,000	16,000	18,000
Shares issued in first quarter at \$.10 per share under PPM	150,000	1,500	13,500	15,000
Equity instruments issued to consultants in first quarter			85,916	85,916
Stock issued upon conversion of debt in first quarter	416,010	4,160	15,840	20,000
Stock issued to pay interest on debt in second quarter	158,333	1,583	20,917	22,500
Shares issued in second quarter at \$.085 per share under PPM	588,236	5,882	44,118	50,000
Shares issued in second quarter at \$.07 per share under PPM	500,000	5,000	30,000	35,000
Stock issued upon conversion of debt and interest	940,737	9,407	22,593	32,000
Value of equity-linked financial instruments issued in connection with stock in second quarter			(20,695)	(20,695)
Stock options issued to management in second quarter			65,204	65,204
Stock options issued to management in third quarter			200,189	200,189
Stock issued to consultants in third quarter	822,842	8,228	46,772	55,000
Shares issued in third quarter at \$.06 per share under PPM	2,916,666	29,167	145,833	175,000
Shares issued in third quarter at \$.07 per share under PPM	571,429	5,715	34,285	40,000
Shares issued in third quarter at \$.075 per share under PPM	583,334	5,833	29,167	35,000
Shares issued in third quarter at \$.20 per share under PPM	562,500	5,625	106,875	112,500
Shares issued upon exercise of a management stock option	100,000	1,000	-	1,000
Net Loss				(1,518,933)
Balance 9/30/2011	29,139,828	\$ 291,398	\$ 6,134,829	\$ (8,901,010)

- (1) Founders shares, 1,000,000 pre-split
- (2) 23,492 (40,000 pre-split) shares valued at \$.0167 per share as compensation for loan guarantees by management
- (3) Investment including 670 shares issued as a 10% finders fee
- (4) For payment of patent legal fees
- (5) Compensation for loan guarantees by management
- (6) For vendor contractual consideration
- (7) Employment agreements
- (8) Investment
- (9) Conversion of convertible notes by management
- (10) Investment, "October 2008 financing".

See Notes to Condensed Financial Statements

BIODRAIN MEDICAL, INC.
(A DEVELOPMENT STAGE COMPANY)
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,		April 23, 2002 (Inception) To September 30, 2011
	2011	2010	2011
Cash flow from operating activities:			
Net loss	\$ (1,518,933)	\$ (956,180)	\$ (8,901,010)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,822	1,822	8,212
Vested stock options and warrants	265,393	11,382	995,035
Equity instruments issued for management and consulting	142,813	655,621	1,406,072
Stock based registration payments	-	-	355,124
Conversion of accrued liabilities to capital	-	-	560,998
Amortization of debt discount	84,999	33,411	258,252
(Gain)Loss on valuation of equity-linked instruments	(213,921)	(1,025,294)	(996,225)
Changes in assets and liabilities:			
Accounts receivable	(19,277)	15,737	(19,277)
Prepaid expense and other	(22,523)	(6,692)	(30,649)
Notes payable to shareholders	-	-	(14,957)
Accounts payable	40,550	314,229	1,266,571
Accrued expenses	53,189	182,835	551,896
Net cash used in operating activities	<u>(1,185,888)</u>	<u>(773,129)</u>	<u>(4,559,958)</u>
Cash flow from investing activities:			
Purchase of fixed assets	-	-	(12,258)
Purchase of intangibles	-	-	(142,495)
Net cash used in investing activities	<u>-</u>	<u>-</u>	<u>(154,753)</u>
Cash flow from financing activities:			
Proceeds from long term and convertible debt	250,500	582,000	1,376,805
Repayment of convertible debt	-	(100,000)	(100,000)
Principal payments on long term debt	(10,267)	(10,677)	(296,531)
Restricted cash in escrow	-	103,333	-
Debt converted to common stock	-	-	174,000
Accrued interest converted to stock	22,500	-	109,860
Issuance of common stock	991,500	202,275	3,528,305
Net cash provided by financing activities	<u>1,254,233</u>	<u>776,931</u>	<u>4,792,439</u>
Net increase in cash	<u>68,345</u>	<u>3,802</u>	<u>77,728</u>
Cash at beginning of period	9,383	16,632	-
Cash at end of period	<u>\$ 77,728</u>	<u>\$ 20,434</u>	<u>\$ 77,728</u>
Non cash transactions:			
Conversion of debt into common stock	\$ 52,000	\$ -	\$ 52,000
Conversion of accounts payable to convertible debt	89,300	-	546,599
Total non cash transactions	<u>\$ 141,300</u>	<u>\$ -</u>	<u>\$ 598,599</u>

See Notes to Condensed Financial Statements

BIODRAIN MEDICAL, INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONDENSED FINANCIAL STATEMENTS

(Amounts presented at and for the three months and nine months ended September 30, 2011 and September 30, 2010 are unaudited)

NOTE 1 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations and Continuance of Operations

BioDrain Medical, Inc. (the "Company") was incorporated under the laws of the State of Minnesota in 2002. The Company is developing an environmentally safe system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has suffered recurring losses from operations and has a shareholders' deficit. These factors raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Management hired an investment banker in 2010 to raise an additional \$3-\$5 million in new equity. The banker was unable to raise the expected \$500,000 by September 30, 2010 and the balance within 3 months, but the Company raised approximately \$229,000 in equity and \$605,000 in convertible debt in 2010 and \$992,000 in equity and \$251,000 in convertible debt in 2011 through alternative means. Although the Company's ability to raise all of this new capital is in substantial doubt it did receive approximately \$2,075,000 through private placements of equity and convertible debt in 2010 and 2011, and the Company's April 1, 2009 510(k) clearance from the FDA to authorize the Company to market and sell its FMS products is being received very positively. The Company engaged a new investment banker in May 2011 to raise approximately \$2 million and if the Company is successful in raising at least \$2 million in new equity it will have sufficient capital to operate its business and execute its business plan for at least the next 12 months. The Company currently has a commitment for \$1 million in convertible debt from an institutional investor that is contingent upon raising an equal amount of equity prior to closing. The Company is continuing its efforts to raise at least \$1 million in equity so that it can take advantage of the \$1 million commitment from the institutional investor. If the Company raises the additional capital by issuing additional equity securities, its existing shareholders will likely experience substantial dilution.

Recent Accounting Developments

In the first quarter 2011 we adopted new guidance on separating consideration in multiple-deliverable arrangements. The guidance addresses how to determine whether an arrangement involving multiple deliverables contains more than one unit of accounting and how the consideration should be allocated among the separate units of accounting. The adoption of this guidance did not have a material impact on our financial statements.

We reviewed all other significant newly issued accounting pronouncements and determined they are either not applicable to our business or that no material effect is expected on our financial position and results of our operations.

Valuation of Intangible Assets

We review identifiable intangible assets for impairment in accordance with ASC 360-*Property Plant and Equipment* ("ASC 360"), whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Our intangible assets are currently solely the costs of obtaining trademarks and patents. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which we operate. If such events or changes in circumstances are present, the undiscounted cash flows method is used to determine whether the intangible asset is impaired. Cash flows would include the estimated terminal value of the asset and exclude any interest charges. If the carrying value of the asset exceeds the undiscounted cash flows over the estimated remaining life of the asset, the asset is considered impaired, and the impairment is measured by reducing the carrying value of the asset to its fair value using the discounted cash flows method. The discount rate utilized is based on management's best estimate of the related risks and return at the time the impairment assessment is made.

Our accounting estimates and assumptions bear various risks of change, including the length of the current recession facing the United States, the expansion of the slowdown in consumer spending in the U.S. medical markets despite the early expressed opinions of financial experts that the medical market would not be as affected as other markets and failure to gain acceptance in the medical market.

Accounting Policies and Estimates

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

Presentation of Taxes Collected from Customers

Sales taxes are imposed on the Company's sales to nonexempt customers. The Company collects the taxes from customers and remits the entire amounts to the governmental authorities. The Company's accounting policy is to exclude the taxes collected and remitted from revenues and expenses.

Shipping and Handling

Shipping and handling charges billed to customers are recorded as revenue. Shipping and handling costs are recorded within cost of goods sold on the statement of operations.

Advertising

Advertising costs are expensed as incurred. There were no advertising expenses in the three months and nine months ended September 30, 2011 and September 30, 2010.

Research and Development

Research and development costs are charged to operations as incurred. There were no research and development expenses in the three months and nine months ended September 30, 2011 and September 30, 2010.

Revenue Recognition

The Company recognizes revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by Staff Accounting Bulletin No. 104 (together, SAB 101), and ASC 605-*Revenue Recognition*.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectability is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. The Company standard terms specify that shipment is FOB BioDrain and the Company will, therefore recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of the FMS units as well as shipments of cleaning solution kits. When these conditions are satisfied, the Company recognizes gross product revenue, which is the price it charges generally to its customers for a particular product. Under the Company's standard terms and conditions there is no provision for installation or acceptance of the product to take place prior to the obligation of the customer. The customer's right of return is limited only to the Company's standard warranty whereby the Company replaces or repairs, at its option, and it would be very rare that the unit or significant quantities of cleaning solution kits may be returned. Additionally, since the Company buys both the FMS units and cleaning solution kits from "turnkey" suppliers the Company would have the right to replacements from the suppliers if this situation should occur.

Receivables

Receivables are reported at the amount the Company expects to collect on balances outstanding. The Company has determined there will be no losses on balances outstanding at September 30, 2011.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets. Estimated useful asset life by classification is as follows:

	<u>Years</u>
Computers and office equipment	3
Furniture and fixtures	5

Upon retirement or sale, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Intangible Assets

Intangible assets consist of patent costs. These assets are not subject to amortization until the property patented is in production. The assets are reviewed for impairment annually, and impairment losses, if any, are charged to operations when identified. No impairment losses have been identified by management.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740- *Income Taxes* ("ASC 740"). Under ASC 740, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carry forwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company reviews income tax positions expected to be taken in income tax returns to determine if there are any income tax uncertainties. The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax positions will be sustained on examination by taxing authorities, based on technical merits of the positions. The Company has identified no income tax uncertainties.

Tax years subsequent to 2006 remain open to examination by federal and state tax authorities.

Patents and Intellectual Property

The Company, in June 2008, completed and executed an agreement to secure exclusive ownership of the patent from an inventor, Marshall Ryan. Mr. Ryan received a combination of cash and warrants, and he will receive a 4% royalty on FMS (the Product) sales for the life of the patent. At the signing of the agreement, Mr. Ryan received \$75,000 in exchange for the exclusive assignment of the patent. In addition, on June 30, 2009, Mr. Ryan, through his Mid-State Stainless, Inc. entity, was entitled to receive \$100,000 as payment (currently recorded as an account payable with the Company) for past research and development activities. Should Mr. Ryan be utilized in the future for additional product development activities, he will be compensated at a rate of ninety five dollars (\$95.00) per hour.

Mr. Ryan also received a warrant, with immediate vesting, to purchase 150,000 shares of the Company's common stock at a price of \$.35 per share. The warrant has a term of five years, ending on June 30, 2013 and is assigned a value of \$28,060 using a Black-Scholes formula and this amount was expensed as consulting expense in 2008 using a 5-year expected life, a 3.73% risk free interest rate, an expected 59% volatility and a zero dividend rate. Should there be a change in control of the Company (defined as greater than 50% of the Company's outstanding stock or substantially all of its assets being transferred to one independent person or entity), Mr. Ryan will be owed a total of \$2 million to be paid out over the life of the patent if the change in control occurs within 12 months of the first sale of the product; or \$1 million to be paid out over the life of the patent if the change in control occurs between 12 and 24 months of the first sale of the product; or \$500,000 to be paid out over the life of the patent if the change in control occurs between 24 and 36 months of the first sale of the product. There will be no additional payment if a change in control occurs more than 36 months after the first sale of the product.

Subsequent Events

The Company has evaluated subsequent events through the date of this filing. The Company does not believe there are subsequent events that require disclosure.

Interim Financial Statements

The Company has prepared the unaudited interim financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. These interim financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to present fairly the Company's financial position, the results of its operations and its cash flows for the interim periods. These interim financial statements should be read in conjunction with the annual financial statements and the notes thereto contained in the Form 10-K filed with the SEC on March 31, 2011. The nature of the Company's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

NOTE 2 – DEVELOPMENT STAGE OPERATIONS

The Company was formed April 23, 2002. Since inception through November 1, 2011, 30,427,328 shares of common stock have been issued between par value and \$1.67. Operations since incorporation have primarily been devoted to raising capital, obtaining financing, development of the Company's product, and administrative services.

NOTE 3 – STOCKHOLDERS' DEFICIT, STOCK OPTIONS AND WARRANTS

In connection with the financing completed in October 2008, the Company has effected two reverse stock splits, one on June 6, 2008 and another on October 20, 2008. In accordance with SAB Topic 4C, all stock options and warrants and their related exercise prices are stated at their post-reverse stock split values.

The Company has an equity incentive plan, which allows issuance of incentive and non-qualified stock options to employees, directors and consultants of the Company, where permitted under the plan. The exercise price for each stock option is determined by the board of directors. Vesting requirements are determined by the board of directors when granted and currently range from immediate to three years. Options under this plan have terms ranging from three to ten years.

Accounting for share-based payment

The Company has adopted ASC 718- *Compensation-Stock Compensation* ("ASC 718"). Under ASC 718 stock-based employee compensation cost is recognized using the fair value based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards as previously calculated under SFAS 123 for pro forma disclosures, using a straight-line method. We elected the modified-prospective method under which prior periods are not retroactively restated.

ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model or other acceptable means. The Company uses the Black-Scholes option valuation model which requires the input of significant assumptions including an estimate of the average period of time employees will retain vested stock options before exercising them, the estimated volatility of the Company's common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions the Company uses in calculating the fair value of stock-based payment awards represent the Company's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the future.

Since the Company's common stock has no significant public trading history, and the Company has experienced no significant option exercises in its history, the Company is required to take an alternative approach to estimating future volatility and estimated life and the future results could vary significantly from the Company's estimates. The Company compiled historical volatilities over a period of 2-7 years of 15 small-cap medical companies traded on major exchanges and 10 mid-range medical companies on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of ordinary options to employees the Company determined the expected life to be the midpoint between the vesting term and the legal term. In the case of options or warrants granted to non-employees the Company estimated the life to be the legal term unless there was a compelling reason to make it shorter.

When an option or warrant is granted in place of cash compensation for services the Company deems the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason the Company also uses the Black-Scholes-Merton option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period the investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of the Company's common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based consulting and/or compensation and, consequently, the related expense recognized.

Since the Company has limited trading history in its stock and no first-hand experience with how its investors and consultants have acted in similar circumstances, the assumptions the Company uses in calculating the fair value of stock-based payment awards represent its best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based consulting and interest expense could be materially different in the future.

Valuation and accounting for options and warrants

The Company determines the grant date fair value of options and warrants using a Black-Scholes-Merton option valuation model based upon assumptions regarding risk-free interest rate, expected dividend rate, volatility and estimated term. For grants during 2008, the Company used a 2.0 to 4.5% risk-free interest rate, 0% dividend rate, 53-66% volatility and estimated term of 2.5 to 7.5 years. Values computed using these assumptions ranged from \$.102 per share to \$.336 per share. Warrants or options awarded for services rendered are expensed over the period of service (normally the vesting period) as compensation expense for employees or an appropriate consulting expense category for awards to consultants and directors. Warrants granted in connection with a common equity financing are included in shareholders' equity, provided that there is no re-pricing provision that requires they be treated as a liability (See Note 10) and warrants granted in connection with a debt financing are treated as a debt discount and amortized using the interest method as interest expense over the term of the debt. Warrants issued in connection with the \$100,000 convertible debt that closed March 1, 2007 created a debt discount of \$40,242 that is being amortized as additional interest over its 5-year term.

Warrants issued in connection with the \$170,000 in convertible "bridge" debt that closed in July 2007 created a calculated debt discount of \$92,700 that was fully expensed over its loan term that matured April 30, 2008. The Company issued \$100,000 in convertible debt in October 2009 and issued a warrant, in connection with the debt, for 200,000 shares of common stock at \$.65 per share. The Company determined that the warrant had an initial value of \$30,150 that was treated as a debt discount and is being amortized as additional interest expense over the 24-month term of the note. The Company also issued \$200,000 in convertible debt in June 2010 and issued a warrant, in connection with the debt, to purchase 1,111,112 shares at \$.46 per share.

The Company determined that the value of the June 2010 warrant is \$96,613. This value is treated as a debt discount and amortized as additional interest expense over the 22-month term of the note. The Company also issued \$32,000 in convertible debt in September, 2010 and issued a warrant to purchase 320,000 shares at \$.46 per share. The Company determined that this warrant has a value of \$15,553 that was treated as a debt discount and amortized as additional interest expense over the 18 month term of the note. In January, 2011 the Company issued three convertible notes of \$50,000 each and also issued warrants to purchase 1,595,239 common shares at \$.20 per share. The value of the warrants was determined to be \$47,908 and this amount is being treated as a debt discount and amortized as additional interest expense over the 24 month term of the notes.

The following summarizes transactions for stock options and warrants for the periods indicated:

	Stock Options (1)		Warrants (1)	
	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Outstanding at December 31, 2005	17,956	\$ 1.67	20,950	\$ 2.62
Issued	23,942	1.67	71,826	0.85
Outstanding at December 31, 2006	41,898	1.67	92,776	1.25
Issued	5,984	1.67	28,502	0.35
Outstanding at December 31, 2007	47,882	1.67	121,278	1.04
Issued	1,243,292	0.20	5,075,204	0.45
Expired			(11,971)	3.76
Outstanding at December 31, 2008	1,291,174	0.26	5,184,511	0.45
Issued	205,000	0.37	2,188,302	0.65
Outstanding at December 31, 2009	1,496,174	0.27	7,372,813	0.49
Issued	2,210,000	0.17	3,435,662	0.34
Expired	(207,956)	0.43	(8,979)	1.67
Exercised			(128,571)	0.46
Outstanding at December 31, 2010	3,498,218	0.19	10,670,925	0.44
Issued	2,483,334	0.01	16,821,508	0.13
Expired	(65,985)	0.47	(2,009,560)	0.46
Exercised	(100,000)	0.01		
Outstanding at September 30, 2011	5,815,567	\$ 0.11	25,482,873	\$ 0.23

(1) Adjusted for the reverse stock splits in total at June 6, 2008 and October 20, 2008.

At September 30, 2011, 4,818,657 stock options are fully vested and currently exercisable with a weighted average exercise price of \$0.14 and a weighted average remaining term of 8.02 years. There are 25,482,873 warrants that are fully vested and exercisable. Stock based compensation recognized in the nine months ended September 30, 2011 was \$265,393 and was \$667,000 in the nine months ended September 30, 2010.

The following summarizes the status of options and warrants outstanding at September 30, 2011:

Range of Exercise Prices	Shares	Weighted Average Remaining Life
Options:		
\$ 0.01	2,926,626	9.22
\$ 0.15	2,060,000	8.85
\$ 0.35	775,000	1.80
\$ 0.50	30,000	1.12
\$ 1.67	23,941	0.37
Total	<u>5,815,567</u>	
Warrants:		
\$ 0.01	200,000	4.19
\$ 0.02	71,826	2.70
\$ 0.075	4,657,745	2.77
\$ 0.10	2,328,572	2.18
\$ 0.12	500,000	2.59
\$ 0.13	631,429	2.03
\$ 0.15	5,333,334	2.41
\$ 0.16	500,000	2.52
\$ 0.17	1,294,118	2.51
\$ 0.18	200,000	2.36
\$ 0.20	2,445,239	2.30
\$ 0.25	562,500	2.95
\$ 0.35	998,597	0.74
\$ 0.46	4,000,035	1.18
\$ 0.65	1,729,550	0.91
\$ 1.67	29,928	0.24
Total	<u>25,482,873</u>	

Stock options and warrants expire on various dates from October 2011 to July 2021.

Under the terms of the Company's agreement with investors in the October 2008 financing, 1,920,000 shares of common stock were the maximum number of shares allocated to the Company's existing shareholders at the time of the offering (also referred to as the original shareholders or the "Founders"). Since the total of the Company's fully-diluted shares of common stock was greater than 1,920,000 shares, in order for the Company to proceed with the offering, the board of directors approved a reverse stock split of 1-for-1.2545. After this split was approved, additional options and warrants were identified, requiring a second reverse stock split in order to reach the 1,920,000 shares. The second reverse stock split on the reduced 1-for-1.2545 balance was determined to be 1-for 1.33176963. Taken together, if only one reverse stock were performed, the number would have been a reverse stock split of 1-for 1.670705.

On June 6, 2008, the board of directors approved the first reverse stock split. The authorized number of common stock of 20,000,000 shares was proportionately divided by 1.2545 to 15,942,607.

On October 20, 2008, the board of directors (i) approved the second reverse stock split pursuant to which the authorized number of shares of common stock of 15,942,607 was proportionately divided by 1.33177 to 11,970,994 shares and (ii) approved a resolution to increase the number of authorized shares of the Company's common stock from 11,970,994 to 40,000,000, which was approved by the Company's shareholders holding a majority of the shares entitled to vote thereon at a special meeting of shareholders held on December 3, 2008.

The shareholders approved an increase in authorized shares to 80 million shares in an annual shareholder meeting on June 22, 2010 and approved an increase in authorized shares to 200 million shares in a special shareholder meeting on September 7, 2011.

Stock, Stock Options and Warrants Granted by the Company

The following table is the listing of stock options and warrants as of September 30, 2011 by year of grant:

Stock Options:

Year	Shares	Price
2006	17,956	\$ 1.67
2007	5,985	1.67
2008	1,243,292	.01-.35
2009	105,000	.35
2010	2,060,000	.15
2011	2,383,334	.01
	5,815,567	\$.01-1.67

Warrants:

Year	Shares	Price
2006	65,841	\$.02-1.67
2007	28,502	.35
2008	2,943,058	.02-.46
2009	2,188,302	.13-.65
2010	3,435,662	.01-.65
2011	16,821,508	.075-.25
Total	25,482,873	\$.01-1.67

NOTE 4 - LOSS PER SHARE

The following table presents the shares used in the basic and diluted loss per common share computations:

	Three Months Ended September 30,		Nine Months Ended September 30,		From April 23, 2002 (Inception) To September 30, 2011
	2011	2010	2011	2010	
Numerator					
Net Loss available in basic and diluted calculation	\$ (654,114)	\$ (158,110)	\$ (1,518,933)	\$ (956,180)	\$ (8,901,010)
Denominator					
Weighted average common shares outstanding-basic	27,236,303	13,159,639	22,193,681	12,428,401	5,136,012
Effect of dilutive stock options and warrants (1)	-	-	-	-	-
Weighted average common shares outstanding-diluted	27,236,303	13,159,639	22,193,681	12,428,401	5,136,012
Loss per common share-basic and diluted	\$ (0.02)	\$ (0.01)	\$ (0.07)	\$ (0.08)	\$ (1.73)

(1) The number of shares underlying options and warrants outstanding as of September 30, 2011 and September 30, 2010 are 31,298,440 and 12,027,714, respectively. The effect of the shares that would be issued upon exercise of such options and warrants has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

NOTE 5 – INCOME TAXES

The provision for income taxes consists of an amount for taxes currently payable and a provision for tax consequences deferred to future periods. Deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred income 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.

There is no income tax provision in the accompanying statement of operations due to the cumulative operating losses that indicate a 100% valuation allowance for the deferred tax assets and state income taxes is appropriate.

Federal and state income tax return operating loss carryovers, as of September 30, 2011, were approximately \$8,300,000 and will begin to expire in 2017.

The valuation allowance has been recorded due to the uncertainty of realization of the benefits associated with the net operating losses. Future events and changes in circumstances could cause this valuation allowance to change.

The components of deferred income taxes at September 30, 2011 and December 31, 2010 are as follows:

	September 30, 2011 (Unaudited)	December 31, 2010
Deferred Tax Asset:		
Net Operating Loss	\$ 1,933,000	\$ 1,579,000
Other	48,000	56,000

Total Deferred Tax Asset	1,981,000	1,635,000
Less Valuation Allowance	1,981,000	1,635,000
Net Deferred Income Taxes	\$ —	\$ —

NOTE 6 - CONVERTIBLE DEBENTURE

The Company issued a convertible debenture to Andcor Companies, Inc. ("Andcor") with principal of \$10,000 and interest at 10.25% that originally matured in 2007. The debenture is convertible into shares of the Company's common stock at the lower of \$0.90 per share or the price per share at which the next equity financing agreement is completed, and is now re-set to \$.35 per share. The convertible debenture has not yet been paid, but the maturity of the note was extended, in May 2010, to March 31, 2012.

NOTE 7 - LONG-TERM DEBT

Long-term debt is as follows:

	September 30, 2011	December 31, 2010
Note payable to bank in monthly installments of \$1,275/including variable interest at 2% above the prevailing prime rate (3.25% at December 31, 2010). The final payment under the note was made in September 2011. The note was personally guaranteed by former executives of the Company.	\$ —	\$ 10,267
Notes payable to two individuals, net of discounts of \$3,353 and \$9,390 with interest only payments at 12% to March 2012 when the remaining balance is payable. The notes are convertible into 285,715 shares of common stock in the Company at \$.35 per share.	96,647	90,610
Note payable issued on October 26, 2009 to the parents of one the Company's officers, net of a discount of \$1,054 and \$12,360 discount, with interest at 8% to March 31, 2012 and convertible into shares of common stock at \$.35 per share.	98,946	87,640
Notes payable issued to two individuals in January 2010. The notes bear interest at 8%, mature March 31, 2012 and are convertible into shares of common stock, at 50% of the weighted average closing bid price over any 10 consecutive days of trading.	100,000	100,000
Note payable issued on June 12, 2010 to the parents of one of the Company's officers, net of a discount of \$28,106 and \$67,629. The note bears interest at 12% to March 31, 2012, and is convertible into common stock at \$.18 per share.	171,894	132,371
Note payable issued on August 2, 2010 to an institutional investor. The note bears interest at 8%, matured May 4, 2011 and was convertible into common stock at 50% of the average of the three lowest closing prices in any 10 day trading period. \$20,000 was converted in the three months ended March 31, 2011 and \$30,000, plus accrued interest, was converted in the three months ended June 30, 2011.	—	50,000
Note payable issued on June 14, 2011 to an institutional investor. The note bears interest at 8%, matures June 14, 2012 and is convertible into common stock at 55% of the average of the five lowest closing prices in any 10 day trading period.	63,000	—
Note payable issued on July 12, 2011 to an institutional investor. The note bears interest at 8%, matures April 16, 2012 and is convertible into common stock at 60% of the average of the five lowest closing prices in any 10 day trading period.	37,500	—
Note payable issued on September 16, 2010 to an institutional investor. The note bears interest at 10%, matures March 15, 2012 and is convertible into common stock at \$.18 per share.	100,000	100,000
Note payable issued on December 23, 2010 to the parents of one of our officers, net of a discount of \$4,489 and \$7,229. The note bears interest at 12%, matures December 23, 2012 and is convertible into common stock at \$.084 per share.	12,311	9,571
Note payable issued December 31, 2010 to a law firm that accepted this note in full payment of their past due legal fees. The Note bears interest at 6%, matures December 31, 2014 and is convertible into common stock at \$.15 per share.	457,300	457,300
Note payable issued on December 23, 2010 to a private investor. The Note matured April 30, 2011, is due on demand, and bears interest at 10%.	6,000	6,000
Note payable issued on September 21, 2010 to the parents of one of our officers, net of a discount of \$4,925 and \$12,702. The note bears interest at 12%, matures December 23, 2012 and is convertible into common stock at \$.18 per share.	27,075	19,298
Notes payable issued in January 2011 to three individuals, net of a debt discount of \$30,393. The notes bear interest at 10%, have a 24 month term and are convertible into common stock at \$0.084 to \$0.10 per share.	119,607	—
Note payable issued January 1, 2011 to a law firm that accepted this note in full payment of their past due legal fees. The Note bears interest at 6%, matures December 31, 2014 and is convertible into common stock at \$.15 per share.	89,300	—
Total	\$ 1,379,580	\$ 1,063,056
Less amount due within one year	673,987	66,267
Long-Term Debt	<u>\$ 705,593</u>	<u>\$ 996,789</u>

Cash payments for interest were \$208 for the nine months ended September 30, 2011 and \$799 for the nine months ended September 30, 2010.

Principal payments required during the 12 month periods ended September 30:

2012	\$ 716,500
2013	\$ 48,800
2014	\$ 150,000
2015	\$ 546,600

NOTE 8 - RENT OBLIGATION

The Company leases its principal office under a non-cancelable lease that extends five years. In addition to rent, the Company pays real estate taxes and repairs and maintenance on the leased property. Rent expense was \$24,293 in the nine months ended September 30, 2011 and \$24,187 in the nine months ended September 30, 2010.

The Company's rent obligation for the years 2011 to 2015 is as follows:

2011	\$	30,000
2012	\$	31,000
2013	\$	26,000
2014	\$	0
2015	\$	0

NOTE 9 – LIABILITY FOR EQUITY-LINKED FINANCIAL INSTRUMENTS

The Company adopted ASC 815- *Derivatives and Hedging* (“ASC 815”) on January 1, 2009. ASC 815 mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. It is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, which was the Company's first quarter of 2009. Many of the warrants issued by the Company contain a strike price adjustment feature, which upon adoption of ASC 815, changed the classification (from equity to liability) and the related accounting for warrants with a \$479,910 estimated fair value of as of January 1, 2009. An adjustment was made to remove \$486,564 from paid-in capital (the cumulative values of the warrants on their grant dates), a positive adjustment of \$6,654 was made to accumulated deficit, representing the gain on valuation from the grant date to January 1, 2009, and booked \$479,910 as a liability. The warrants issued in 2011 do not contain a strike price adjustment feature and, therefore, are not treated as a liability.

The January 1, 2009 valuation was computed using the Black-Scholes valuation model based upon a 2.5-year expected term, an expected volatility of 63%, an exercise price of \$.46 per share, a stock price of \$.35, a zero dividend rate and a 1.37% risk free interest rate. Subsequent to January 1, 2009 these warrants were revalued at the end of each quarter and a gain or loss was recorded based upon their increase or decrease in value during the quarter. Likewise, new warrants that were issued during 2009 and 2010 were valued, using the Black-Scholes valuation model on their date of grant and an entry was made to reduce paid-in capital and increase the liability for equity-linked financial instruments. These warrants were also re-valued at the end of each quarter based upon their expected life, the stock price, the exercise price, assumed dividend rate, expected volatility and risk free interest rate. A significant reduction in the liability was realized in 2010 primarily due to a reduction from \$.50 to \$.22 per share in the underlying share price. The Company realized a slight increase in the liability for existing warrants during the first quarter of 2011 primarily due to a reduction in the spread between the exercise price and the market price of the underlying shares, but this was more than offset by a decrease in the liability for new warrants that were issued during the quarter as a result of a reduction in the underlying market price of the stock.

The inputs to the Black-Scholes model during 2011 and 2010 were as follows:

Stock price	\$.08 to \$.50
Exercise price	\$.01 to \$.65
Expected life	2.00 to 6.5years
Expected volatility	54% to 68%
Assumed dividend rate	-%
Risk free interest rate	.13% to 2.97%

The original valuations, annual gain/(loss) and end of year valuations are shown below:

	Initial Value	2009 Gain (Loss)	2010 Gain(Loss)	YTD 2011 Gain(Loss)	Value at 9/30/2011
January 1, 2009 Adoption	\$ 479,910	\$ (390,368)	\$ 868,772	1,506	\$ 0
Warrants issued in quarter ended 6/30/2009	169,854	20,847	149,007	(10,498)	12,101
Warrants issued in quarter ended 9/30/2009	39,743	(738)	40,419	(2,902)	2,964
Warrants issued in quarter ended 12/31/2009	12,698	617	12,053	(1,068)	1,095
Subtotal	\$ 702,205				
Warrants issued in quarter ended 3/31/2010	25,553		25,014	(7,115)	7,654
Warrants issued in quarter ended 6/30/2010	31,332		30,740	(7,677)	8,269
Warrants issued in quarter ended 9/30/2010	31,506		20,811	(44,834)	55,449
Warrants issued in quarter ended 3/31/2011	265,815			265,815	0
Warrants issued in quarter ended 6/30/2011	20,692			20,692	0
Total	\$ 1,077,104	(369,642)	\$ 1,145,292	\$ 213,919	\$ 87,533

NOTE 10 – RELATED PARTY

The Company entered into agreements, in 2008, with our Chairman of the Board, Lawrence Gadbaw, and in 2009 with board member, Peter Morawetz, to pay Mr. Gadbaw \$25,000 and Mr. Morawetz \$30,000 upon the Company raising \$3 million in new equity. Mr. Gadbaw will also be paid the balance, if any, due under his separation agreement from 2008. This amount was \$46,000 upon signing the agreement in 2008, is payable at \$2,000 per month, and \$12,000 remains in accounts payable as of September 30, 2011. Mr. Morawetz will also receive a stock option for 75,000 shares at \$.35 per share and Mr. Gadbaw will receive a stock option for 160,000 shares at \$.35 per share upon the Company raising \$3 million.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Overview

Our Company was incorporated in Minnesota in April 2002. We are an early-stage company developing an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. We achieved our first sale in June 2009. Since our inception in 2002, we have invested significant resources into product development and in preparing for approval from the FDA. We believe that our success depends upon converting the traditional process of collecting and disposing of infectious fluids from the operating rooms of medical facilities to our wall-mounted Fluid Management System ("FMS") and use of our proprietary cleaning fluid.

Since inception, we have been unprofitable. We incurred a net loss of approximately \$1,353,000 for the fiscal year ended 2010 and a net loss of approximately \$1,519,000 for the nine months ended September 30, 2011 compared to a loss of approximately \$956,000 for the nine months ended September 30, 2010. As of September 30, 2011 we had an accumulated deficit of approximately \$8,901,000. As a company in the early stage of development, our limited history of operations makes prediction of future operating results difficult. We believe that period to period comparisons of our operating results should not be relied on as predictive of our future results.

We have focused on finalizing our production and obtaining final FDA clearance to sell our product to the medical facilities market. FDA final clearance was obtained on April 1, 2009. Our innovative FMS is being sold through experienced, independent medical distributors and manufacturers representatives who we believe enhance acceptability of our product in the marketplace. We are currently in the process of signing agreements with independent sales representatives and product installation organizations and conducting training sessions. We achieved our first billable shipment in June 2009. Since our FDA clearance to sell our FMS product was only received on April 1, 2009, it is too early to know with a high degree of confidence how quickly, and in what amounts, new orders will develop.

Since we do not expect to generate sufficient revenues in 2011 to fund our capital requirements, our capital needs for the next 12 months are expected to be approximately \$2 million even though we plan to use outside third party contract manufacturers to produce the FMS and independent sales representatives to sell the FMS. Our future cash requirements and the adequacy of available funds will depend on our ability to sell our FMS and related products now that FDA final clearance has been obtained. We expect that we will require additional funding to finance operating expenses and to enter the international marketplace.

As of September 30, 2011, we have funded our operations through a bank loan of \$41,400, an equity investment of \$68,000 from the Wisconsin Rural Enterprise Fund ("WREF") and \$30,000 in early equity investment from several individuals. WREF had also previously held debt in the form of three loans of \$18,000, \$12,500 and \$25,000. In December 2006, WREF converted two of the loans totaling \$37,500 into 43,000 shares of our Common Stock. In August 2006, we secured a \$10,000 convertible loan from one of our vendors. In February 2007, we obtained \$4,000 in officer and director loans and in March 2007, we arranged a \$100,000 convertible note from two private investors. In July 2007, we obtained a convertible bridge loan of \$170,000. In June 2008, we paid off the remaining \$18,000 loan from WREF and raised approximately \$1.6 million through our October 2008 financing. The \$170,000 convertible bridge loan and the \$4,000 in officer and director loans were converted into shares of the Company's Common Stock in October 2009. During 2009 we raised an additional \$725,000 in a private placement of stock units and/or convertible debt, with each stock or debt unit consisting of, or converting into, respectively, one share of our Common Stock, and a warrant to purchase one share of our Common Stock at \$.65 per share. In 2010 we raised approximately \$605,000 from the issuance of convertible debt and approximately \$220,000 from the sale of Units of stock and warrants. The conversion price on the debt and the Unit price of the stock and warrants ranged from \$.10 to \$.65 per share.

In the first nine months of 2011 we have raised \$250,500 through the issuance of convertible debt and \$991,500 from the sale of stock Units. Convertible debt, in the amount of \$150,000 contains a conversion price of \$.084 to \$.10 per share, a 10% interest rate and a 24 month maturity. We also issued warrants to purchase 1,525,239 shares of common stock at \$.20 per share in connection with this debt issuance. Convertible debt in the amount of \$100,500 bears interest at 8%, has a maturity of 12 months and contains a conversion price based upon 55-60% of the 10 day volume weighted average stock price. We sold 12,699,617 stock Units at a unit price from \$.06 to \$.20 and also issued warrants to purchase 12,699,617 shares at prices of \$.075 to \$.25 per shares in connection with the sale of stock Units.

Critical Accounting Policies and Estimates and Recent Accounting Developments Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our audited Financial Statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of our financial statements, the reported amounts of revenues and expenses during the reporting periods presented, as well as our disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and assumptions, including, but not limited to, fair value of stock-based compensation, fair value of acquired intangible assets and goodwill, useful lives of intangible assets and property and equipment, income taxes, and contingencies and litigation.

We base our estimates and assumptions on our historical experience and on various other information available to us at the time that these estimates and assumptions are made. We believe that these estimates and assumptions are reasonable under the circumstances and form the basis for our making judgments about the carrying values of our assets and liabilities that are not readily apparent from other sources. Actual results and outcomes could differ from our estimates.

Our significant accounting policies are described in Note 1 *Summary of Significant Accounting Policies*, in the Notes to Financial Statements of this Form 10-Q. We believe that the following discussion addresses our critical accounting policies and reflect those areas that require more significant judgments, and use of estimates and assumptions in the preparation of our Financial Statements.

Revenue Recognition We recognize revenue in accordance with the SEC's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, as amended by Staff Accounting Bulletin No. 104 (together, SAB 101), and ASC 605 *Revenue Recognition*.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the fee is fixed and determinable and collectability is probable. Delivery is considered to have occurred upon either shipment of the product or arrival at its destination based on the shipping terms of the transaction. Our standard terms specify that shipment is FOB BioDrain and we will, therefore recognize revenue upon shipment in most cases. This revenue recognition policy applies to shipments of our FMS units as well as shipments of cleaning solution kits. When these conditions are satisfied, we recognize gross product revenue, which is the price we charge generally to our customers for a particular product. Under our standard terms and conditions there is no provision for installation or acceptance of the product to take place prior to the obligation of the customer. The customer's right of return is limited only to our standard warranty whereby we replace or repair, at our option, and it would be very rare that the unit or significant quantities of cleaning solution kits may be returned. Additionally, since we buy both the FMS units and cleaning solution kits from "turnkey" suppliers, we would have the right to replacements from the suppliers if this situation should occur.

Stock-Based Compensation. The Company has adopted ASC 718-Compensation-Stock Compensation ("ASC 718"). Under ASC 718 stock-based employee compensation cost is recognized using the fair value based method for all new awards granted after January 1, 2006 and unvested awards outstanding at January 1, 2006. Compensation costs for unvested stock options and non-vested awards that were outstanding at January 1, 2006, are being recognized over the requisite service period based on the grant-date fair value of those options and awards as previously calculated under SFAS 123 for pro forma disclosures, using a straight-line method. We elected the modified-prospective method in under which prior periods are not retroactively restated.

ASC 718 requires companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model or other acceptable means. The Company uses the Black-Scholes option valuation model which requires the input of significant assumptions including an estimate of the average period of time employees will retain vested stock options before exercising them, the estimated volatility of the Company's common stock price over the expected term, the number of options that will ultimately be forfeited before completing vesting requirements, the expected dividend rate and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions the Company uses in calculating the fair value of stock-based payment awards represent the Company's best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the future.

Because we do not have significant historical trading data on our stock we relied upon trading data from a composite of 10 medical companies traded on major exchanges and 15 medical companies traded on the OTC Bulletin Board to help us arrive at expectations as to volatility of our own stock when public trading commences. Likewise, we have no history of option and warrant exercises, so we were required to make a significant judgment as to expected option and warrant exercise patterns in the future regarding employee and director options and warrants. In the case of options and warrants issued to consultants and investors we used the legal term of the option/warrant as the estimated term unless there was a compelling reason to use a shorter term. The measurement date for employee and non-employee options and warrants is the grant date of the option or warrant. The vesting period for options that contain service conditions is based upon management's best estimate as to when the applicable service condition will be achieved. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized. The assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based compensation expense could be materially different in the future. See Note 3, *Stock-Based Compensation*, in Notes to Financial Statements, for additional information.

When an option or warrant is granted in place of cash compensation for services we deem the value of the service rendered to be the value of the option or warrant. In most cases, however, an option or warrant is granted in addition to other forms of compensation and its separate value is difficult to determine without utilizing an option pricing model. For that reason we also use the Black-Scholes-Merton option-pricing model to value options and warrants granted to non-employees, which requires the input of significant assumptions including an estimate of the average period that investors or consultants will retain vested stock options and warrants before exercising them, the estimated volatility of our common stock price over the expected term, the number of options and warrants that will ultimately be forfeited before completing vesting requirements and the risk-free interest rate. Changes in the assumptions can materially affect the estimate of fair value of stock-based compensation and, consequently, the related expense recognized that. Since we have limited trading history in our common stock and no first-hand experience with how our investors and consultants have acted in similar circumstances, the assumptions we use in calculating the fair value of stock-based payment awards represent our best estimates, which involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our equity-based consulting and interest expense could be materially different in the future.

Since our common stock has limited public trading history we were required to take an alternative approach to estimating future volatility and the future results could vary significantly from our estimates. We compiled historical volatilities over a period of 2-7 years of 15 small-cap medical companies traded on major exchanges and 10 mid-size medical companies on the OTC Bulletin Board and combined the results using a weighted average approach. In the case of standard options to employees we determined the expected life to be the midpoint between the vesting term and the legal term. In the case of options or warrants granted to non-employees we estimated the life to be the legal term unless there was a compelling reason to make it shorter.

Valuation of Intangible Assets We review identifiable intangible assets for impairment in accordance with ASC 360-Property Plant and Equipment ("ASC 360"), whenever events or changes in circumstances indicate the carrying amount may not be recoverable. Our intangible assets are currently solely the costs of obtaining trademarks and patents. Events or changes in circumstances that indicate the carrying amount may not be recoverable include, but are not limited to, a significant change in the medical device marketplace and a significant adverse change in the business climate in which we operate. If such events or changes in circumstances are present, the undiscounted cash flows method is used to determine whether the intangible asset is impaired. Cash flows would include the estimated terminal value of the asset and exclude any interest charges. If the carrying value of the asset exceeds the undiscounted cash flows over the estimated remaining life of the asset, the asset is considered impaired, and the impairment is measured by reducing the carrying value of the asset to its fair value using the discounted cash flows method. The discount rate utilized is based on management's best estimate of the related risks and return at the time the impairment assessment is made.

Our accounting estimates and assumptions bear various risks of change, including the length of the current recession facing the United States, the expansion of the slowdown in consumer spending in the U.S. medical markets despite the early expressed opinions of financial experts that the medical market would not be as affected as other markets and failure to gain acceptance in the medical market.

Recent Accounting Developments

See Note 1 - "Summary of Significant Accounting Policies" to the Condensed Financial Statements of this Quarterly Report on Form 10-Q for a discussion of recent accounting developments.

Results of Operations

Three months and nine months ended September 30, 2011 and 2010

Revenue. The Company recorded \$20,264 in revenue in the three months and \$22,638 in the nine months ended September 30, 2011, zero in the three months and \$288 in the nine months ended September 30, 2010. The revenue in the third quarter of 2011 included the sale of one Streamway® system and disposable supplies to operate the Streamway. Revenue in 2010 was solely for disposable supplies for an evaluation unit. The Company has recently begun installing Streamway units in hospitals for evaluation purposes and, in one case, for production purposes, and expects the revenue for Streamway units to increase significantly at such time as the hospitals approve the use of the unit for their application and place orders for billable units.

Cost of sales. Cost of sales was \$11,161 in the three months and \$13,981 in the nine months ended September 30, 2011, zero in the three months and \$140 in the nine months ended September 30, 2010. The gross profit margin was only 43% for the system and the procedure kits in the three months and nine months ended September 30, 2011, primarily due to a discount offer to encourage the customer to fully utilize the equipment, but should increase over time as volume purchasing discounts on both the equipment and the cleaning solution begin to take effect.

General and Administrative expense. General and administrative (G&A) expense primarily consists of management salaries, professional fees, consulting fees, travel expense, administrative fees and general office expenses.

General and Administrative (G&A) expenses increased to \$429,000 from \$381,000 in the three months ended September 30, 2011 compared to September 30, 2010, and decreased to \$1,015,000 in the nine months ended September 30, 2011 compared to \$1,532,000 in the nine months ended September 30, 2010.

The increase in the three-month period was primarily due to an increase of \$41,000 in investor relations expense and an increase of \$84,000 in stock based compensation offset, in part, by a decrease of \$54,000 in stock based consulting expense and \$20,000 in other consulting expense. The increase in stock based compensation expense was due to an award of stock options to the management team during the quarter and the increase in investor relations expense was due to a significant effort to promote the current revenue ramp-up effort that the Company is undertaking.

The \$517,000 decrease in G&A expenses for the nine-month period of 2011, compared to 2010, is primarily due to a \$439,000 reduction in consulting expense and a \$65,000 reduction in salary expense. Although the Company has continued to compensate consulting with stock based instruments, the total value of the stock, and the number of shares has decreased. Salary expense declined in 2011 by comparison to 2010 due to a \$70,000 charge to expense in 2010 to estimate the costs to settle a termination matter with a former officer. Total G&A expenses are expected to increase due to increased insurance premiums, investor relations expenses and audit and legal fees, resulting from becoming a public company, but otherwise remain relatively constant over the next several quarters.

Operations expense. Operations expense primarily consists of expenses related to product development and prototyping and testing in the company's current stage.

Operations expense increased to \$135,000 in the three months ended September 30, 2011 compared to \$56,000 in the three months ended September 30, 2010, and increased to \$402,000 in the nine months ended September 30, 2011 compared to \$165,000 in the nine months ended September 30, 2010.

The increase in operations expense in 2011 is primarily due to an increase of \$94,000 in stock based compensation and an increase in manufacturing supplies and components expense of \$128,000 for the year as the operations department continued to revise and adjust various parts and components in the Streamway unit to respond to results of operating the equipment in live surgical settings. The increase in stock based compensation was due to an award of stock options to management in the third quarter. Operations expense in the next several quarters is expected to increase significantly as the Company expects to increase shipments of the Streamway unit as customers complete their evaluations and place orders for billable units.

Sales and Marketing expense. Sales and marketing expense consists of expenses required to sell products through independent reps, attendance at trades shows, product literature and other sales and marketing activities.

Sales and marketing expense increased to \$61,000 in the three months ended September 30, 2011 compared to \$36,000 in the three months ended September 30, 2010, but decreased to \$149,000 in the nine months ended September 30, 2011 compared to \$177,000 in the nine months ended September 30, 2010.

During the last several quarters the Company has operated on a very slim marketing budget as a result of limited funding. The VP of Sales position remained vacant for several months and we curtailed our travel and spending on promotional activities. The decrease in the nine-month period is primarily the result of a decrease of \$56,000 in salary expense offset, in part, by an increase of \$15,000 in stock based compensation and an increase of \$13,000 in sales commissions. Sales and Marketing expense is expected to increase significantly in the future as we recently hired a Director of Sales and we expect to hire additional sales and sales support personnel and increase our trade show, promotion and travel expense significantly after we receive significant funding.

Interest expense.

Interest expense increased to \$61,000 in the three months ended September 30, 2011 compared to \$34,000 in the three months ended September 30, 2010, and increased to \$176,000 in the nine months ended September 30, 2011 compared to \$108,000 in the nine months ended September 30, 2010. The increase in interest expense in the three-month period and the nine-month period was due to a higher level of interest bearing debt and amortization of larger debt discounts attributable to new convertible debt issued with warrants.

The (Gain)/Loss on revaluation of equity-linked financial instruments reflected a gain of \$23,000 in the three months ended September 30, 2011 compared to a gain of \$349,000 in the three months ended September 30, 2010, and reflected a gain of \$214,000 in the nine months ended September 30, 2011 compared to a \$1,025,000 gain in the nine months ended September 30, 2010. The reduction in gain in the current periods resulted primarily from a narrowing of the spread between the exercise price on warrants and due to reaching the expiration date on a significant portion of the warrants during the period.

Liquidity and Capital Resources

Capital Structure

We had a cash balance of \$78,000 as of September 30, 2011 and \$20,000 as of September 30, 2010. Since our inception, we have incurred significant losses. As of September 30, 2011, we had an accumulated deficit of approximately \$8,901,000. We have not achieved profitability and anticipate that we will continue to incur net losses for the foreseeable future. We expect that our operations, sales and marketing and general and administrative expenses will increase, and as a result we will need to generate significant revenue to achieve profitability.

There is no certainty that access to needed capital will be successful. We have not depended on the future exercise of outstanding warrants to provide additional funding.

To date, our operations have been funded through a bank loan and private convertible debt in the amount of approximately \$1,377,000 and equity investments totaling approximately \$3,562,000. As of September 30, 2011, we had accounts payable of \$720,000 and accrued liabilities of \$552,000. Account payable has declined to \$720,000 as of September 30, 2011 from \$769,000 as of December 31, 2010 primarily due to the issuance of a convertible note in the amount of \$89,300 to one of our law firms as full settlement of the accounts payable balance as of January 1, 2011.

Cash Flows

Net cash used in operating activities was \$1,186,000 in the nine months ended September 30, 2011 compared to \$773,000 net cash used in operating activities in the nine months ended September 30, 2010. The increase in cash used in operations was primarily the result of more payments against delinquent accounts payable than we had been able to achieve in the past due to an increase in cash from financing activities.

Net cash used in investing activities was zero in the nine months ended September 30, 2011 and 2010. There have been no investing activities since the Company invested in new furniture and patents in 2008. The Company will likely increase its cash used in investing activities in the next several quarters as we prepare to support the expected growth in sales.

Net cash provided by financing activities was \$1,254,000 in the nine months ended September 30, 2011 compared to \$777,000 in the same 2010 period. The Company expects to show additional cash provided by financing activities in the next few quarters provided we are successful in raising money with our investment banker.

Based on our current operating plan we believe that we have sufficient cash, cash equivalents and short-term investment balances to last approximately through November 2011 after which additional financing will be needed to continue to satisfy our obligations. While holders of our warrants could exercise and provide cash to us during that time frame, we are not depending on that in our fundraising efforts.

Management hired an investment banker in 2010 to raise an additional \$3-\$5 million in new equity. The banker was unable to raise the expected \$500,000 by September 30, 2010 and the balance within 3 months, but the Company raised approximately \$229,000 in equity and \$605,000 in convertible debt in 2010, and \$992,000 in equity and \$251,000 in convertible debt in 2011 through alternative means. Although the Company's ability to raise this new capital is in substantial doubt it received approximately \$2,075,000 through private placements of equity and convertible debt in 2010 and 2011, and the Company's April 1, 2009 510(k) clearance from the FDA to authorize the Company to market and sell its FMS products is being received very positively. The Company engaged a new investment banker in May 2011 to raise approximately \$2 million and if the Company is successful in raising at least \$2 million in new equity it will have sufficient capital to operate its business and execute its business plan for at least the next 12 months. The Company has a commitment from an institutional investor for \$1 million in convertible debt that is contingent on the Company raising a minimum of \$1 million in new equity. If the Company raises the additional capital by issuing additional equity securities, its existing shareholders will likely experience substantial dilution.

The funds from our October 2008 offering have allowed us to complete the testing and certification of our FMS unit and to receive, on April 1, 2009, final FDA clearance. We believe that our existing funds will also be sufficient to pay for normal operating expenses as we wait for additional funding. We have doubts about raising capital because of our early stage position and history of losses. We also note the recent economic downturn which has made the overall market nervous about investing.

Our operating plan assumes that we will achieve certain levels of operating costs and expenses, as to which there can be no assurance that we will be able to achieve. This plan is completely dependent on our ability to raise additional capital through future financings. In addition, if events or circumstances occur such that we are unable to meet our operating plan as expected, we will be required to seek additional capital, pursue other strategic opportunities, or we will be forced to reduce the level of expenditures, which could have a material adverse effect on our ability to achieve our intended business objectives and to continue as a going concern. Even if we achieve our operating plan, we will be required to seek additional financing or strategic relationships.

The current economic turmoil has a significant impact on the overall funding environment, and we cannot assure you that our opportunity will be positively received by potential investors. We are not planning on any significant capital or equipment investments, and we will only have a few human resource additions over the next 12 months. A significant amount of funds will be utilized to launch our product into the market. With the expenses associated with FDA clearance having already been incurred, and with the product development primarily complete, future funds, if any, will be used primarily to launch our product into the market.

There can be no assurance that any additional financing will be available on acceptable terms, or at all. Furthermore, any equity financing likely will result in dilution to existing shareholders and any debt financing likely will include restrictive covenants.

We expect to continue to depend upon outside financing to sustain our operations for at least the next 12 months. Our ability to arrange financing from third parties will depend upon our operating performance and market conditions. Our inability to raise additional working capital at all or to raise it in a timely manner would negatively impact our ability to fund our operations, to generate revenues, and to otherwise execute our business plan, leading to the reduction or suspension of our operations and ultimately forcing us to go out of business. Should this occur, the value of any investment in our securities could be adversely affected, and an investor could lose a portion of or all of their investment.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

Information Regarding Forward-Looking Statements

This Form 10-Q contains “forward-looking statements” that indicate certain risks and uncertainties related to the Company, many of which are beyond the Company’s control. The Company’s actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including those set forth below and elsewhere in this report. Important factors that may cause actual results to differ from projections include:

- Adverse economic conditions;
- Inability to raise sufficient additional capital to operate our business;
- Unexpected costs and operating deficits, and lower than expected sales and revenues, if any;
- Adverse results of any legal proceedings;
- The volatility of our operating results and financial condition;
- Inability to attract or retain qualified senior management personnel, including sales and marketing personnel; and
- Other specific risks that may be alluded to in this report.

All statements, other than statements of historical facts, included in this report regarding the Company’s growth strategy, future operations, financial position, estimated revenue or losses, projected costs, prospects and plans and objectives of management are forward-looking statements. When used in this report, the words “will,” “may,” “believe,” “anticipate,” “intend,” “estimate,” “expect,” “project,” “plan” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this report. The Company does not undertake any obligation to update any forward-looking statements or other information contained herein. Potential investors should not place undue reliance on these forward-looking statements. Although the Company believes that its plans, intentions and expectations reflected in or suggested by the forward-looking statements in this report are reasonable, the Company cannot assure potential investors that these plans, intentions or expectations will be achieved. The Company discloses important factors that could cause the Company’s actual results to differ materially from its expectations in the “Risk Factors” section of the Post-Effective Amendment No. 1 to our Registration Statement on Form S-1 filed with Securities and Exchange Commission on May 5, 2010 and elsewhere in this report. These cautionary statements qualify all forward-looking statements attributable to the Company or persons acting on its behalf.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

ITEM 4. Control and Procedures

Disclosure Controls

Our management, including our President, Chief Executive Officer and Chief Financial Officer (referred to as the “Certifying Officer”), evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Exchange Act as of the end of the period covered by this Report on Form 10-Q. Based on that evaluation, the Certifying Officer concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) are effective, in all material respects, to ensure that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our President, Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

Changes in Internal Controls

There were no changes in our internal controls over financial reporting during the third quarter of fiscal year 2011 that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. Legal Proceedings

None.

ITEM 1A. Risk Factors

Not required.

ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

On August 17, 2011 the Company issued 62,500 shares of common stock and a warrant to purchase 62,500 shares of common stock at \$.25 per share to an investor in return for his \$12,500 investment in the Company.

On August 31, 2011 the Company issued 475,000 shares of common stock and a warrant to purchase 475,000 shares of common stock at \$.075 per share to a fund raising consultant.

On August 31, 2011 the Company issued 290,699 shares of common stock to a consultant as partial compensation for investor relations consulting work.

On September 15, 2011 the Company issued 500,000 shares of common stock and a warrant to purchase 500,000 shares of common stock at \$.25 per share to an investor in return for his \$100,000 investment in the Company.

On October 3, 2011 the Company issued 500,000 shares of common stock and a warrant to purchase 500,000 shares of common stock at \$.25 per share to an investor in return for his \$100,000 investment in the Company.

On October 6, 2011 the Company issued 100,000 shares of common stock and a warrant to purchase 100,000 shares of common stock at \$.25 per share to an investor in return for his \$20,000 investment in the Company.

On October 6, 2011 the Company issued 50,000 shares of common stock and a warrant to purchase 50,000 shares of common stock at \$.25 per share to an investor in return for his \$10,000 investment in the Company.

On October 11, 2011 the Company issued 575,000 shares of common stock to a consultant as sole compensation for investor relations consulting work.

Unless otherwise specified above, the Company believes that all of the above transactions were transactions not involving any public offering within the meaning of Section 4(2) of the Securities Act, since (a) each of the transactions involved the offering of such securities to a substantially limited number of persons; (b) each person took the securities as an investment for his/her/its own account and not with a view to distribution; (c) each person had access to information equivalent to that which would be included in a registration statement on the applicable form under the Securities Act; and (d) each person had knowledge and experience in business and financial matters to understand the merits and risk of the investment; therefore no registration statement needed to be in effect prior to such issuances.

ITEM 3. Defaults Upon Senior Securities

None.

ITEM 4. [Removed and Reserved]

ITEM 5. Other Information

None.

ITEM 6. Exhibits

See the attached exhibit index.

SIGNATURES:

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIODRAIN MEDICAL, INC.

Date: November 14, 2011

By: /s/ Kevin R. Davidson
President, Chief Executive Officer and
Chief Financial Officer
(Principal Executive Officer and
Principal Financial and Accounting Officer)

EXHIBIT INDEX

BIODRAIN MEDICAL, INC.
Form 10-Q

The quarterly period ended September 30, 2011

<u>Exhibit No.</u>	<u>Description</u>
3.1 (1)	Articles of Incorporation, as amended.
3.2 (1)	Bylaws, as amended.
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial and Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

(1) Filed on March 31, 2011 as an exhibit to our Annual Report on Form 10-K, and incorporated herein by reference.

**CERTIFICATION
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Kevin R. Davidson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioDrain Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principals;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2011

/s/ Kevin R. Davidson

Kevin R. Davidson

Chief Executive Officer (Principal Executive Officer)

**CERTIFICATION
PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Kevin R. Davidson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioDrain Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principals;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2011

/s/ Kevin R. Davidson

Kevin R. Davidson
Chief Financial Officer (Principal Financial Officer)

**CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of BioDrain Medical, Inc. (the "Company") for the quarter ended September 30, 2011 as filed with the Securities and Exchange Commission (the "Report"), I, Kevin R. Davidson, Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer) of the Company, hereby certify as of the date hereof, solely for purposes of § 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. § 1350, that to the best of my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

Date: November 14, 2011

/s/ Kevin R. Davidson
Kevin R. Davidson
Chief Executive Officer (Principal Executive Officer)
and Chief Financial Officer (Principal Financial Officer)
