

MILESTONE SCIENTIFIC INC.

Form 10-Q

November 10, 2011

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**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: 001-14053**

**MILESTONE SCIENTIFIC INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

**13-3545623**

(State or other jurisdiction of incorporation or  
organization)

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

**220 South Orange Avenue, Livingston, New Jersey 07039**

(Address of principal executive offices)

**(973) 535-2717**

(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 Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated Filer ☐ Non-accelerated filer ☐ Smaller reporting company ☒

(Do not check if a 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

As of November 10, 2011, the Issuer had a total of 15,489,156 shares of Common Stock, \$.001 par value outstanding.



## **PART I FINANCIAL INFORMATION**

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**FORWARD-LOOKING STATEMENTS**

*When used in this Quarterly Report on Form 10-Q, the words may , will , should , expect , believe , anticipate , continue , estimate , project , intend and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ) regarding events, conditions and financial trends that may affect Milestone 's future plans of operations, business strategy, results of operations and financial condition. Milestone wishes to ensure that such statements are accompanied by meaningful cautionary statements pursuant to the safe harbor established in the Private Securities Litigation Reform Act of 1995. Prospective investors are cautioned that any forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties and the actual results may differ materially from those included within the forward-looking statements as a result of various factors. Such forward-looking statements should, therefore, be considered in light of various important factors, including those set forth herein and others set forth from time to time in Milestone 's reports and registration statements filed with the Securities and Exchange Commission (the Commission ). Milestone disclaims any intent or obligation to update such forward-looking statements.*

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## ITEM 1. FINANCIAL STATEMENTS

MILESTONE SCIENTIFIC INC.  
CONDENSED BALANCE SHEETS

	September 30, 2011 (Unaudited)	December 31, 2010
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 370,669	\$ 627,082
Accounts receivable, net of allowance for doubtful accounts of \$202,160 in 2011 and 2010	1,043,141	796,221
Inventories, net	733,911	986,947
Advances to contract manufacturer	728,508	730,491
Prepaid expenses and other current assets	236,350	247,465
Total current assets	3,112,579	3,388,206
Accounts receivable-long term, net of allowance for doubtful accounts of \$354,840 as of September 30, 2011 and \$438,840 as of December 31, 2010	257,160	361,160
Advances to contract manufacturer, non current	2,606,512	1,713,794
Investment in distributor, at cost	76,319	76,319
Investment in Joint Venture	185,551	
Furniture, Fixtures & Equipment net of accumulated depreciation of \$440,655 as of September 30, 2011 and \$426,482 as of December 31, 2010	56,936	66,936
Patents, net of accumulated amortization of \$325,400 as of September 30, 2011 and \$294,934 as of December 31, 2010	713,048	944,858
Other assets	38,317	57,750
Total assets	\$ 7,046,422	\$ 6,609,023
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities:		
Accounts payable short term	\$ 2,704,436	\$ 2,883,587
Accrued expenses and other payable	883,907	511,304
Total current liabilities	3,588,343	3,394,891
Long-term Liabilities:		
Accounts payable long term	877,298	440,376
Notes Payable-net of discount of \$4,597 and \$8,361 respectively	445,403	441,639
Total long-term liabilities	1,322,701	882,015

Commitments and Contingencies

Stockholders' Equity

Common stock, par value \$.001; authorized 50,000,000 shares;

15,294,954 shares issued 1,462,913 shares to be issued and 15,261,621 shares outstanding as of September 30, 2011; 14,915,959 shares issued,

637,013 shares to be issued, and 14,882,626 shares outstanding as of

December 31, 2010

Additional paid-in capital

Accumulated deficit

Treasury stock, at cost, 33,333 shares

Total stockholders' equity

Total liabilities and stockholders' equity

	16,757	15,552
	63,485,148	62,606,043
	(60,455,011)	(59,377,962)
	(911,516)	(911,516)

2,135,378 2,332,117

\$ 7,046,422 \$ 6,609,023

See Notes to Condensed Financial Statements (Unaudited)



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MILESTONE SCIENTIFIC INC.  
CONDENSED STATEMENTS OF OPERATIONS  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2011	2010	2011	2010
Product sales, net	\$ 1,745,876	1,926,889	\$ 6,635,983	\$ 7,708,136
Cost of products sold	597,528	725,795	2,345,191	2,788,353
Gross profit	1,148,348	1,201,094	4,290,792	4,919,783
Selling, general and administrative expenses	1,695,908	1,704,896	5,121,831	5,024,791
Research and development expenses	(7,403)	60,533	92,540	228,734
Total operating expenses	1,688,505	1,765,429	5,214,371	5,253,525
Loss from operations	(540,157)	(564,335)	(923,579)	(333,742)
Other income (expense)				61,916
Interest expense	(35,636)	(18,552)	(89,713)	(45,841)
Interest-Amortization of debt issuance	(1,532)	(699)	(3,764)	(2,097)
Interest income	14	60	34	520
Loss on Earnings from Joint Venture	(60,027)		(60,027)	
Net loss applicable to common stockholders	\$ (637,338)	\$ (583,526)	\$ (1,077,049)	\$ (319,244)
Net loss per share applicable to common stockholders				
Basic and diluted	\$ (0.04)	\$ (0.04)	\$ (0.07)	\$ (0.02)
Weighted average shares outstanding and to be issued				
Basic and diluted	15,121,221	14,862,549	15,073,725	14,806,272

See Notes to Condensed Financial Statements (Unaudited)

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CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
NINE MONTHS ENDED SEPTEMBER 30, 2011  
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Total
Balance, January 1, 2011	15,552,972	\$ 15,552	\$ 62,606,043	\$ (59,377,962)	\$ (911,516)	\$ 2,332,117
Options issued to consultants			181,913			181,913
Options exercised	100,000	100	24,900			25,000
Common stock to be issued to employee for bonuses	554,545	555	349,445			350,000
Common stock to be issued to consultants	171,355	171	95,642			95,813
Sale of common stock-to be issued	99,999	100	29,900			30,000
Common stock issued for directors compensation	75,000	75	44,925			45,000
Common stock issued for payment of consulting services to settle accounts payable	176,167	176	105,908			106,084
Proceeds on sale of option rights			24,000			24,000
Common stock issued for payment of employee compensation	27,829	28	22,472			22,500
Net Loss				(1,077,049)		(1,077,049)
Balance, September 30, 2011	16,757,867	\$ 16,757	\$ 63,485,148	\$ (60,455,011)	\$ (911,516)	\$ 2,135,378

See Notes to Condensed Financial Statements (Unaudited)

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MILESTONE SCIENTIFIC INC.  
CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2011	2010
Cash flows from operating activities:		
Net loss	\$ (1,077,049)	\$ (319,244)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	16,265	39,813
Amortization of patents	64,459	62,228
Amortization of debt discount	3,764	2,097
Common stock and options issued for compensation, consulting and vendor services	705,497	433,943
Loss on Earnings on Joint Venture	60,027	
Bad debt expense (decrease) increase	(84,000)	5,000
Changes in operating assets and liabilities:		
Increase in accounts receivable	(58,920)	(1,063,386)
Decrease (Increase) in inventories	253,036	(348,287)
Increase to advances to contract manufacturer	(890,735)	(1,730,791)
Decrease to prepaid expenses and other current assets	56,115	66,903
Decrease in other assets	19,433	59,257
Increase in accounts payable	257,771	1,900,035
Decrease in accrued expenses	372,603	167,734
Net cash used in operating activities	(301,735)	(724,698)
Cash flows from investing activities:		
Purchases of property and equipment	(6,265)	(29,355)
Payment for patents rights	(27,414)	(69,350)
Net cash used in investing activities	(33,679)	(98,705)
Cash flows from financing activities:		
Proceeds from exercise of stock options	25,000	
Proceeds on sale of option rights	24,000	
Proceeds from the sale of common stock	30,000	
Net cash provided by financing activities	79,000	
NET DECREASE IN CASH AND CASH EQUIVALENTS	(256,413)	(823,403)
Cash and cash equivalents at beginning of period	627,082	1,029,129
Cash and cash equivalents at end of period	\$ 370,669	\$ 205,726
Supplemental disclosure of cash flow information:		
Interest paid	\$ 23,000	\$ 69,000

Invest in Joint Venture (contribution of patent rights)	\$	194,765	\$
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See Notes to Condensed Financial Statements (Unaudited)

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**MILESTONE SCIENTIFIC INC.  
NOTES TO CONDENSED FINANCIAL STATEMENTS  
(UNAUDITED)**

**ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION**

Milestone Scientific Inc. ( Milestone or the Company ) was incorporated in the State of Delaware in August 1989. The unaudited financial statements of Milestone have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

These unaudited financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2010 included in Milestone's Annual Report on Form 10-K.

In the opinion of Milestone, the accompanying unaudited financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present Milestone's financial position as of September 30, 2011 and December 31, 2010 and the results of its operations for the three and nine months ended September 30, 2011 and 2010.

The results reported for the three and nine months ended September 30, 2011 are not necessarily indicative of the results of operations which may be expected for a full year.

The Company had negative cash flows from operating activities of \$301,735 and \$724,698 for the nine months ended September 30, 2011 and September 30, 2010, respectively. At September 30, 2011, the Company had cash and cash equivalents of \$370,669 and a negative working capital of \$475,764. The Company borrowed \$450,000 in 2008 from a shareholder, with a due date of January 2009. This additional borrowing was refinanced at December 31, 2008 and refinanced again on June 29, 2011 with the due date extended to July 2013. The Company is continuing the pursuit of positive cash flows from operating activities through an increase in revenue based upon management's assessment of present contracts and current negotiations and reductions in operating expenses. The Company may require the need for a higher level of marketing and sales efforts that at present it cannot fund. If the Company is unable to continue positive cash flows from its operating activities it will need to raise additional capital. There is no assurance that the Company will be able to achieve positive operating cash flows or that capital can be raised on terms and conditions satisfactory to the Company, if at all. If positive cash flow cannot be achieved or if additional capital is required and it cannot be raised, then the Company would be forced to curtail its development activities, reduce marketing expenses for existing dental products or adopt other cost saving measures, any of which might negatively affect the Company's operating results.

The Company's historical losses raise substantial doubt about its ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**NOTE 1 SUMMARY OF ACCOUNTING POLICIES**

**Cash and Cash Equivalents**

Milestone considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents.

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**Accounts Receivable**

The realization of Accounts Receivable current and long-term will have a significant impact on the Company. Consequently, Milestone estimates losses resulting from the inability of its customers to make payments for amounts billed. The collectability of outstanding amounts is continually assessed.

**Inventories**

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or market. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess and obsolete inventory is recorded, if required, based on past and expected future sales.

**Investment in Joint Venture**

The Company has entered into a Joint Venture with a third party for the development and commercialization of two medical products. The Company owns fifty percent of the joint venture and has recorded its investment on the equity basis of accounting. The Company's proportionate share of expenses incurred by the Joint Venture is charged to the Statement of Operations and adjusted against the Investment in Joint Venture.

**Patents**

Patents are recorded at actual cost to prepare and file the applicable documents with the United States Patent Office, or internationally with the applicable governmental office in the respective country. Although certain patents have not yet been approved, the costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. If the applicable patent application is ultimately rejected, the remaining unamortized balance will be expensed in the period in which the Company receives a notice of such rejection. Patent applications filed and patents obtained in foreign countries are subject to the laws and procedures that differ from those in the United States. Patent protection in foreign countries may be different from patent protection under United States laws and may not be favorable to the Company. The Company also attempts to protect our proprietary information through the use of confidentiality agreements and by limiting access to our facilities. There can be no assurance that our program of patents, confidentiality agreements and restricted access to our facilities will be sufficient to protect our proprietary technology.

**Accounts Payable**

Current and long term accounts payable represents amounts due to suppliers of the Company. Long term accounts payable is based on an informal payment agreement with the supplier to assist in the purchasing of instruments and handpieces, beyond one year from the balance sheet date.

**Revenue Recognition**

Revenue from product sales is recognized net of discounts and allowances to the domestic distributor on the date of shipment of the goods, for essentially all shipments, since the terms are FOB warehouse. The Company will recognize revenue on date of arrival where shipments are FOB destination. Shipments to the international distributors are FOB the warehouse and revenue is therefore recognized on shipment. In both cases, the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone has no obligation on these sales for any post sale installation, set-up or maintenance, these being the responsibility of the buyer. Customer acceptance is considered made at delivery. The only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the allowance for doubtful accounts, inventory valuation, cash flow assumptions regarding evaluation for impairment of long-lived assets and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

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**Fair Value Measurements:** We follow the provisions of ASC 820, *Fair Value Measurements and Disclosures* related to financial assets and liabilities that are being measured and reported on a fair value basis. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). We are required to classify fair value measurements in one of the following categories:

Level 1 inputs which are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs which are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities.

Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement requires judgment, and may effect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

The carrying amounts reported in the balance sheet for cash, accounts receivable, advances to contract manufacturer, accounts payable and accrued expenses approximate fair value based on the maturity of these instruments.

### **Recent Accounting Pronouncements**

In May 2011, the FASB issued ASU No. 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*, which is intended to improve comparability of fair value measurements presented and disclosed in financial statements prepared in accordance with U.S. generally accepted accounting principles and International Financial Reporting Standards. This standard clarifies the application of existing fair value measurement requirements including (1) the application of the highest and best use valuation premise, (2) the methodology to measure the fair value of an instrument classified in a reporting entity's shareholders' equity, (3) disclosure requirements for quantitative information on Level 3 fair value measurements and (4) guidance on measuring the fair value of financial instruments managed within a portfolio. In addition, the standard requires additional disclosures of the sensitivity of fair value to changes in unobservable inputs for Level 3 securities. This standard is effective for interim and annual reporting periods ending on or after December 15, 2011. The adoption of this guidance is not expected to have a significant impact on the Company's financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Presentation of Comprehensive Income*, which requires that comprehensive income be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The standard also requires entities to disclose on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net earnings. This standard no longer allows companies to present components of other comprehensive income only in the statement of equity. This standard is effective for interim and annual reporting periods beginning after December 15, 2011. The adoption of this guidance is not expected to have a significant impact on the Company's financial statements other than the prescribed change in presentation.

### **NOTE 2 BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE**

Milestone presents basic and fully diluted earnings (loss) per common share applicable to common stockholders, and, if applicable, diluted earnings (loss) per common share applicable to common stockholders pursuant to the provisions of FASB ASC Topic 260. Basic earnings (loss) per common share is calculated by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding and to be issued during each period. The calculation of diluted earnings per common share is similar to that of basic earnings per common share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if all potentially dilutive common shares, such as those issuable upon the exercise of stock options and warrants were issued during the period.





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Since Milestone had net losses for the three and nine months ended September 30, 2011 and 2010, the assumed effects of the exercise of outstanding stock options and warrants were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 1,330,503 and 1,644,474 at September 30, 2011 and 2010, respectively.

### **NOTE 3 ACCOUNTS RECEIVABLE CURRENT AND LONG TERM**

The Company sells a significant amount of its product on credit terms to its major distributors. The Company estimates losses from the inability of its customers to make payments on amounts billed. A majority of credit sales are due within sixty days from invoicing. In 2010, the Company shipped a significant order to a major international distributor. At the time of the shipment, regulatory approval to sell the product in the respective country was in process. Obtaining such regulatory approval was not a condition of the purchase order and sale to the distributor. The regulatory approval has been delayed and as such the customer has not paid the full amount of the invoiced shipment. The Company is receiving periodic payments from the international distributor. Based on the periodic payment plan prepared by the international distributor, the Company has recorded a long term net accounts receivable of \$257,160 as of September 30, 2011 and \$361,160 at December 31, 2010. The current portion of this net accounts receivable was approximately \$163,000 and \$163,000 at September 30, 2011 and December 31, 2010, respectively. The Company reserved \$552,000 of the total accounts receivable from this distributor at September 30, 2011 and \$636,000 at December 31, 2010.

### **NOTE 4 JOINT VENTURE**

In March 2011, Milestone entered into a new agreement with a People's Republic of China ( PRC ) entity to establish a joint venture entity in the PRC to develop intra-articular and epidural drug delivery instruments utilizing Milestone's patented *CompuFlo* technology. The PRC entity agreed to contribute up to \$1.5 million to this joint venture entity, based on progress reports from Milestone and subject to refund if the instruments are not developed because of technological problems within 30 months of the inception date. The initial \$500,000 capital contribution was to have been made at inception. The PRC joint venture entity was established in September 2011. However, to move the process forward, Milestone organized a domestic research and development corporation to which its joint venture partner completed a capital contribution of \$500,000 to the US research and development corporation. The joint venture is owned fifty percent by the PRC entity and fifty percent by Milestone. Milestone contributed the rights to use *CompuFlo* technology to the joint venture which has been valued at approximately \$245,000 and has accounted for its investment in the joint venture using the equity method of accounting.

The joint venture reimbursed Milestone approximately \$105,000 for previously incurred research and development expenses, which has been included as a credit to research and development expenses in the accompanying statement of operations. The joint venture's total year-to-date expenses were approximately \$120,000 of which Milestone's share of approximately \$60,000 has been reflected in the accompanying statement of operations as the proportionate share of losses from the joint venture. Further, Milestone also entered into an agreement with a significant vendor to develop the two instruments included in the joint venture. As of September 30, 2011, \$387,000 has been deposited with this third party product developer. As of September 30, 2011, the developer has expensed \$15,086 on the project.

### **NOTE 5 STOCK OPTION PLANS**

FASB ASC Topic 505, *Share-Based Payment*, requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations over the service period, as an operating expense, based on the grant-date fair values.

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A summary of option activity for employees under the plans as of September 30, 2011, and changes during the nine months ended, is presented below:

	<b>Number of Options</b>	<b>Weighted Averaged Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Aggregate Intrinsic Options Value</b>
Outstanding, January 1, 2011	928,504	\$ 1.07	3.92	\$
Granted				
Exercised				
Forfeited or expired	58,000	1.15		
Outstanding, September 30, 2011	870,504	1.07	3.40	35,100
Exercisable, September 30, 2011	455,708	0.95	2.35	34,865

Milestone recognizes compensation expense on a straight line basis over the requisite service period. During the nine months ended September 30, 2011, Milestone recognized \$152,692 of total compensation cost. As of September 30, 2011, there was \$133,950 of total unrecognized compensation cost related to non-vested options which Milestone expects to recognize over a weighted average period of 1.54 years. A six percent rate of forfeitures is assumed in the calculation of the compensation cost for the period.

Expected volatilities are based on historical volatility of Milestone's common stock over a period commensurate with anticipated term. Milestone uses historical data to estimate option exercise and employee termination within the valuation model.

A summary of option activity for non-employees under the plans as of September 30, 2011, and changes during the nine months ended, is presented below:

	<b>Number of Options</b>	<b>Weighted Averaged Exercise Price</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Aggregate Intrinsic Options Value</b>
Outstanding, January 1, 2011	534,999	1.85	1.51	
Granted	100,000	0.24	2.75	
Exercised	100,000	0.25		
Forfeited or expired	120,000	1.75		
Outstanding, September 30, 2011	414,999	1.87	1.68	55,150
Exercisable, September 30, 2011	399,443	1.90	1.61	55,150

During the nine months ended September 30, 2011, Milestone recognized \$42,581 of expenses related to non-employee options that vested during the period. The total unrecognized compensation cost related to non-vested options was \$3,870 as of September 30, 2011.

In accordance with the provisions of FASB ASC 505-50-15, all other issuances of common stock, stock options or other equity instruments to non-employees as consideration for goods or services received by Milestone are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of any options or similar equity instruments issued is estimated based on the Black-Scholes option-pricing model, and the assumption that all of the options or other equity instruments will ultimately vest. Such fair value is measured as of an appropriate date pursuant to the guidance, (generally, the earlier of the date the other party becomes committed to provide goods or services or the date of performance by the other party is complete) and capitalized or expensed as if Milestone had paid cash for the goods or services.

The Company held its Annual Meeting of the Stockholders on June 16, 2011. There was an approval of the Company's 2011 Stock Option Plan for the issuance of up to 2,000,000 common shares.

**Table of Contents****NOTE 6 CONCENTRATION OF CREDIT RISK**

Milestone's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and trade accounts receivable, and advances to contract manufacturer. Milestone places its cash and cash equivalents with large financial institutions. At times, such investments may be in excess of the Federal Deposit Insurance Corporation insurance limit. Milestone has not experienced any losses in such accounts and believes it is not exposed to any significant credit risks. Financial instruments which potentially subject Milestone to credit risk consist principally of trade accounts receivable, as Milestone does not require collateral or other security to support customer receivables, and advances to contract manufacturer. Milestone entered into a purchase agreement with a vendor to supply Milestone with 5,000 instruments of *CompuDent* and 12,000 *STA Instruments*. As part of these agreements, Milestone has advanced approximately \$3,335,020 and \$2,444,285 to the vendor for purchase of materials at September 30, 2011 and December 31, 2010, respectively. The advance will be credited to Milestone as the goods are delivered. Milestone does not believe that significant credit risk exists with respect to this advance to the contract manufacturer. Milestone closely monitors the extension of credit to its customers while maintaining allowances, if necessary, for potential credit losses. On a periodic basis, Milestone evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit conditions. Management has provided a reserve that it believes is sufficient record accounts receivable at net realizable value as of September 30, 2011 and December 31, 2010.

A five percent shareholder of the Company is also a major supplier of handpieces to the Company and additionally, is a member of the PRC entity which entered into a joint venture agreement with the Milestone as described in Note 4. The Company purchased \$1,235,809 and \$1,772,105 from the supplier for the period ended September 30, 2011 and 2010, respectively. The Company owes \$944,541 and \$1,118,757 to this supplier as of September 30, 2011 and December 31, 2010, respectively.

**NOTE 7 ADVANCES TO CONTRACT MANUFACTURER**

The net advances to contract manufacturer represent funding of future STA, CompuDent and Wand Plus inventory purchases. The balance of the net advances as of September 30, 2011 and December 31, 2010 is \$3,335,020 and \$2,444,285, respectively. The portion of this advance expected to be utilized in the next twelve months is classified as current asset, with the remainder classified as non-current asset. The Company has an outstanding accounts payable of \$1,872,690 and \$1,520,533 at September 30, 2011 and December 31, 2010, respectively to the contract manufacture specifically related to the advances. The Company is making monthly payments to the contract manufacturer. Additionally, the Company accrued a finance fee of \$15,245 to the contractor for the three months ended September 30, 2011 and \$30,091 for the nine months ended September 30, 2011.

**NOTE 8 LINE OF CREDIT AND NOTE PAYABLE**

On June 28, 2007 the Company secured a \$1 million line of credit from a stockholder. This borrowing was amended to \$1,300,000 as of September 30, 2008 under the same terms and conditions as the original. The \$1.3 million Line of Credit was converted into shares of Milestone's common stock in December 2009 at a conversion rate of \$1.58 per share. A total of 822,785 shares were issued and the debt liquidated at that date. Interest accrued on the Line of Credit of aggregated \$68,082 and \$88,021 as of September 30, 2011 and December 31, 2010, respectively. \$23,000 of this accrued interest was paid in the nine months ended September 30, 2011. The remaining interest will be paid in 2012. The Company borrowed an additional \$450,000 from the same shareholder in 2008. The borrowing was originally on short term loan with a maturity date of January 19, 2009. In December 2008, this borrowing was refinanced with the shareholder with a due date of June 30, 2012. The loan was refinanced again on June 29, 2011, without cost to the Company, and the due date was extended to July 2013. The borrowing includes a 12% interest rate, interest compounded quarterly, with interest and principal due at the maturity. Further, the note has warrants exercisable for five years at the price of \$0.32 per share for 45,000 shares of stock. The warrants were valued using the Black-Scholes model and are reflected as a discount against the debt. At September 30, 2011 and December 31, 2010, the remaining unamortized discount was \$4,597 and \$8,361, respectively.

Interest expense on this Line of Credit for the nine months ended September 30, 2011 and 2010 is \$59,622 and \$45,841, respectively. Accrued interest related to the line of credit was \$249,287 and \$214,824 at September 30, 2011 and December 31, 2010, respectively. The charge for amortization of Debt Discount related to this Line of Credit is

\$3,764 and \$2,097 for the nine months ended September 30, 2011 and September 30, 2010, respectively.

**Table of Contents****NOTE 9 STOCK ISSUANCE**

During the nine months ended September 30, 2011, the Company issued 176,167 shares of common stock valued at \$106,084 to two parties owed in connection with consulting expenses. Additionally, 27,829 shares of common stock valued at \$22,500 were issued for payment of employee compensation. 100,000 shares were issued upon exercise of stock options for \$25,000 (\$0.25 per share). The Company issued 75,000 shares (25,000 shares per outside directors), to the members of the Company's Board of Directors as partial compensation for serving on the Board for the 2011-2012 period. The cost of the compensation was \$45,000 or \$.60 per share. The expense will be amortized over a nine month period. The company also provided for 554,545 shares (cost \$350,000) to be issued to officers of the company for bonuses earned, but not paid during the nine months ending September 30, 2011. The Company recorded 171,355 of common stock to be issued for services rendered and future services to be provided. Additionally, 99,999 shares of common stock was purchased by two outsiders.

**NOTE 10 SIGNIFICANT CUSTOMERS**

Milestone had net product sales to two customers (distributors) for the nine months ended September 30, 2011 of which in the aggregate accounted for approximately 43% of total sales. Additionally, three customers (distributors) which in the aggregate accounted for approximately 63% of revenue for nine months ended September 30, 2010. Milestone had sales to one of these major customers (a worldwide distributor of Milestone's products based in China) of \$1,847,468 (24%) for the nine months ended September 30, 2010. Accounts receivable from these customers amounted to \$838,238 and \$533,191 representing 64% and 44% of gross accounts receivable as of September 30, 2011 and December 31, 2010, respectively.

Milestone's sales by product and by geographical region are as follows:

	Three Months Ended September 30,	
	2011	2010
<i>Instruments</i>	\$ 416,582	\$ 427,362
Handpieces	1,328,167	1,473,204
Other	1,127	26,323
	\$ 1,745,876	\$ 1,926,889
United States	\$ 849,344	\$ 865,967
Canada	163,171	97,954
Other Foreign	733,361	962,968
	\$ 1,745,876	\$ 1,926,889
	Nine Months Ended September 30,	
	2011	2010
<i>Instruments</i>	\$ 2,381,115	\$ 2,851,614
Handpieces	4,188,135	4,781,987
Other	66,733	74,535
	\$ 6,635,983	\$ 7,708,136

United States	\$ 3,527,595	\$ 3,329,793
Canada	468,786	468,462
Other Foreign	2,639,602	3,909,881
	\$ 6,635,983	\$ 7,708,136

**NOTE 11 COMMITMENTS AND OTHER***Contract Manufacturing Arrangement*

Milestone has informal arrangements for the manufacture of its products. *CompuDent*, *STA* and *CompuMed* instruments are manufactured for Milestone by Tricor Systems, Inc. pursuant to specific purchase orders. *The Wand* disposable handpiece without a needle were manufactured for Milestone in Mexico pursuant to scheduled production requirements. *The Wand* handpiece (with and without needles) is supplied to Milestone by a product broker that arranges for its manufacture by manufacturers in China.

The termination of the manufacturing relationship with any of the above manufacturers could have a material adverse effect on Milestone's ability to produce and sell its products. Although alternate sources of supply exist and new manufacturing relationships could be established, Milestone would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, whether or not as a result of termination of such a relationship, would adversely affect Milestone.

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In January 2010, the Company issued a purchase order to Tricor Instruments for the purchase of 12,000 *Wand/STA Instruments* to be delivered over the next three years. The purchase order is for \$5,261,640. The Company will be required to make periodic payments over the next eighteen months to purchase the parts necessary to complete this production. As of September 30, 2011, the Company's production and sales of instruments for this commitment has been delayed. Consequently, advances to contractor and accounts payable has been classified as current and long term at September 30, 2011.

*Other Events*

In December 2009, Milestone announced that it signed an Agreement of Intent with China National Medicines Corporation, Ltd. and Yichang Humanwell Pharmaceutical Co. Ltd., both incorporated in the People's Republic of China (PRC), to develop intra-articular and epidural drug delivery instruments utilizing Milestone's patented *CompuFlo* technology. Milestone and its two PRC joint venture partners agreed to establish a joint venture entity for this purpose in 2010. The required initial funding for the new entity, estimated by the parties at \$1.4 million, was to have been provided by the two PRC companies, although Milestone would determine the proposed uses of their contribution. The Company has notified China National Medicines, LTD and Yichang Humanwell Pharmaceutical Co. Ltd, both signatories to the December 2009, Agreement of Intent, to develop these medical instruments, that the Company has terminated this Agreement of Intent, effective July 13, 2011.

The Company entered into a finder's agreements with selected individuals for the purpose of identifying and closing medical device joint venture. As of September 30, 2011, none of the potential agreements has been consummated and therefore no expenses have been incurred.

**NOTE 12 SUBSEQUENT EVENTS**

We have completed an evaluation of the impact of any subsequent events through the date these financial statements were issued and determined that there were no subsequent events requiring disclosure in or adjustment to these financial statements.



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

The following discussions of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Form 10-Q. Certain statements in this discussion and elsewhere in this report constitute forward-looking statements, within the meaning of section 21E of the Exchange Act, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements.

#### **OVERVIEW**

In 2011, Milestone remains focused on advancing efforts to achieve our two primary objectives; those being:

Optimizing our tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with our proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, the *STA Single Tooth Anesthesia Instrument (STA Instrument)*; and

Identifying and pursuing strategic collaborations with third parties to jointly develop new products utilizing our patented *CompuFlo* pressure force technology for novel new medical applications.

#### ***STA Instrument Awards    Industry Recognition***

Since its market introduction in the spring of 2007, the *STA Instrument* has received favorable reviews and awards from the dental industry. In July 2007, noted industry publication *Dentistry Today* featured the *STA Instrument* as one of the Top 100 Products in 2007, helping to promote much broader recognition of the instrument and validating the *STA Instrument*'s value proposition for dentists and patients alike. In April 2008, *Medical Device & Diagnostic Industry* magazine distinguished the *STA Instrument* as a 2008 Medical Design Excellence Award winner in the Dental Instruments, Equipment and Supplies product category. Of the 33 products to receive this coveted award, the *STA Instrument* was one of only two winning products that serve dental practitioners.

In December 2008, the *STA Instrument* was again recognized as one of the dental industry's best technological innovations, winning a Townie Choice Award from *Dentaltown Magazine* in the category Anesthetics: Technique Instrument. This marked the second consecutive year that Milestone won a Townie Choice Award; in 2007, we won the same award for our *CompuDent/The Wand*. Also in December 2008, our *Wand/STA Instrument* was named as a *Dental Products Report* Top 100 2008 Product of Distinction. Each year, *DPR* spotlights the year's Top 100 products. Of these 100 products, 50 are the ones most often inquired about by *DPR*'s readers via an online and Product Information Card reader service program. The other 50 represent New Classics, which recognize both old and newer products and categories chosen by *DPR*'s editorial staff for their perceived impact on driving innovation or helping to establish a new, higher standard of care for patients. The *STA Instrument* was recognized as a New Classic in the Technology category.

In July 2010, the *STA Instrument* was recognized as one of *Dentistry Today*'s, Top 100 Products, for the third consecutive year. This honor is significant because it is unprecedented in Milestone's history and serves to support our objective of establishing our instrument as the new global standard of care for painless dental injections.

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***Second Annual Symposium on C-CLAD***

On May 1 through 3, 2009, we hosted the Second International Annual Symposium on C-CLAD in Amelia Island, Florida. Stanley Malamed, DDS, Professor of Anesthesia & Medicine at the University of Southern California, School of Dentistry, again served as Chairman of the invitational event. With attendance triple that of 2008, the Second Symposium covered a broad range of C-CLAD related topics including:

The History of C-CLAD

Treating with Connection

Heart Rate Study

STA Compassionate Care in the 21<sup>st</sup> Century

Injection Advances and Challenges

Physiologic and Clinical Characteristics of PDL Anesthesia Delivered by a High Pressure Hand piece and a Computerized Device

The STA for Tots and Teens

Computerized Local Anesthesia in Dentistry: A Review

Today's Technology

Managing a Successful Dental Practice: Why People Keep Coming Back

STA The Dental School's Perspective

Futuristic Vistas: The Dentist/Hygienist Partnership

In 2010, we published and broadly distributed more than 100,000 copies of a comprehensive monograph reflecting the topics discussed at the Symposium and a consensus on the attendees' attitudes, ideas and suggestions relating to promoting global industry adoption of C-CLAD technologies as the new standard of care for administering dental injections.

***STA System Growth***

Since its market introduction in early 2007, the *STA System*, a prior computerized controlled local anesthesia delivery product, has been used to deliver tens of millions of safe, effective and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the *STA System* is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide. The utility and value of the *STA System* is perhaps best summarized by Dr. Joe Blaes, who wrote in the December 2008 edition of *Dental Economics*, "I tried the *STA System* and my patients absolutely love it. This is a no brainer - go get one ASAP!"

***Global Distribution Network***

**North America Market**

The *STA Instrument* and related hand pieces are marketed to the dental industry in the United States and Canada by many of the nation's leading dental supply companies, including Henry Schein, Inc., Patterson Dental Supply, Atlanta Dental, Benco Dental, Burkhart Dental, Cedar Dental, Darby Dental Supply, Dental Health Products, Goetze Dental, Iowa Dental, Nashville Dental. In Canada, our independent distributors include Dental 2000, Medclub, and Specialty Dental.

In the third quarter of 2010, we added a Domestic Sales Director to refocus our attention on the USA and Canadian markets. The mission of the Domestic Sales Director is to grow our business through marketing our STA Instrument to Dental Group Practices, as well as individual dental practitioners. Through direct marketing to the Dental Group Practices and utilizing a group of independent hygienists, the instrument and handpiece sales should increase substantially in the future. We closed our first Group Dental Practice in January 2011, Towncare Dental, and are continuing our efforts in 2011 on this business sector.

**International Market**

On the global front, we also have granted exclusive marketing and distribution rights for the *Wand/STA Instrument* to select dental suppliers in various international regions in Asia, Africa, South America and Europe. They include Istrodent in South Africa and Unident in the Scandinavian countries of Denmark, Sweden, Norway and Iceland.

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In April 2009, we signed an Exclusive Distribution and Marketing Agreement with China National Medicines Corporation, d/b/a Sinopharm, which is China's largest domestic manufacturer, distributor and marketer of pharmaceuticals and importer of medical devices and the country's largest domestic distributor of dental anesthetic carpules to the Chinese dental industry. Prior to the end of 2009, China National Medicines issued Milestone a blanket purchase order for 12,000 *STA Instruments* to be delivered over 36 months, thereby marking our initial penetration into China's emerging dental market.

As of September 30, 2011, China National Medicine has not received the appropriate registration approval from the regulatory body in China, therefore, shipment of *Wand/STA Instruments* and handpieces have been suspended pending the approval to sell and distribute these products in China. It is expected that the approval by the appropriate Chinese regulatory body will be received by first quarter 2012.

According to a report published by the U.S. Department of Commerce, titled "China's Emerging Markets: Opportunities in the Dental and Dental Lab Industry," China's dental market lags behind other healthcare services and has largely been neglected in the past. In fact, CS Market Research reports that of China's 1.3 billion plus population, 50% of the adults and 70% of the children are estimated to have decayed tooth problems, and over 90% have periodontal disease. However, with increasing affluence of the Chinese population, as well as increasing attention towards personal care, demand for dental services has been growing. Market research firm Freedonia agrees, noting that demand for dental products in China is expected to climb to 21.5 billion RMB (US\$3.15 billion) by 2012, due primarily to escalating personal income levels and government programs promoting awareness of the benefits of good oral care.

Shortly before the end of the second quarter 2009, we announced that we were refining our international marketing strategy to gain greater access to and penetration of the international dental markets for the *Wand/STA Instrument*, *CompuDent* and related disposable hand pieces. The new sales strategy provides for increasing hands-on oversight and support of our existing international distribution network, while also attracting new distributors throughout Europe, Asia and South America. To assist in this endeavor, Milestone added in the spring of 2010 an International Sales Director to focus on growth of our products outside the USA and Canada. The new addition to our staff has proven to be a positive improvement to our sales and marketing effort outside the USA and Canada.

### ***Medical Instruments Joint Venture***

In July 2011, we entered into a definitive joint venture agreement with Beijing 3H (Heart-Help-Health) Scientific Technology Co., Ltd. (Beijing 3H) for the development, commercialization, manufacture and marketing of epidural and intra-articular injection instruments. Milestone Scientific has a 50% interest in the joint venture and Beijing 3H together with a number of individuals, including a large shareholder in Milestone who is also the principal of a supplier to Milestone, will also have a 50% interest in joint venture.

The joint venture provided for Milestone's contribution of an exclusive worldwide royalty-free license to use its patents. Beijing 3H will contribute \$1.5 million to the joint venture to develop and design the prototype using Milestone's CompuFl® technology and disposables. Milestone will have distribution responsibility in the U.S. and Canada while Beijing 3H will distribute products exclusively in the Peoples Republic of China, Macao, Hong Kong and other regions of Asia.

**Table of Contents*****Segmented Sales Performance***

The following table shows a breakdown of our product sales (net), domestically and internationally, by product category, and the percentage of product sales (net) by each product category:

	Three Months Ended September 30,			
	2011		2010	
<b>DOMESTIC</b>				
<i>Instruments</i>	\$ 91,451	10.8%	\$ 177,387	20.5%
Handpieces	762,726	89.8%	672,817	77.7%
Other	(4,833)	-0.6%	15,763	1.8%
Total Domestic	\$ 849,344	100.0%	\$ 865,967	100.0%
<b>INTERNATIONAL</b>				
<i>Instruments</i>	\$ 325,131	36.3%	\$ 249,975	23.6%
Handpieces	565,441	63.1%	800,387	75.4%
Other	5,960	0.7%	10,560	1.0%
Total International	\$ 896,532	100.0%	\$ 1,060,922	100.0%
<b>DOMESTIC/INTERNATIONAL ANALYSIS</b>				
Domestic	\$ 849,344	48.6%	\$ 865,967	44.9%
International	896,532	51.4%	1,060,922	55.1%
Total Product Sales	\$ 1,745,876	100.0%	\$ 1,926,889	100.0%
	Nine Months Ended September 30,			
	2011		2010	
<b>DOMESTIC</b>				
<i>Instruments</i>	\$ 1,100,288	31.2%	\$ 761,376	22.9%
Handpieces	2,389,121	67.7%	2,511,426	75.4%
Other	38,186	1.1%	56,991	1.7%
Total Domestic	\$ 3,527,595	100.0%	\$ 3,329,793	100.0%
<b>INTERNATIONAL</b>				
<i>Instruments</i>	\$ 1,280,827	41.2%	\$ 2,090,238	47.7%
Handpieces	1,799,014	57.9%	2,270,561	51.9%
Other	28,547	0.9%	17,544	0.4%
Total International	\$ 3,108,388	100.0%	\$ 4,378,343	100.0%
<b>DOMESTIC/INTERNATIONAL ANALYSIS</b>				
Domestic	\$ 3,527,595	53.2%	\$ 3,329,793	43.2%
International	3,108,388	46.8%	4,378,343	56.8%

Total Product Sales	\$ 6,635,983	100.0%	\$ 7,708,136	100.0%
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Our gross profit margins were 66% and 62% for the three months ended September 30, 2011 and 2010, respectively. However, our revenues and related gross profits have not been sufficient to support our overhead, new product introduction and research and development expenses. Although we anticipate expending funds for research and development in 2011, these amounts will vary based on the operating results for each quarter. We have incurred operating losses since our inception. We are actively pursuing the generation of sustainable positive cash flows from operating activities through increases in revenue, to be derived from a change in the business model in U.S. and Canada. This change in business model incorporates a team of local dental hygienists training and educating the respective dentist in their territories. This business model replaces our prior sale force and third party manufactures rep's business model.

#### ***New Product Development and Commercialization Utilizing CompuFlo Technology***

Over the last decade, the drug delivery industry has evolved to become a key area in the development of value-added pharmaceutical products. According to market research firm Business Insights, The global market grew from \$15 billion to \$40 billion during 2000-2006 as companies increasingly turned to drug delivery technologies as a means of expanding product lifecycles, enhancing drug efficacy and maximizing revenues. Moreover, industry analysts agree that as patients live longer and are diagnosed with chronic and often debilitating ailments, the result will be a dramatic increase in self-administration of drug therapies in non-traditional settings for a number of conditions. This trend is creating an increased interest in routes of administration that are patient-friendly and cost-effective. It appears that pharma company decision makers are realizing that new drug product success no longer depends only on the medication itself, but also on achieving a patient-friendly form of delivery.

Central to Milestone's robust IP portfolio, currently comprised of 24 issued patents, is its FDA-approved *CompuFlo*® system for the precise delivery and aspiration of all medicaments. Milestone's patented *CompuFlo*® system and *DPS Dynamic Pressure Sensing*® technology are revolutionary technologies that are relevant for the entire category of subcutaneous drug delivery injections and fluid aspiration enabling healthcare practitioners to achieve multiple unique benefits that cannot currently be accomplished with existing technologies.

The negative side effects possible when using the manual hypodermic syringe are well documented in the medical and dental literature, and include tissue damage, transient or permanent paralysis, subjective pain response, post-operative complications, and the risk of medical emergencies, which in certain circumstances can result in a patient fatality. Patient pain and tissue damage are a direct physical result of a clinician's inability to accurately control a wide range of variables when using the manual syringe.

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**In contrast, the technical advantages of the *CompuFlo*® system with *DPS Dynamic Pressure Sensing*® technology are numerous and dramatic.** They include precise controlling and monitoring of **all** critical variables during drug delivery, including:

a true painless experience for all injections

eliminates disruptive injection behavior

site specific targeting

controlled needle exit-pressure

precise flow rate and drug volumes

patient treatment documentation

superior ergonomics

elimination of needle deflection (causing missed injections, lost time and anxiety )

advanced tactile needle control

precision fluid metering

The use of Milestone's technology also enables the clinician to receive real-time continuous feedback relating to the local tissue conditions during the injection process. This real-time feedback enables the accurate differentiation and identification of specific tissues types and anatomical locations, making subcutaneous drug delivery safer, easier and more effective, thereby fundamentally transforming what formerly was an art into a science.

Recognized as a world leader in advanced computer-controlled injection technologies, Milestone has spent over a decade developing and perfecting its portfolio of technologies that eliminate pain and enable unequaled precision that can be applied to a wide array of subcutaneous injections routinely used in the practice of Medicine and Dentistry. Moreover, none of Milestone's *C-CLAD* injection products look like a syringe or feel like a syringe, and they perform far better than the antiquated manual syringe, resulting in a much enhanced experience for the patient, the practitioner and the business of dentistry.

Based on an independent 2006 study, the number of potential applications for the *CompuFlo*® technology stands at more than 700. Due to the sizable number of product development opportunities within the medical arena for the technology, Milestone created an internal review committee to assess and analyze the opportunities in a variety of medical sectors. Consequently, we elected to focus on those medical uses of the *CompuFlo*® system which have shown to be most promising for obtaining a return on investment while simultaneously representing new product introductions that will have the greatest impact on patients and the medical profession. Areas of initial interest include developing *CompuFlo*®-based injection/aspiration systems for use in Epidurals, Intra-Articular Injections, Self-Administered Injections, Neurosurgery, Ophthalmic surgery and Derma Filler/Cosmetic surgery.

It should be noted that the *CompuFlo*® system is embedded in an FDA-approved prototype. This technology is currently commercially available in the *STA Single Tooth Anesthesia System*®, which is being sold worldwide in the dental market. Over 40 million patient injections have been given with Milestone's technologies to date.

Milestone's technological innovations have been tried and proven by healthcare providers with over 50 publications validating the efficacy and safety in a variety of medical and dental injection applications. It is anticipated that future devices that are developed utilizing the *CompuFlo*® system will only require a basic 510K approval from the FDA, thus minimizing development cost and time to market.

## ***Intellectual Property***

In August 2009, we were issued a Notice of Allowance by the U.S. Patent and Trademark Office for our patent application directed for the use of our disposable hand piece for fluid administration. Our award-winning handpiece is an instrument currently utilized in conjunction with our *STA Single Tooth Anesthesia System*®, the *CompuDent*® instrument and the *CompuMed*® instrument.

In September 2009, the U.S. Patent and Trademark Office issued a Notice of Allowance for our U.S. patent application, titled Computer Controlled Drug Delivery System with Dynamic Pressure Sensing. This intellectual property represents one of the key technological components of our product development strategy relating to the development of advanced computer-controlled injection products for specific applications in the medical industry most notably intra-articular injections and epidurals.



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During the second quarter of 2010, Milestone was issued a Notice of Allowance by the U.S. Patent and Trademark Office for its U.S. patent application, titled Self-Administration Injection System. Milestone's innovative computer-controlled drug delivery platform has been designed to reduce the anxiety and pain of self-administration of medications for the rapidly expanding home-use market. The computer-controlled self-administration system provides a less threatening, virtually painless means for patients to safely self-administer a variety of injections.

To date, we have been awarded and presently hold 24 U.S. utility and design patents relating to our *C-CLAD* technologies.

### **Summary of Significant Accounting Policies, Judgments and Estimates**

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to accounts receivable, inventories, stock-based compensation, and contingencies. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

#### *Accounts Receivable*

The realization of Accounts Receivable current and long-term will have a significant impact on us. Consequently, Milestone estimates allowance for doubtful accounts resulting from the inability of its customers to make payments for amounts billed. The collectability of outstanding amounts is continually assessed.

#### *Inventories*

Inventory costing, obsolescence and physical control are significantly important to the on-going operation of the business. Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or market. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess and obsolete inventory is recorded if required based on past and expected future sales.

#### *Investment in Joint Venture*

We entered into a Joint Venture with a third party for the development and commercialization of two medical products. We own fifty percent of the joint venture and has recorded its investment on the equity basis of accounting. The Company proportionate share of expenses incurred by the Joint Venture will be charged to the Statement of Operations on a periodic basis.

#### *Impairment of Long-Lived Assets*

Our long lived assets of principally patents and trademarks are the base features of the business. We review long-lived assets for impairment whenever circumstances and situations change such that there is an indication that the carrying amounts may not be recoverable. The carrying value of the asset is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets.

#### *Accounts Payable*

Current and long term accounts payable represents amounts due to suppliers of ours. Long term accounts payable is based on an informal financing agreement with the supplier to assist in the purchasing of instruments and handpieces, beyond one year from the balance sheet date.

**Table of Contents*****Revenue Recognition***

Revenue from product sales is recognized net of discounts and allowances to domestic distributor on the date of shipment for essentially all shipments, since the shipment terms are FOB warehouse. We will recognize revenue on date of arrival of the goods at the customer's location where shipments are FOB destination. Shipments to international distributors are FOB the warehouse and revenue is therefore recognized on shipment. In both cases the price to the buyer is fixed and the collectability is reasonably assured. Further, we have no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Customer acceptance is considered made at delivery. Milestone's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period, which have historically been immaterial.

***Results of Operations***

The consolidated results of operations for the three and nine months ended September 30, 2011 compared to the same three and nine month period in 2010 reflect our focus and development on the *Wand/STA Instruments*, as well as continuing efforts on identifying collaborative partners for new product development utilizing our *CompuFlo* technology.

The following table sets forth for the periods presented statement of operations data as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2011		2010		2011		2010	
Products sales, net	\$ 1,745,876	100%	\$ 1,926,889	100%	\$ 6,635,983	100%	\$ 7,708,136	100%
Cost of products sold	597,528	34%	725,795	38%	2,345,191	35%	2,788,353	36%
Gross Profit	1,148,348	66%	1,201,094	62%	4,290,792	65%	4,919,783	64%
Selling, general and administrative expenses	1,695,908	97%	1,704,896	88%	5,121,831	77%	5,024,791	65%
Research and development expenses	(7,403)	0%	60,533	3%	92,540	1%	228,734	3%
Total operating expenses	1,688,505	97%	1,765,429	91%	5,214,371	79%	5,253,525	68%
Loss from operations	(540,157)	-31%	(564,335)	-29%	(923,579)	-14%	(333,742)	-4%
Other income								
interest & expense	(37,154)	-2%	(19,191)	-1%	(93,443)	-1%	14,498	0%
Loss on Earnings from Joint Venture	(60,027)	-3%		0%	(60,027)	-1%		0%
Net loss	\$ (637,338)	-37%	\$ (583,526)	-30%	\$ (1,077,049)	-16%	\$ (319,244)	-4%

***Three months ended September 30, 2011 compared to three months ended September 30, 2010***

Total revenues for the three months ended September 30, 2011 and 2010 were \$1,745,876 and \$1,926,889, respectively. The decrease in product sales of \$181,013 or 9% in 2011 over 2010 is primarily due to a decrease of \$11,000 in instruments and approximately \$145,000 in handpiece sales. Domestic *STA Single Tooth Anesthesia System®* instruments sales decreased \$67,973 in 2011 over 2010. This decrease is due to reduced summer sales at the distributor and the group dental practice level in the domestic market. In the domestic market, handpiece sales increased by \$89,909 or 13.4%. This increase is due to our continued focus on training of the dentist on the various

applications of the STA handpieces in the third quarter of this year. On the international front, total revenue aggregated \$896,532 in 2011, a 15.5% decrease over 2010. International *STA Single Tooth Anesthesia System*® instruments sales increased in the third quarter of 2011 over 2010 by \$141,731 or 78%. International handpiece sales in the third quarter of 2011 over 2010 decreased by \$234,946 or 29% due to an decrease demand for *Wand Plus* handpieces in the international market. Overall, the international revenue for the three months ended September 30, 2011 decreased by \$164,390 over the same period in 2010. This decrease is due to the period slow down of our international footprint and demand for our product. We do not expect the trend to continue.

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Cost of products sold for the three months ended September 30, 2011 and 2010 were \$597,528 and \$725,795 respectively. The \$128,267 or 18% the major reason for this change is attributable to a decrease in sales volume.

For the three months ended September 30, 2011, Milestone generated a gross profit of \$1,148,348 or 66% as compared to a gross profit of \$1,201,094, or 62%, for the three months ended September 30, 2010. The total decrease in gross profit of \$52,746 is due to a decrease in sales volume, while the gross profit margin percentage increase is due to a reduction in the manufacturing costs for the STA instruments in 2011.

Selling, general and administrative expenses for the three months ended September 30, 2011 and 2010 were \$1,695,908 and \$1,704,896, respectively. The \$8,989 or .5% net decrease in selling, general and administrative expenses is due to an increase in sales expenses of \$77,287, an increase in salary expense of \$80,115 offset by a reduction in: (i) Marketing Expenses of \$67,271 and (ii) other G&A Expenses of \$96,003 including, but not limited to, decreases in International Sales Commission of \$60,826 based on decreased international sales and a recovery of bad debt expense of \$48,000. Consulting expenses increased by \$30,000.

Research and development expenses was a negative \$7,402 for the three months ended September 30, 2011 and a positive \$60,533, for the three months ended September 30, 2010. The decrease in expense for the quarter, September 30, 2011 is due to application of \$104,968 from the Joint Venture for reimbursement of expenses previously incurred by us.

The loss from operations for the three months ended September 30, 2011 was \$540,157 as compared to a loss from operations for the three months ended September 30, 2010 of \$564,335. The difference of \$24,178 or 4% decrease in loss from operations is explained above.

Interest expense was \$35,636 and amortization of debt issuance costs was \$1,532 relating to conversion of the \$1.3 million line of credit into common stock in December 2009 was charged for the three months ended September 30, 2011, compared to interest expense and amortization of debt issuance of \$18,553 and \$699, respectively, for the same period in 2010.

Loss on Joint Venture of \$60,027 for the quarter ending September 30, 2011, is due to development cost on the medical devices incurred by the joint venture during the quarter.

For the reasons explained above, net loss for the three months ended September 30, 2011 was \$637,338 as compared to a net loss of \$583,526 for the three months ended September 30, 2010. The \$53,812 or 9% increase in net loss is primarily a result of the decrease in sales and gross profit and an increase in payroll expenses, along with the net loss on the investment of the Joint Venture of \$60,027.

### ***Nine months ended September 30, 2011 compared to the nine months ended September 30, 2010***

Total revenues for the nine months ended September 30, 2011 and 2010 were \$6,635,983 and \$7,708,136, respectively. Total revenues decreased by \$1,072,153 or 14%. This decrease in revenue was due to \$1,289,900 of STA instrument sales and \$557,468 of handpiece sales (total \$1,847,368) to a Chinese distributor in 2010 that did not occur in 2011. On a comparative basis, excluding the 2010 sales to the Chinese distributor, total revenues increased by \$781,315. International revenue decreased \$1,269,955, or 29%, as compared to the 2010 period, as previously noted, as a result of the decrease in revenues from China. Excluding the 2010 sales to the Chinese distributor, the international revenue increased by \$577,413, as we continue our expansion in the international market. Domestic product revenue increased \$197,802 in 2011, or 6%, the increase is due to the increase in STA Single Tooth Anesthesia System® instruments sales, as management implements a new sales strategy focusing on group dental practices in the U.S. Domestic disposable handpiece sales decreased by \$122,305, or 5%. International sales of disposable handpieces decreased by \$471,547 or 21%, based on not shipping handpieces to China in 2011. On a comparative basis, excluding China handpiece sales for the nine months ending September 30, 2011 international handpiece sales increased by \$85,921. Overall, we believe that the domestic market focus on independent hygienist to train dentists throughout the USA will assist in the growth in handpiece sales in the future and the international market will continue to grow as more international distributors in other geographical areas of the world are added to our distributor portfolio.



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Gross profit for the nine months ended September 30, 2011 and 2010 was \$4,290,792 or 65% and \$4,919,783, or 64%, respectively. Gross profit dollars in the nine months of 2011 decreased by \$628,991, 13% due to a decrease in sales volume and gross profit margin in 2011 over 2010. The gross profit margin percentage increase is due to a reduction in the manufacturing costs for the *STA Single Tooth Anesthesia System*® instruments in 2011.

Selling, general and administrative expenses for the nine months ended September 30, 2011 and 2010 were \$5,121,831 and \$5,024,791, respectively. The increase of \$97,040 or 2% is primarily attributable to a decrease in Marketing Expenses of \$96,393; increases in Sales Expenses of \$151,705, an increase in Salary Expenses of \$440,024 offset by decrease in General and Administrative (G&A) Expense of \$440,495. Marketing expense decreased is principally due to a reduction in printing costs of \$30,016. Sales expenses increased by \$151,705, due to an overall increase in business travel domestic and international. Also included in the category are the costs related to our independent third party hygienists. Salary expenses increase by \$440,024 due primarily to a bonus to the Chief Executive Officer of \$300,000 for finalizing a joint venture agreement with a third party to develop two medical instruments and the increased costs of Directors of International and Domestic Sales. Other General and Administrative expenses decreased by \$440,495, primarily due to the decreased international commission of \$174,002, decrease in royalty expense of \$37,526, based on reduced total sales. Additionally, recovery of bad debt expense, \$89,000, based on partial collection of previously recorded bad debt reserve for an international accounts receivable. Employer recruitment cost decreased \$36,603, a decrease in finders fees of \$64,800 and a reduction in investor relations fee of \$31,125.

Research and development expenses for the nine months ended September 30, 2011 and 2010 were \$92,540 and \$228,734, respectively. The decrease of \$136,194 is due principally to application of \$104,968 from the Joint Venture for reimbursement of expenses previously incurred by us.

The loss from operation for nine months ended September 30, 2011 and 2010 was \$923,579 and \$333,742, respectively. The \$589,837 or 64% increase is explained above.

Other Income includes \$61,916 for the nine months ended in September 30, 2010. This represents the balance of the sale of tax credits under the New Jersey Technology Tax Certificate Program. This did not occur in 2011.

Interest expense of \$89,713 and amortization of debt issuance was \$3,764 relating to the conversion of the \$1.3 million line of credit into common stock in December 2009 was charged for the nine months ended September 30, 2011, compared to \$45,841 and \$2,097, respectively, for the same period in 2010.

Interest income of \$34 was earned for the nine months ended September 30, 2011 compared to \$520 for the same period in 2010.

Loss on Joint Venture of \$60,027 for the nine months ended September 30, 2011, is due to development cost of medical devices incurred by the joint venture.

For the reasons explained above, net loss for the nine months ended September 30, 2011 was \$1,077,049 as compared to a net loss of \$319,244 for the nine months ended September 30, 2010. The \$757,805 or 237% increase in net loss is primarily a result of a decrease in gross margin dollars of \$628,991 offset by an increase in selling, general and administrative expenses of \$97,040 offset by a reduction in research and development expense of \$136,194 and a reduction of \$61,916 (2010 sale of tax credit) in other income.

Working capital as of September 30, 2011 is a negative \$475,764 as explained in the following liquidity and capital resources section.

### **Liquidity and Capital Resources**

As of September 30, 2011 we had cash and cash equivalents of \$370,669 and a negative working capital of \$475,764, a decrease in working capital from December 31, 2010 of \$574,047. Milestone incurred a net loss of \$1,077,049 and \$319,244 for the nine months ended September 30, 2011 and 2010, respectively. There was a negative cash flow from operating activities of \$301,735 and \$724,698 for the nine months ended September 30, 2011 and September 30, 2010, respectively. The significant decrease in working capital of \$469,079 in 2011 was caused by a delay in obtaining regulatory approval to sell our instruments and handpieces in China. Based on the initial purchase order from our distributor in China in 2009, we ramped up purchasing of parts in anticipation of significant sales in 2010 and future years. As a result of the delay in shipping, the advances to contract manufacturer has increased significantly, (current and long term), in 2011 as compared to 2010. Additionally, the accounts payable due to

suppliers has also increased and is classified as current and long term. And finally, the accounts receivable from the China distributor has been classified between current and long term net of a reserve of doubtful accounts of \$552,000.

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The Company has entered into a Joint Venture with a third party for the development and commercialization of two medical products. We own fifty percent of the joint venture and has recorded our investment on the equity basis accounting.

We have also incurred increases in non current advances to contract manufacturer of \$892,718 and an increase in non current accounts payable of \$436,922 as a result of the delay in shipping instruments and handpieces to our distributor in China. We continue to take positive steps to maintain adequate inventory levels and advances to contract manufacturers to maintain available inventory to meet our domestic and international sales requirements. Cash flows from operating activities for the nine months ended September 30, 2011 and 2010 was a negative \$301,735 and \$724,698, respectively.

For the nine months ended September 30, 2011, our net cash used in operating activities was \$301,735. This was attributable primarily to a net loss of \$1,077,049 adjusted for noncash items of \$766,012 principally common stock and options issued for compensation, consulting and vendor services and changes in operating assets and liabilities of \$9,303. The changes in operating assets and liabilities are due to building up of inventory and the increase in advances for the expected sales growth in the fourth quarter of 2011.

For the nine months ended September 30, 2011, Milestone used \$33,679 in investing activities. This was attributable to \$27,414 of legal fees related to new patent application. Capital expenditures of \$6,265 were primarily for the leasehold improvement in the Livingston, New Jersey office.

For the nine months ended September 30, 2011, \$79,000 was provided by financing activities. This was attributable to the exercising of stock options and the sale of common stock.

As of September 30, 2011 and December 31, 2010, Milestone had recorded on the Balance Sheet a long term note payable of \$450,000 from a stockholder. This note was amended on June 29, 2011, to include an extended due date of July 2013, at no additional cost to the Company, other than additional interest expense to be incurred in future periods. We have incurred operating losses and negative cash flows from operating activities since inception, except for 2009. We are actively pursuing the generation of positive cash flows from operating activities through increases in revenues based upon management's assessment of present contracts and current negotiations and reductions in operating expenses. As of September 30, 2011, we believe that we have sufficient cash reserves to meet all of our anticipated obligations for the next twelve months. However, if we require a need for a higher level of marketing and sales effort, or if we are unable to continue generating positive cash flows from its operating activities we will need to raise additional capital. There is no assurance that we will be able to continue to achieve positive operating cash flows or that additional capital can be raised on the terms and conditions satisfactory to us if at all. If additional capital is required and it cannot be raised, then we would be forced to curtail its development activities, reduce marketing expenses for existing dental products or adopt other cost savings measures, any of which might negatively affect our operating results.

Our recurring losses and negative operating cash flows raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements do not include any adjustment that might result from the outcome of this uncertainty.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

As a smaller reporting company we are not required to provide the information required by this Item.



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**Item 4. Controls and Procedures**

The Company's management, including the Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of September 30, 2011 are effective to ensure that information required to be disclosed in the reports the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding disclosure.

There were no changes in the Company's internal control over financial reporting identified in connection with the evaluation that occurred during the Company's last fiscal quarter ended September 30, 2011 that have materially affected, or that are reasonably likely to materially affect, the Company's internal controls over financial reporting.

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**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None.

**ITEM 1A. RISK FACTORS**

As a smaller reporting company we are not required to provide the information required by this Item.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

Recent Sales of Unregistered Securities

In the nine months ended September 30, 2011, Milestone issued total 378,996 shares valued at \$198,584 as follows:

	Shares	\$
Shares issued for director's fee	75,000	\$ 45,000
Shares issued for employee compensation	27,829	22,500
Shares issued for services	176,167	106,084
Options exercised	100,000	25,000
	378,996	\$ 198,584

These issuances were exempt from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended (the Act) and a legend restricting the sale, transfer, or other disposition of these shares other than in compliance with the Act was imprinted on stock certificates evidencing the shares.

**ITEM 3. DEFAULT UPON SENIOR SECURITIES**

None.

**ITEM 4. [Removed and Reserved]**

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The following exhibits are filed herewith:

- 31.1 Chief Executive Officer Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Chief Operating Officer Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Chief Executive Officer Certification pursuant to section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Chief Operating Officer Certification pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

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101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.

\*\*      Furnished with this report. In accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

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**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.

**MILESTONE SCIENTIFIC INC.**

/s/ Leonard Osser  
Leonard Osser  
Chief Executive Officer

/s/ Joseph D Agostino  
Joseph D Agostino  
Chief Operating Officer  
and Chief Financial Officer

Date: November 10, 2011