

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, 2013**

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**

(State or other jurisdiction of incorporation or organization)

**13-3545623**

(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)

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(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  Non-accelerated filer  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 12, 2013, the registrant had a total of 17,615,096 shares of Common Stock, \$.001 par value outstanding.

MILESTONE SCIENTIFIC INC

FORM 10-Q

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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.*

MILESTONE SCIENTIFIC INC.  
CONDENSED BALANCE SHEETS

	September 30, 2013 (Unaudited)	December 31, 2012
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 401,836	\$ 165,249
Accounts receivable, net of allowance for doubtful accounts of \$17,862 as of September 30, 2013 and \$179,259 as of December 31, 2012	1,570,308	978,982
Receivable from Milestone Medical Inc	132,787	-
Inventories	874,559	638,561
Advances on contracts	501,469	476,969
Prepaid expenses and other current assets	116,945	239,061
Total current assets	3,597,904	2,498,822
Accounts receivable-long term, net of allowance for doubtful accounts of \$167,971 as of December 31, 2012	-	119,201
Advances on contracts	2,052,092	2,350,477
Investment in Milestone Education LLC	50,000	-
Furniture, Fixtures & Equipment net of accumulated depreciation of \$471,822 as of September 30, 2013 and \$458,708 as of December 31, 2012	26,622	36,624
Patents, net of accumulated amortization of \$478,916 as of September 30, 2013 and \$420,556 as of December 31, 2012	607,992	648,662
Other assets	12,917	7,317
Total assets	\$ 6,347,527	\$ 5,661,103
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 1,806,404	\$ 2,336,594
Accrued interest on Notes Payable	-	356,563
Accrued expenses and other payables	747,296	581,407
Total current liabilities	2,553,700	3,274,564
Long-term Liabilities:		
Notes Payable	-	450,000
Total long-term liabilities	-	450,000
Total liabilities	2,553,700	3,724,564
Commitments and Contingencies		
Stockholders' Equity		
Common stock, par value \$.001; authorized 50,000,000 shares; 17,572,055 shares issued 1,655,317 shares to be issued and 17,538,722 shares outstanding as of September 30, 2013; 16,563,306 shares issued, 1,635,709 shares to be issued, and 16,529,973 shares outstanding as of December 31, 2012	19,228	18,199
Additional paid-in capital	65,973,206	64,560,224
Accumulated deficit	(61,287,091)	(61,730,368)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total stockholders' equity	3,793,827	1,936,539
Total liabilities and stockholders' equity	\$ 6,347,527	\$ 5,661,103

See Notes to Condensed Financial Statements

MILESTONE SCIENTIFIC INC.  
CONDENSED STATEMENTS OF OPERATIONS  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Product sales	\$ 2,444,195	\$ 2,129,241	\$ 7,211,973	\$ 6,377,574
Cost of products sold	677,792	625,710	2,233,944	2,142,661
Gross profit	<u>1,766,403</u>	<u>1,503,531</u>	<u>4,978,029</u>	<u>4,234,913</u>
Selling, general and administrative expenses	1,317,433	1,391,521	4,045,465	4,330,847
Research and development expenses	12,698	60,363	177,419	139,176
Total operating expenses	<u>1,330,131</u>	<u>1,451,884</u>	<u>4,222,884</u>	<u>4,470,023</u>
Income (loss) from operations	436,272	51,647	755,145	(235,110)
Other income (expenses)				
Other income	-	-	17,543	-
Interest expense	(5,550)	(36,497)	(70,119)	(142,217)
Interest-Amortization of debt issuance	-	-	-	(3,065)
Loss on Earnings from Medical Joint Venture	(212,199)	-	(259,291)	(124,179)
Total other expenses	<u>(217,749)</u>	<u>(36,497)</u>	<u>\$ (311,868)</u>	<u>\$ (269,461)</u>
Net income (loss)	<u>\$ 218,523</u>	<u>\$ 15,150</u>	<u>\$ 443,277</u>	<u>\$ (504,571)</u>
Net income (loss) per share applicable to common stockholders -				
Basic	<u>\$ 0.01</u>	<u>\$ 0.00</u>	<u>\$ 0.03</u>	<u>\$ (0.03)</u>
Diluted	<u>\$ 0.01</u>	<u>\$ 0.00</u>	<u>\$ 0.03</u>	<u>\$ (0.03)</u>
Weighted average shares outstanding and to be issued -				
Basic	<u>17,333,941</u>	<u>16,244,800</u>	<u>16,955,048</u>	<u>15,953,925</u>
Diluted	<u>17,716,964</u>	<u>16,369,814</u>	<u>17,322,388</u>	<u>15,953,925</u>

See Notes to Condensed Financial Statements

MILESTONE SCIENTIFIC INC.  
CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
NINE MONTHS ENDED SEPTEMBER 30, 2013  
(Unaudited)

	Common Stock		Additional	Accumulated	Treasury	Total
	Shares	Amount	Paid-in Capital	Deficit	Stock	
Balance, January 1, 2013	18,199,015	\$ 18,199	\$ 64,560,224	\$ (61,730,368)	\$ (911,516)	\$ 1,936,539
Options to employees and consultants	-	-	56,205	-	-	56,205
Common stock to be issued to employee for bonuses	19,608	20	19,980	-	-	20,000
Common stock issued for directors compensation	39,129	39	44,961	-	-	45,000
Common stock issued for payment of consulting services	250,934	251	317,249	-	-	317,500
Common stock issued for conversion of notes payable and accrued interest	614,344	614	859,466	-	-	860,081
Common stock issued for payment of employee compensation	28,628	29	35,596	-	-	35,625
Exercise of stock options	40,000	40	29,560	-	-	29,600
Sale of Common Stock	35,714	36	49,964	-	-	50,000
Net income	-	-	-	443,277	-	443,277
Balance, September 30, 2013	19,227,372	\$ 19,228	\$ 65,973,206	\$ (61,287,091)	\$ (911,516)	\$ 3,793,827

See Notes to Condensed Financial Statements

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	2013	2012
Cash flows from operating activities:		
Net income (loss)	\$ 443,277	\$ (504,571)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation expense	13,114	14,482
Amortization of patents	58,360	57,097
Amortization of debt discount	-	3,065
Common stock and options issued for compensation, consulting and vendor services	512,846	281,648
Accrued interest expense on notes payable	-	64,329
Bad debt reversal	(295,488)	(140,293)
Loss on sale/disposal of equipment	-	1,604
Loss on Earning on Medical Joint Venture	259,291	124,179
Changes in operating assets and liabilities:		
(Increase) Decrease in accounts receivable	(309,424)	596,931
(Increase) Decrease in inventories	(235,998)	119,839
Decrease to advances on contracts	273,885	315,736
Decrease to prepaid expenses and other current assets	137,117	168,237
(Increase) Decrease in other assets	(5,600)	20,503
Decrease in accounts payable	(530,190)	(1,326,398)
Increase in accrued expenses	120,889	256,404
Net cash provided by operating activities	442,079	52,792
Cash flows from investing activities:		
Investment in Milestone Education LLC	(50,000)	-
Investment in Milestone Medical Inc.	(259,291)	-
Purchases of property and equipment	(3,111)	(4,061)
Payments for patent rights	(17,690)	(21,529)
Net cash used in investing activities	(330,092)	(25,590)
Cash flows from financing activities:		
Proceeds from exercise of stock options	29,600	-
Proceeds from the sale of common stock	50,000	150,000
Proceeds from related party loan	50,000	-
Repayment of related party loan	(5,000)	-
Net cash provided by financing activities	124,600	150,000
NET INCREASE IN CASH AND CASH EQUIVALENTS	236,587	177,202
Cash and cash equivalents at beginning of period	165,249	96,324
Cash and cash equivalents at end of period	\$ 401,836	\$ 273,526
Supplemental disclosure of cash flow information:		
Shares issued to directors for the exercise of stock options	\$ 29,600	\$ -
Shares issued to directors for compensation	\$ 45,000	\$ 45,000
Shares issued for conversion of notes payable and accrued interest	\$ 860,081	\$ -
Shares issued to employees in lieu of cash compensation	\$ 35,625	\$ 31,250

See Notes to Condensed Financial Statements

# MILESTONE SCIENTIFIC INC.

## NOTES TO CONDENSED FINANCIAL STATEMENTS (UNAUDITED) September 30, 2013

### 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, 2012 included in Milestone's Annual Report on Form 10-K.

In the opinion of management, 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, 2013 and the results of its operations for the three and nine months then ended.

The results reported for the three and nine months ended September 30, 2013 are not necessarily indicative of the results of operations which may be expected for a full year.

Milestone had a positive cash flow from operating activities for the nine months ended September 30, 2013 and 2012 of \$442,079 and \$52,792, respectively. At September 30, 2013, Milestone had cash and cash equivalents of \$401,836 and a positive working capital of \$1,044,204. The working capital increased by \$1,819,946 as compared to December 31, 2012 negative working capital of \$775,742. The positive change in working capital is due to the Company's increase in current assets (cash and accounts receivable) and a substantial reduction in accounts payable. Milestone borrowed \$450,000 in 2008 from a shareholder. This note and the related accrued interest was converted to common stock on August 8, 2013. The Company is actively pursuing the generation 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. As of September 30, 2013, Milestone does not expect to have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. Milestone may require a higher level of marketing and sales efforts that at present it cannot fund. If Milestone is unable to generate positive cash flows from its operating activities it will need to raise additional capital. There is no assurance that Milestone will be able to achieve positive operating cash flows or that traditional capital can be raised on terms and conditions satisfactory to Milestone, if at all. If positive cash flow cannot be achieved or if additional capital is required and it cannot be raised, then Milestone 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 Milestone's operating results.

Milestone's recurring 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**

### **Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board (the “FASB”) issued guidance to improve the transparency of reporting reclassifications out of accumulated other comprehensive income, by requiring an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under U.S. GAAP to be reclassified in its entirety to net income. For other amounts that are not required under U.S. GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under U.S. GAAP that provide additional detail about those amounts. The guidance was effective prospectively for reporting periods beginning after December 15, 2012. As this guidance relates to presentation only, the adoption of this guidance did not impact the Company’s financial position or results of operations.

In July 2013, the FASB issued guidance to eliminate the diversity in practice in presentation of unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. This new guidance requires the netting of unrecognized tax benefits against a deferred tax asset for a loss or other carryforward that would apply in settlement of the uncertain tax positions. Under the new guidance, unrecognized tax benefits will be netted against all available same-jurisdiction loss or other tax carryforward that would be utilized, rather than only against carryforwards that are created by the unrecognized tax benefits. The guidance is effective prospectively, but allows optional retrospective adoption (for all periods presented), for reporting periods beginning after December 15, 2013. As this guidance relates to presentation only, the adoption of this guidance will not impact the Company’s financial position or results of operations.

### **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.

Since Milestone had a net loss for the nine months ended September 30, 2012, the assumed effects of the exercise of outstanding stock options and warrants, and the conversion of convertible debt were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 1,445,614 at September 30, 2012.

### **NOTE – 3 ACCOUNTS RECEIVABLE**

Milestone sells a significant amount of its product on credit terms to its major distributors. Milestone 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, Milestone 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. A segment of the regulatory approval has been delayed and as such the customer has not paid the full amount of the invoiced shipment. The remaining balance due from this distributor is \$24,160 and \$527,172 as of September 30, 2013 and December 31, 2012, respectively. Milestone is receiving periodic payments from the international distributor and a substantial portion has been paid in 2013. Milestone reserved \$12,862 and \$308,350 of the total accounts receivable from this distributor as of September 30, 2013 and December 31, 2012, respectively.

#### NOTE – 4 INVESTMENT IN JOINT VENTURE

In March 2011, Milestone entered into an agreement with a People's Republic of China ("PRC") entity Beijing 3H Scientific Technology Co., Ltd (Beijing 3H), to establish a Medical Joint Venture entity in the PRC to develop intra-articular and epidural drug delivery instruments utilizing Milestone's patented *CompuFlo* technology (the "Medical Joint Venture"). Beijing 3H agreed to contribute up to \$1.5 million to this Medical 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. Milestone evaluates the technological feasibility of the products to be developed using the *CompuFlo* technology periodically and at every reporting date to establish if circumstances indicate that the technology continues to be feasible. Based on the available evidence Milestone concluded that the contingency associated with the return of capital to Beijing 3H would be remote as of September 30, 2013 and accordingly no amounts have been accrued in the accompanying financial statements relating to this contingency. Milestone, with the consent of Beijing 3H, organized a domestic research and development corporation to which the principal shareholders of Beijing 3H and other shareholders completed a capital contribution of \$ 1,500,000. The Medical Joint Venture entity is owned fifty percent by shareholders of Beijing 3H and fifty percent by Milestone. Milestone contributed an exclusive worldwide royalty-free license to use CompuFlo technology to the Medical Joint Venture which had a net book value of approximately \$245,000 and has accounted for its investment in the Medical Joint Venture using the equity method of accounting. Further, Milestone was authorized by the Medical Joint Venture to manage and oversee the development of the two products for the Medical Joint Venture. In connection with this authorization, Milestone also entered into an agreement with a significant vendor to develop the two instruments included in the Medical Joint Venture.

Milestone will have distribution responsibility in the U.S. and Canada. Beijing 3H will distribute products exclusively in the PRC, Macao, Hong Kong and other regions of Asia. The rest of the world responsibilities will be shared by Milestone and Beijing 3H.

Milestone recorded a Loss on Medical Joint Venture of \$259,291 for the nine months ended September 30, 2013 and \$212,199 for the three months ended September 30, 2013. The losses described represent fifty percent of the applicable losses record by medical joint venture during the periods. Milestone utilizes the equity of accounting to recognize its financial results of the joint venture.

Milestone expended approximately \$112,000 in the third quarter of 2013 for legal fees related to the FDA (510k) certifications. As part of the joint venture agreement, the Company is to pay all fees related to the USA FDA certification process.

The Medical Joint Venture's cumulative expenses since inception are approximately \$2 million. Milestone had reduced its investment to the Medical Joint Venture to zero in 2012. The accumulative loss that is not recognized on the statement of operations is approximately \$89,000. These losses will not be charged to the statement of operations as Milestone has not guaranteed and has no obligation to fund losses of the Medical Joint Venture in excess of its equity contribution.

Milestone provides management, financial, engineering and accounting services to Milestone Medical, Inc the value of these services prior to July 31, 2013, was not reimbursed by Milestone Medical, Inc and were charged to the investment in medical joint venture as shared services expenditures.

As of July 1, 2013, Milestone Scientific Inc. and Milestone Medical Inc., signed an agreement for the reimbursement of specific expenses incurred by Milestone Scientific Inc. specifically for the benefit of Milestone Medical Inc. Reimbursable expenses related to the agreement were approximately \$133,000 for the quarter ending September 30, 2013. The expenses related to the agreement have not been paid as of September 30, 2013 and are included in account receivable, net.

In July 2013, Milestone entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare. During the three year strategic partnership, the distributor will hold the exclusive rights to

market, resell, label and distribute Milestone's *CompuFlo* injection technology for use in epidural applications for childbirth and other pain management needs in hospitals in the U.S.

Milestone established a joint venture, Milestone Education, LLC, in the first quarter of 2013. Milestone contributed \$50,000 as did the other joint venture partner. Each of the partners owns fifty (50) percent of the joint venture. The joint venture is expected to provide training and education to our dentists throughout the world. There were no income and expenses associated with this joint venture in the third quarter of 2013. The Company accounted for its investment in the Education Joint Venture using the equity method of accounting.

#### NOTE – 5 STOCK OPTION PLANS

A summary of option activity for employees under the plans and changes during the nine months ended September 30, 2013, 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, 2013	1,283,741	0.79	3.07	768,692
Granted	-	-	-	-
Exercised	40,000	0.74	-	-
Forfeited or expired	36,666	0.94	-	-
Outstanding, September 30, 2013	1,207,075	0.87	2.49	614,768
Exercisable, September 30, 2013	794,620	0.84	1.93	421,506

Milestone recognizes compensation expense on a straight line basis over the requisite service period. For the three months ended September 30, 2013, the Company recognized \$18,735 of total compensation cost. During the nine months ended September 30, 2013, Milestone recognized \$56,205 of total compensation cost. As of September 30, 2013, there was \$109,971 of total unrecognized compensation cost related to non-vested options which Milestone expects to recognize over a weighted average period of 2 years. A six percent rate of forfeiture 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 and changes during the nine months ended September 30, 2013, 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, 2013	239,999	1.56	1.32	168,166
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited or expired	66,667	2.50	-	-
Outstanding, September 30, 2013	173,332	0.48	0.85	151,750
Exercisable, September 30, 2013	170,533	0.48	0.82	150,805

During the nine months ended September 30, 2013, Milestone had no expenses related to non-employee options that vested during the year. There was no unrecognized compensation cost related to non-vested options as of September 30, 2013.

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.

#### **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 on contracts. 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 on contracts. Milestone entered into a purchase agreement with a vendor to supply Milestone with 12,000 *STA Instruments* (7,585 instruments are remaining on the purchase order as of September 30, 2013). As part of these agreements, Milestone has advanced approximately \$2,554,000 and \$2,827,000 to the vendor for purchase of materials at September 30, 2013 and December 31, 2012, 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 to record accounts receivable at net realizable value as of September 30, 2013 and December 31, 2013.

#### **NOTE – 7 ADVANCES ON CONTRACTS**

The net advances on contracts represent funding of future *STA* inventory purchases. The balance of the net advances as of September 30, 2013 and December 31, 2012 is approximately \$2,554,000 and \$2,827,000, 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. Milestone has an outstanding accounts payable of approximately \$18,000 and \$705,000 at September 30, 2013 and December 31, 2012, respectively to the contract manufacturer specifically related to the advances. Milestone is making monthly payments to the contract manufacturer.

Additionally, Milestone has an agreement with the manufacturer of the *CompuDent* and *STA* instruments to accrue interest on their outstanding accounts payable balance. For the three months ending September 30, 2013 and 2012, the interest expense for this indebtedness was zero and \$13,805, respectively. For the nine months ending September 30, 2013 and 2012, the interest expense for this indebtedness was \$14,573 and \$75,945, respectively.

#### **NOTE – 8 LINE OF CREDIT AND NOTES PAYABLE**

Milestone borrowed \$450,000 from a shareholder in 2008. The loan was originally a short term loan with a maturity date of January 19, 2009. In December 2008, May 30, 2012 and again on March 29, 2013, this loan was extended with the shareholder and the due date has been extended to January 5, 2015. The loan accrues interest at 12% per annum, interest compounds quarterly, and interest and principal is due at the maturity. The loan (\$450,000) and related interest

(\$333,907) was converted to common stock on August 8, 2013. Further, the lender was granted 45,000 warrants exercisable at \$0.32 per share, which expired unexercised in 2012.

Interest expense for the three months ended September 30, 2013 and 2012 was \$5,550 and \$36,497, respectively. Interest expense for the nine months ended September 30, 2013 and 2012 was \$70,119 and \$142,217, respectively. The Company converted the accrued interest to common stock on August 8, 2013. The Company had also secured a line of credit, from this shareholder, for \$1.3 million which was converted into equity in 2009. The accrued interest, of \$76,174, on the line of credit was converted to common stock on August 8, 2013. For the three months ended September 30, 2013 and 2012, the charge for amortization of Debt Discount related to the outstanding line of credit is zero. The charge for amortization of Debt Discount related to the outstanding line of credit is zero and \$3,065 for the nine months ended September 30, 2013 and September 30, 2012, respectively.

#### **NOTE – 9 STOCK ISSUANCES**

During the nine months ended September 30, 2013, Milestone issued 35,714 units, at \$1.40 per unit and raised gross proceeds of \$50,000. Each unit consists of one share of common stock and one sixty day option to purchase a share of common stock at \$1.40 per share. Milestone issued 28,628 shares of common stock valued at \$35,625 for payment of employee compensation in the nine months ended September 30, 2013. Milestone issued 39,129 (13,043 shares to each of the non-employee directors), to the members of the Company's Board of Directors as partial compensation, (full year is \$30,000 per director), for serving on the Board for the 2013-2014 period. The cost of the compensation, for nine months, is \$45,000 or \$1.15 per share. The expense is being amortized over a six month period. Additionally, Milestone issued 40,000 shares of common stock to two independent directors for \$29,600 on their exercised stock options at \$0.74 per share, and 250,934 shares valued at \$317,500 were issued for payment of consulting services and reduction on the account payable balance. The Company issued 614,344 shares of common stock, valued at \$860,081 or \$1.40 per share, for the conversion of note payable and accrued interest, as identified in Note - 8.

#### **NOTE – 10 RELATED PARTY TRANSACTIONS**

A shareholder of Milestone is also a shareholder of a major supplier of handpieces to Milestone. In addition, he is an investor in the PRC entity, Beijing 3H, which entered into a Medical Joint Venture agreement with Milestone.

Milestone purchased \$2,146,096 and \$1,439,640 from the supplier for the nine months ended September 30, 2013 and 2012, respectively. Milestone owed \$854,680 and \$808,908 to this supplier as of September 30, 2013 and December 31, 2012, respectively, which is included in accounts payable on the accompanying condensed balance sheet.

In the first quarter of 2013, the CEO of Milestone loaned the Company \$50,000 for use in capitalizing a fifty percent equity portion in the joint venture with Milestone Education LLC. This balance is included in the accrued expenses on the condensed balance sheets. There is no interest to this agreement. \$5,000 of the loan has been paid to the CEO and the remaining balance will be paid by December 31, 2013.

In August 2013, a shareholder of the Company entered a three year agreement with the Milestone to provide financial and business strategic services. The fee for these services are \$100,000 annually.

#### **NOTE – 11 SIGNIFICANT CUSTOMERS & GEOGRAPHICAL INFORMATION**

For the three months ended September 30, 2013, Milestone had three customers (distributors) that approximately 57% of its net product sales and two customers (distributors) that approximately 54% of its net product sales for the three months ended September 30, 2012. Milestone had four customers (distributors) for the nine months ended September 30, 2013 that approximately 52% of its net product sales and two customers (distributors) that had approximately 40% of its net product sales for nine months ended September 30, 2012, respectively. Milestone had accounts receivable for two customers that amounted to \$919,381, representing 54% of the gross accounts receivable as of September 30, 2013 and accounts receivable for three customers that amounted to \$421,890 representing 38% of gross accounts receivable as of December 31, 2012, respectively.

	<u>Three Months Ended September 30,</u>			<u>Nine Months Ended September 30,</u>	
	<u>2013</u>	<u>2012</u>		<u>2013</u>	<u>2012</u>
<i>Instruments</i>	\$ 491,179	\$ 368,036	<i>Instruments</i>	\$ 1,760,079	\$ 1,495,773
Handpieces	1,927,391	1,717,201	Handpieces	5,328,751	4,756,482
Other	25,625	44,004	Other	123,143	125,319
	<u>\$ 2,444,195</u>	<u>\$ 2,129,241</u>		<u>\$ 7,211,973</u>	<u>\$ 6,377,574</u>
United States	\$ 1,526,608	\$ 1,342,798	United States	\$ 3,907,560	\$ 3,256,933
Canada	119,594	133,605	Canada	241,937	470,451
Other Foreign	797,993	652,838	Other Foreign	3,062,476	2,650,190
	<u>\$ 2,444,195</u>	<u>\$ 2,129,241</u>		<u>\$ 7,211,973</u>	<u>\$ 6,377,574</u>

## NOTE – 12 COMMITMENTS AND OTHER

### *Contract Manufacturing Arrangement*

Milestone has informal arrangements for the manufacture of its products. *STA*, single tooth anesthesia, *CompuDent* and *CompuMed* instruments are manufactured for Milestone by Tricor Systems, Inc. pursuant to specific purchase orders. The *STA* and *The Wand* Handpiece with Needle are supplied to Milestone by a contractor in the United States, which arranges for its manufacture 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 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.

The technology underlying the *SafetyWand* and *CompuFlo*, and an improvement to *CompuDent* were developed by the Director of Clinical Affairs and assigned to us. Milestone purchased this technology pursuant to an agreement dated January 1, 2005. The Director will receive additional payments of 2.5% of the total sales of products using certain of these technologies, and 5% of the total sales of products using certain other of the technologies. In addition, the Director is granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant, 8,333 shares of the common stock upon the issuance of each additional patent relating to these technologies. If products produced by third parties use any of these technologies (under license from us) then the Director will receive the corresponding percentage of the consideration received by Milestone for such sale or license. For the three months ended September 30, 2013 and 2012, Milestone expensed the Director's royalty fee of \$77,886 and \$70,330, respectively. Milestone expensed the Director's royalty fees of \$256,127 and \$221,987 for the nine months ended September 30, 2013 and 2012, respectively. Additionally, for the three months ended September 30, 2013 and 2012, the Company expensed consulting fees to the Director of \$12,350 and \$39,000, respectively. Milestone expensed consulting fees to the Director of \$90,350 and \$117,000 for the nine months ended September 30, 2013 and 2012, respectively.

In January 2010, the Company issued a purchase order to Tricor Instruments for the purchase of 12,000 *STA Instruments* to be delivered over the next three years. The purchase order is for \$5,261,640. The Company was invoiced \$3,095,763 advance of the purchase order and has paid the advance in full at September 30, 2013. As of September 30, 2013, the Company's production and sales of instruments as it relates to this commitment has been delayed. Consequently, advances on contracts have been classified as current and long term at September 30, 2013.

### *Other Events*

Milestone entered into finder's agreements with selected individuals for the purpose of identifying and closing a medical joint venture. As of September 30, 2013, none of the potential agreements has been consummated and therefore no expenses have been incurred. There is no expiration to these agreements.

In July 2013, Milestone entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare. During the three year strategic partnership, the distributor will hold the exclusive rights to market, resell, label and distribute Milestone's *CompuFlo* injection technology for use in epidural applications for childbirth and other pain management needs in the U.S. hospital sector.

In August 2013, a shareholder of the Company entered a three year agreement with the Milestone to provide financial and business strategic services. The fee for these services are \$100,000 annually.

#### *Subsequent Events*

In October 2013, the Company's fifty (50) percent owned medical joint venture, Milestone Medical Inc., signed subscription agreements for the sale of 2 million shares of Milestone Medical's common stock at \$1.50 per share in a private placement in Poland. The consummation of the private placement is subject to the satisfaction of all the closing conditions including, but not limited to, the admission of the Milestone Medical common stock for trading in the Alternative Trading System on the NewConnect market of the Warsaw Stock Exchange in Poland. As of the date of this report, the payment by the new investors have been fully received in escrow. Upon closing, the Company will own approximately forty-five (45) percent (post-transaction) of Milestone Medical Inc.

## **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 Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements.

### **OVERVIEW**

In 2013, Milestone remains focused on advancing efforts to achieve our two primary objectives; those being:

- Enhancing our global reach by partnering with distribution companies in the medical sector and
- 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, including the *STA Single Tooth Anesthesia Instrument (STA Instrument)*.

#### ***STA Instrument Growth***

Since its market introduction in early 2007, the *STA Instrument* and prior computerized controlled local anesthesia delivery products have been used to deliver over 48 million 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 Instrument* is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

#### ***Global Distribution Network***

##### **United States and Canadian Market**

In August 2013, Milestone entered an exclusive distributor agreement (beginning October 1, 2013), with Henry Schein, for the sale and distribution of the *CompuDent* handpieces in the United States and Canada.

In July 2013, Milestone entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare. During the three year strategic partnership, the distributor will hold the exclusive rights to market, resell, label and distribute Milestone's *CompuFlo* injection technology for use in epidural applications for childbirth and other pain management needs in the U.S. hospital sector.

In November 2012, Milestone entered an exclusive distribution and marketing agreement with a well known U.S. domestic manufacturer and distributor, for the sale and distribution of the *STA instruments* and *handpieces* in United States and Canada.

##### **International Market**

On the global front, we also have granted exclusive marketing and distribution rights for the *STA Instrument* to select dental suppliers in various international regions in Asia, Africa, South America and Europe.

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 Milestone's initial penetration into China's emerging dental market.

In early October 2012, the State Food and Drug Administration (SFDA) of the People's Republic of China approved Milestone's *Single Tooth Anesthesia System*® (*STA System*). Unfortunately, the SFDA bifurcated approval of the *STA Systems* from the *Wand*® handpieces.

As of September 30, 2013, Milestone Scientific has not received the appropriate registration approval from the regulatory body in China. It is expected that the approval by the Chinese regulatory body will be received by 2014.

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 *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 the growth of our products outside the USA and Canada.

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 medical instruments. Milestone Scientific has a 50% interest in the joint venture and shareholders of Beijing 3H and others have a 50% interest (the "Medical Joint Venture"). The Beijing 3H shareholders include a large shareholder in Milestone who is also the principal of a supplier to Milestone.

Milestone contributed an exclusive worldwide royalty-free license to use its patents as they pertain to these two instruments and disposables only to the Medical Joint Venture. Beijing 3H and its shareholders contributed \$1.5 million to the joint venture to enable the joint venture to design and develop two commercial instruments and related disposables using Milestone's *CompuFlo*® technology. Milestone will have distribution responsibility in the U.S. and Canada while Beijing 3H will distribute products exclusively in the People's Republic of China, Macao, Hong Kong and other regions of Asia. As of September 30, 2013, the Medical Joint Venture and the development project is ongoing and nearing the completion of the two medical instruments.

In October 2013, our fifty (50) percent owned medical joint venture, Milestone Medical Inc., signed subscription agreements for the sale of 2 million shares of Milestone Medical's common stock at \$1.50 per share in a private placement in Poland. The consummation of the private placement is subject to the satisfaction of all the closing conditions including, but not limited to, the admission of the Milestone Medical common stock for trading in the Alternative Trading System on the NewConnect market of the Warsaw Stock Exchange in Poland. As of the date of this report, the payment by the new investors have been fully received in escrow. Upon closing, we will own approximately forty-five (45) percent (post-transaction) of Milestone Medical Inc.

### ***Segmented Sales Performance***

The following table shows a breakdown of Milestone's 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,				Nine Months Ended September 30,			
	2013		2012		2013		2012	
<b>DOMESTIC</b>								
Instruments	\$ 251,104	16.4%	\$ 147,012	10.9%	\$ 842,788	21.6%	\$ 554,392	17.0%
Handpieces	1,248,636	81.8%	1,170,108	87.1%	2,971,609	76.0%	2,621,801	80.5%
Other	26,868	1.8%	25,678	2.0%	93,163	2.4%	80,740	2.5%
Total Domestic	<u>\$ 1,526,608</u>	<u>100.0%</u>	<u>\$ 1,342,798</u>	<u>100.0%</u>	<u>\$ 3,907,560</u>	<u>100.0%</u>	<u>\$ 3,256,933</u>	<u>100.0%</u>
<b>INTERNATIONAL</b>								
Instruments	\$ 240,075	26.2%	\$ 221,024	28.1%	\$ 917,291	27.8%	\$ 941,381	30.2%
Handpieces	678,755	74.0%	547,093	69.6%	2,357,142	71.3%	2,134,681	68.4%
Other	(1,243)	-0.2%	18,326	2.3%	29,980	0.9%	44,579	1.4%
Total International	<u>\$ 917,587</u>	<u>100.0%</u>	<u>\$ 786,443</u>	<u>100.0%</u>	<u>\$ 3,304,413</u>	<u>100.0%</u>	<u>\$ 3,120,641</u>	<u>100.0%</u>
<b>DOMESTIC/INTERNATIONAL ANALYSIS</b>								
Domestic	\$ 1,526,608	62.5%	\$ 1,342,798	63.1%	\$ 3,907,560	54.2%	\$ 3,256,933	51.1%
International	917,586	37.5%	786,443	36.9%	3,304,413	45.8%	3,120,641	48.9%
Total Product Sales	<u>\$ 2,444,194</u>	<u>100.0%</u>	<u>\$ 2,129,241</u>	<u>100.0%</u>	<u>\$ 7,211,973</u>	<u>100.0%</u>	<u>\$ 6,377,574</u>	<u>100.0%</u>

Milestone earned gross profits of 72% and 71% for the three months ended September 30, 2013 and 2012, respectively, and 69% and 66% for the nine months ended September 30, 2013 and 2012, respectively. However, the revenues and related gross profits have not been sufficient to support overhead, new product introduction and research and development expenses. Although we anticipate expending funds for research and development in 2013, these amounts will vary based on the operating results for each quarter. We incurred operating losses every year since our inception, except for the three months and nine months periods ended September 2013 and for the quarter ended June 30, 2009. At September 30, 2013, we believe that we do not have sufficient cash reserves to meet all of our anticipated obligations for the next twelve months. We are actively pursuing the generation of positive cash flows from operating activities through increase in revenue, assessment of current contracts and current negotiations. There is no assurance that we will be able to achieve positive operating cash flows or that additional capital raised on 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 our development activities, reduce marketing for existing products or adopt other cost saving measures, any of which might negatively affect our operating results.

### 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 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 Medical Joint Venture*

Milestone entered into a Medical Joint Venture with a third party, Beijing 3H, for the development and commercialization of two medical products. Milestone owns fifty percent of the Medical Joint Venture and have recorded our investment on the equity basis of accounting. Milestone's proportionate share of expenses incurred by the Medical Joint Venture will be charged to the Statement of Operations on a periodic basis.

### *Impairment of Long-Lived Assets*

Our long lived assets consisting principally of 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.

### *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 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 periods, which have historically been immaterial.

## **Results of Operations**

The consolidated results of operations for the three and nine months ended September 30, 2013 compared to the same three and nine months period in 2012 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, the 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,			
	2013		2012		2013		2012	
Products sales	\$2,444,195	100%	\$2,129,241	100%	\$ 7,211,973	100%	\$ 6,377,574	100%
Cost of products sold	677,792	28%	625,710	29%	2,233,944	31%	2,142,661	34%
Gross Profit	1,766,403	72%	1,503,531	71%	4,978,029	69%	4,234,913	66%
Selling, general and administrative expenses	1,317,433	54%	1,391,521	65%	4,045,465	56%	4,330,847	68%
Research and development expenses	12,698	1%	60,363	3%	177,419	2%	139,176	2%
Total operating expenses	1,330,131	55%	1,451,884	68%	4,222,885	58%	4,470,023	70%
Income (loss) from operations	436,272	17%	51,647	3%	755,145	11%	(235,110)	-4%
Other expenses - interest & expenses	(5,550)	0%	(36,497)	-2%	(52,576)	-1%	(145,282)	-2%
Loss on Earnings from Medical Joint Venture	(212,199)	-9%	-	0%	(259,291)	-4%	(124,179)	-2%
Net Income (loss)	\$ 218,523	8%	\$ 15,150	1%	\$ 443,277	6%	\$ (504,571)	-8%

### ***Three months ended September 30, 2013 compared to three months ended September 30, 2012***

Total product sales for the three months ended September 30, 2013 and 2012 were \$2,444,195 and \$2,129,241, respectively. The total increase in product sales of \$314,954, or 15%, in 2013 from 2012 is principally the result of increased domestic revenues. Domestic *STA* instruments sales increased by \$112,192 in 2013 from 2012. Additionally, in the domestic market, total handpiece sales increased by \$78,528, or 6.7% in 2013 over 2012. The increase in domestic instruments is due to the marketing efforts of our exclusive *STA Instrument* and handpiece distributor. The increase in handpieces was due to an exclusive distributor's agreement with Henry Schein for the purchases of *CompuDent* handpieces in the third quarter of 2013. On the international front, instruments sales increased in the third quarter of 2013 from 2012 by \$19,051, or 8.6%. Significant new market countries for the *STA Instruments* have not come on board in the quarter ending September 30, 2013. Internationally, handpiece sales increased by \$131,662, or 24% in 2013 over 2012. *CompuDent/Wand Plus* handpieces increased by \$99,013 or 33% and *STA* handpiece sales increased by \$32,649, or 13% for the third quarter 2013 over 2012. This trend supports the increased value of the *STA Instruments* being sold internationally versus the sale of the legacy *CompuDent/Wand Plus Instruments*.

Cost of products sold for the three months ended September 30, 2013 and 2012 were \$677,792 and \$625,710, respectively, an increase of \$52,082, or 8.3%.

For the three months ended September 30, 2013, Milestone generated a gross profit of \$1,766,403, or 72%, as compared to a gross profit of \$1,503,531, or 71%, for the three months ended September 30, 2012. The total increase in gross profit dollars of \$262,872 is primarily due to an increase in revenue.

Selling, general and administrative expenses for the three months ended September 30, 2013 and 2012 were \$1,317,433 and \$1,391,521, respectively. This reduction in expenses of \$74,088, or 5.32%, is described in the following sections of this report. Marketing expenses decreased by approximately \$28,000; sales expenses decreased by approximately \$55,000; salary decreased by approximately \$148,000; legal increased by approximately \$9,000 and other expenses increased by approximately \$147,000. Milestone continues to focus on controlling expenses in all categories. The third quarter of 2013 noted several areas of savings as Milestone continues on its planned business model change, through the training and education hygienist program. The decrease in marketing is due to the reduction of trade show and related expenses (travel, fees and staffing) of approximately \$4,000, marketing key opinion leaders and brochures of approximately \$16,000 and advertising of approximately \$7,000. Milestone targeted this venue as a more costly method to present our *Wand/STA Instrument*. Milestone has decided to focus its attention to the national shows that are more focused on larger attendance by the individual as well as dental practice groups. Additionally, a large portion of our previous marketing and selling costs in the U. S. and Canada are now incurred by our exclusive *STA* distributor. Sales expenses also decreased by approximately \$55,000, due to decrease in travel, tradeshow attendance and hygienists. The increase in other expenses of approximately \$147,000 is primarily due to an increase in payment of an international commission of approximately \$91,000 and the excise tax of approximately \$8,000. The reduction in salary expenses is due to the approximately \$60,000 shared expense for compensation for the Medical Joint Venture and

the reversal of bonus accruals of approximately \$35,000. Legal fees decreased by approximately \$6,000 in the aggregate, for routine litigation and patent annuities. Stock Based Compensation decreased by approximately \$9,000.

Research and development expenses for the three months ended September 30, 2013 and 2012 was \$12,698 and \$60,363, respectively, a decrease of \$47,665.

The income from operations for three months ended September 30, 2013 and 2012 were \$436,272 and \$51,647, respectively. The \$384,625, increase is explained above.

Interest expense of \$5,550, relating to the \$1.3 million line of credit which was subsequently converted into common stock in December 2009 and the \$450,000 long term note payable, was charged for the three months ended September 30, 2013, as compared to \$22,053 for the same period in 2012, (see Note 8 to the financials). Additionally, Milestone accrued interest expense of zero and \$13,805 for the overdue accounts payable on the balance to the instrument's contract manufacturer at September 30, 2013 and 2012, respectively.

Loss on the Medical Joint Venture of \$212,199 and zero for the quarter ending September 30, 2013 and 2012, respectively, is due to development cost on the medical devices incurred by the Medical Joint Venture during the quarter.

For the reasons explained above, the net income for the three months ended September 30, 2013 and 2012 were \$218,523 and \$15,150, respectively. The \$203,373, or 1342%, increase in net income is primarily a result of an increase in gross margin dollars of \$262,872 enhanced by a decrease in selling, general and administrative expenses of \$74,088, decrease in research and development expense of \$47,665 and a decrease in interest expense of \$30,947.

#### ***Nine months ended September 30, 2013 compared to the nine months ended September 30, 2012***

Total revenues for the nine months ended September 30, 2013 and 2012 were \$7,211,973 and \$6,377,574, respectively. Total revenues increased by \$834,399, or 13%. Domestic product revenue increased \$650,627 in 2013, or 20%, the increase is due to the increase in *STA Single Tooth Anesthesia System*® instruments sales by \$364,458. This increase is due in part to management's implementation of an exclusive domestic distributor and the sales and training strategy focused on concentrated geographical sales effort and increased support for all customers. The domestic disposable handpiece sales increased by \$349,808, or 13% due to a buying of *CompuDent* handpieces as a part of their exclusive distributor agreement with Milestone for the marketing and distribution of the *CompuDent* handpieces in the United States and Canada. International revenue increased by \$183,772. International sales of disposable handpieces increased by \$222,461 or 10.4%.

Cost of products sold for the nine months ended September 30, 2013 and 2012 were \$2,233,944 and \$2,142,661, respectively, an increase of \$91,283, or 4.3%.

Gross profit for the nine months ended September 30, 2013 and 2012 was \$4,978,029 or 69%, and \$4,234,913, or 66%, respectively. Gross profit dollars in the nine months of 2013 increased by \$743,116, or 18%, due to an increase in sales volume and gross profit margin in 2013 over 2012.

Selling, general and administrative expenses for the nine months ended September 30, 2013 and 2012 were \$4,045,465 and \$4,330,847, respectively. The decrease of \$285,382 or 6.6% is primarily attributable to a decrease in marketing expenses of \$57,018; a decrease in sales expenses of \$155,445, increase in general and administrative (G&A) expenses of \$31,694 and a decrease in salary expenses of \$91,087, principally due to a shared expense compensation of approximately \$60,000 related to the Medical Joint Venture. The marketing expenses decrease is principally due to a reduction in advertising and media placement costs of \$17,406, free goods and gifts by \$41,360 and tradeshow attendance by \$44,260 offset by the international marketing rebate program of \$47,000. Milestone has decided to focus its attention to the national shows that are more focused on larger attendance by the individual as well as dental practice groups. Additionally, a large portion of our previous marketing and selling costs in the U. S. and Canada are now incurred by our exclusive *STA* distributor. Sales expenses decrease by \$155,445, due to an overall decrease in business

travel domestic and international. Also included in the category are the costs related to our independent third party hygienists. Other general and administrative expenses increased by \$31,694. Additionally, recovery of bad debt expense, \$155,195, based on partial collection of previously recorded bad debt reserve for an international accounts receivable.

Research and development expenses for the nine months ended September 30, 2013 and 2012 were \$177,419 and \$139,176, respectively. The increase of \$38,243, or 27% is primarily due to the enhancement of *STA* instrument.

The income from operations for the nine months ended September 30, 2013 was \$755,145 and the loss from operations for nine months ended September 30, 2012 was \$235,110, respectively. The \$990,255, increase is explained above.

Other income is \$17,543 for the nine months ended September 30, 2013. This represents the sale of tax credits under the New Jersey Technology Business Tax Certificate Program. This did not occur in 2012.

Interest expense of \$53,518, relating to the converted \$1.3 million line of credit into common stock in December 2009 and the \$450,000 long term note payable, was charged for the nine months ended September 30, 2013, compared to \$64,329 for the same period in 2012, (see Note 8 to the financials). Additionally, Milestone accrued interest expense of \$14,573 and \$75,945 for the overdue accounts payable balance to the instrument manufacturer at September 30, 2013 and 2012, respectively.

Loss on the Medical Joint Venture of \$259,291 and \$124,179 for the nine months ended September 30, 2013 and 2012, respectively, is due to development cost on the medical devices incurred by the Medical Joint Venture.

For the reasons explained above, net income for the nine months ended September 30, 2013 was \$443,277 and the net loss for September 30, 2012 was \$504,571, respectively. The \$947,848, increase in net income is primarily a result of an increase in gross margin dollars of \$743,116 offset by a decrease in selling, general and administrative expenses of \$285,382; an increase in research and development expense of \$38,243; other income of \$17,543; a decrease in interest expense by \$75,163 and the increase to non-cash Loss on the Medical Joint Venture of \$135,112.

Working capital as of September 30, 2013 is a positive \$1,044,204, as explained in the following liquidity and capital resources section.

### **Liquidity and Capital Resources**

As of September 30, 2013, Milestone had cash and cash equivalents of \$401,836 and a positive working capital of \$1,044,204. Milestone had net income of \$443,277 and a net loss of \$504,571 for the nine months ended September 30, 2013 and 2012, respectively. The working capital of \$1,044,204 in 2013 was the positive result of increased current assets (cash and accounts receivable) and the substantial reduction of accounts payable due to a contract manufacturer, this in spite of the continued 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, Milestone 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 on contracts has decreased, (current and long term), at September 30, 2013 as compared to December 31, 2012. Additionally, the accounts receivable from the China distributor has been classified as current asset net of a reserve of doubtful accounts of \$12,862.

The positive working capital at September 30, 2013 was \$1,044,204 as compared to a negative working capital at December 31, 2012 was \$775,442. The substantial improvement in working capital is \$1,819,946. The significant current asset changes are: current accounts receivable increased by \$724,113, cash increased by \$236,587, and inventory increased by \$235,998. Current liabilities decreased by \$720,864, substantially due to a reduction in the accounts payable to our contract manufacturer.

Milestone has also incurred a decrease in noncurrent advances on contracts of \$298,385. Milestone continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements. Cash flows from operating activities for the nine months ended September 30, 2013 and 2012 were \$442,079 and 52,792, respectively.

For the nine months ended September 30, 2013, our net cash provided by operating activities was \$442,079. This was attributable primarily to a net income of \$443,277 adjusted for noncash items of \$548,123, principally common stock and options issued for compensation, consulting and vendor services, and changes in operating assets and liabilities of \$549,321.

For the nine months ended September 30, 2013, cash used in investing activities was \$330,092 as compared to \$25,590 for the same prior year period. The increase of \$304,502 was primarily attributable to an increase of \$245,237 of investment in the Medical Joint Venture.

For the nine months ended September 30, 2013, \$124,600 was provided by financing activities. We issued 35,714 units at \$1.40 per unit. Each unit consists of one share of common stock and one sixty day option to purchase a share of common stock at \$1.40 per share. The options were not exercised. Milestone also sold 40,000 shares of common stock to two independent directors for \$29,600 on their exercising of stock options. We issued 614,344 shares of common stock, valued at \$860,881, or \$1.40 per share, for the conversion of a note payable and accrued interest as identified in Note-8.

Milestone has incurred operating losses and negative cash flows from operating activities since its inception, except for June 30, 2009 and the nine months ended September 30, 2013. Milestone is 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, 2013, Milestone believes that it does not have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months. However, if Milestone requires a need for a higher level of marketing and sales effort, or if Milestone is unable to continue generating positive cash flows from its operating activities it will need to raise additional capital. There is no assurance that Milestone 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 Milestone if at all. If additional capital is required and it cannot be raised, then Milestone 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 Milestone's operating results.

### **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.

### **Item 4. Controls and Procedures**

Milestone's management, including the Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of Milestone'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, Milestone's Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of September 30, 2013 are effective to ensure that information required to be disclosed in the reports Milestone 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 Milestone's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding disclosure.

There were no changes in Milestone's internal control over financial reporting identified in connection with the evaluation that occurred during Milestone's last fiscal quarter ended September 30, 2013 that have materially affected, or that are reasonably likely to materially affect, Milestone's internal controls over financial reporting.

## 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, 2013, Milestone issued total 1,008,749 shares valued at \$1,337,806 as follows:

	<u>Shares</u>	<u>\$</u>
Shares issued for director's compensation	39,129	\$ 45,000
Shares issued for employee compensation	28,628	35,625
Shares issued for conversion of notes payable & accrued interest	614,344	860,081
Shares issued for services	250,934	317,500
Exercise of stock options for directors	40,000	29,600
Sale of Common Stock	35,714	50,000
	<u>1,008,749</u>	<u>\$ 1,337,806</u>

These issuances were exempt from registration pursuant to Section 4 (a)(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. MINE SAFETY DISCLOSURES

Not applicable.

### 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.\*

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.\*

\*Filed herewith.

## 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  
(Principal Executive Officer)

/s/ Joseph D'Agostino

Joseph D'Agostino  
Chief Operating Officer  
Chief Financial Officer  
(Principal Financial Officer)

Date: November 12, 2013

**Rule 13a-14(a)/15d-14(a) Certification**

I, Leonard Osser, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Milestone Scientific 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 my supervision, to ensure that material information relating to Milestone, 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 principles;
  - 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, Milestone'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 12, 2013

/s/ Leonard Osser  
Leonard Osser  
Chief Executive Officer  
(Principal Executive Officer)

## Exhibit 31.2

### Rule 13a-14(a)/15d-14(a) Certification

I, Joseph D'Agostino, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Milestone Scientific 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 my supervision, to ensure that material information relating to Milestone, 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 principles;
  - 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, Milestone'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 12, 2013

/s/ Joseph D'Agostino  
Joseph D'Agostino  
Chief Operating Officer  
Chief Financial Officer  
(Principal Financial Officer)

**Exhibit 32.1**

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 of Milestone Scientific Inc (the “Company”) on Form 10-Q for the period ending September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Leonard Osser, Chief Executive Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone

Dated: November 12, 2013

/s/ Leonard Osser

Leonard Osser  
Chief Executive Officer  
(Principal Executive Officer)

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.

**Exhibit 32.2**

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 of Milestone Scientific Inc (the "Company") on Form 10-Q for the period ending September 30, 2013 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph D'Agostino, Chief Financial Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone

Dated: November 12, 2013

/s/ Joseph D'Agostino

Joseph D'Agostino  
Chief Operating Officer  
Chief Financial Officer  
(Principal Financial Officer)

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.