MILESTONE SCIENTIFIC INC. Form 10-Q November 15, 2010

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-Q

(Mark One)

**DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** 

For the quarterly period ended September 30, 2010

or

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

For the transition period from \_\_\_\_\_

Commission File Number: <u>001-14053</u> <u>MILESTONE SCIENTIFIC INC.</u>

(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. b Yes o 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). o Yes o 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 Non-accelerated filer o accelerated filer Filer o

Smaller reporting company b

(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). o Yes b No

As of November 12, 2010, the Issuer had a total of 14,909,262 shares of Common Stock, \$.001 par value outstanding.

# PART I FINANCIAL INFORMATION

Item	1	Finana	acial	<b>Statements</b>
TICIII	1.	rmana	ıcıaı	Statements

Condensed Balance Sheets September 30, 2010 (Unaudited) and December 31, 2009 (Audited)	4
Condensed Statements of Operations Three Months and Nine Months Ended September 30, 2010 and 2009 (Unaudited)	5
Condensed Statement of Changes in Stockholders Equity Nine Months Ended September 30, 2010 (Unaudited)	6
Condensed Statements of Cash Flows Nine Months Ended September 30, 2010 and 2009 (Unaudited)	7
Notes to Condensed Financial Statements (Unaudited)	8
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3. Quantitative and Qualitative Disclosures About Market Risk	23
Item 4. Controls and Procedures	23
PART II OTHER INFORMATION	
Item 1. Legal Proceedings	24
Item 1A. Risk Factors.	24
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.	25
Item 3. Defaults Upon Senior Securities.	25
Item 4. [Removed and Reserved]	25
Item 5. Other Information.	25
<u>Item 6. Exhibits</u>	26
<u>SIGNATURES</u>	
Exhibit 31.1 Exhibit 31.2 Exhibit 32.1 Exhibit 32.2	

#### **Table of Contents**

#### 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 and Section 21E of 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.

# **Table of Contents**

# MILESTONE SCIENTIFIC INC. CONDENSED BALANCE SHEETS

	September 30, 2010 (Unaudited)	December 31, 2009
ASSETS	(,	
Current Assets: Cash and cash equivalents	\$ 207,726	\$ 1,029,129
Accounts receivable, net of allowance for doubtful accounts of \$10,000 in 2010 and \$5,000 in 2009 Inventories	2,122,128 1,153,023	1,063,742 804,736
Advances to contract manufacturer	1,941,946	151,995
Prepaid expenses and other current assets	243,498	254,501
Total current assets Advances to contract manufacturer, non current	5,668,321 252,070	3,304,103 311,230
Investment in distributor, at cost Furniture, Fixtures & Equipment net of accumulated depreciation of \$435,443 as of September 30, 2010 and \$395,630 as of December 31,	76,319	76,319
2009 Patents, net of accumulated amortization of \$273,767 as of	66,896	77,353
September 30, 2010 and \$211,539 as of December 31, 2009	952,437	947,315
Other assets	74,417	133,674
Total assets	\$ 7,090,460	\$ 4,849,994
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities: Accounts payable Accrued interest - 6% note, current	\$ 3,054,048 92,000	\$ 1,154,013
Accrued expenses and other payable	564,031	524,017
Total current liabilities	3,710,079	1,678,030
Long-term Liabilities:		
Accrued Interest - 6% note, non current Accrued Interest - 12% note, non current	18,409 109,312	92,000
Notes Payable-net of discount of \$9,060 and \$11,157 respectively	440,940	438,843
Total long-term liabilities	568,661	530,843
Commitments and Contingencies Stockholders Equity		
Common stock, par value \$.001; authorized 50,000,000 shares; 14,909,262 shares issued 692,498 shares to be issued and 14,875,929 shares outstanding as of September 30, 2010; 14,781,295 shares issued,	15,601	15,472

692,499 shares to be issued, and 14,747,962 shares outstanding as of

Additional paid-in capital	62,790,333	62,300,619
Accumulated deficit	(59,082,698)	(58,763,454)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total stockholders equity	2,811,720	2,641,121

\$

7,090,460

\$

4,849,994

See Notes to Condensed Financial Statements (Unaudited)

Total liabilities and stockholders equity

# **Table of Contents**

# MILESTONE SCIENTIFIC INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

	T	Three Months Ended September 30,			Nine Months Ended September 30,			September
		2010	-,	2009		2010	·,	2009
Product sales, net Cost of products sold	\$	1,926,889 725,795		1,909,263 709,003	\$	7,708,136 2,788,353	\$	6,150,984 2,488,294
Gross profit		1,201,094		1,200,260		4,919,783		3,662,690
Selling, general and administrative								
expenses		1,704,896		1,477,948		5,024,791		4,960,000
Research and development expenses		60,533		57,972		228,734		157,941
Total operating expenses		1,765,429		1,535,920		5,253,525		5,117,941
Loss from operations		(564,335)		(335,660)		(333,742)		(1,455,251)
Other income (expense)						61,916		
Interest expense		(18,552)		(30,230)		(45,841)		(115,619)
Interest-Amortization of debt issuance		(699)		(7,875)		(2,097)		(23,625)
Interest income		60		495		520		3,041
Net loss applicable to common	Φ	(502 526)	Φ.	(272, 270)	Ф	(210.244)	Φ.	(1.501.454)
stockholders	\$	(583,526)	\$	(373,270)	\$	(319,244)	\$	(1,591,454)
Net loss per share applicable to common								
stockholders - Basic and diluted	\$	(0.04)	\$	(0.03)	\$	(0.02)	\$	(0.12)
Weighted average shares outstanding and to be issued - Basic and diluted		14,862,549		13,486,513		14,806,272		13,139,276
See Notes to Condensed Financial Statements (Unaudited)								

#### **Table of Contents**

# MILESTONE SCIENTIFIC INC. CONDENSED STATEMENT OF CHANGES IN STOCKHOLDERS EQUITY NINE MONTHS ENDED SEPTEMBER 30, 2010 (Unaudited)

	Common	Stock	Additional Paid-in	Accumulated	Treasury	
	Shares	Amount	Capital	Deficit	Stock	Total
Balance, January 1, 2010 Options issued to employees and	15,473,794	\$ 15,472	\$ 62,300,619	\$ (58,763,454)	\$ (911,516)	\$ 2,641,121
consultants			314,988			314,988
Common stock issued for directors compensation Common stock issued for payment of consulting	34,614	35	44,965			45,000
services to settle accounts payable Common stock issued for	76,661	77	103,923			104,000
payment of employee compensation Net Loss	16,692	17	25,838	(319,244)		25,855 (319,244)
Balance, September 30, 2010	15,601,761	\$ 15,601	\$ 62,790,333	\$ (59,082,698)	\$ (911,516)	\$ 2,811,720

See Notes to Condensed Financial Statements (Unaudited)

**Table of Contents** 

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

	NINE MONTHS ENDED SEPTEMI 30,				
		2010	٠,	2009	
Cash flows from operating activities:	ф	(210.244)	ф	(1.501.454)	
Net loss	\$	(319,244)	\$	(1,591,454)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation expense		39,813		39,030	
Amortization of patents		62,228		56,174	
Amortization of debt discount		2,097		23,625	
Common stock and options issued for compensation, consulting and		,		,	
vendor services		433,943		787,040	
Bad debt expense		5,000			
Changes in operating assets and liabilities:					
(Increase) Decrease in accounts receivable		(1,063,386)		424,862	
(Increase) in inventories		(348,287)		(168,739)	
(Increase) Decrease to advances to contract manufacturer		(1,730,791)		192,695	
Decrease to prepaid expenses and other current assets		66,903		82,162	
Decrease (Increase) in other assets		59,257		(136,329)	
Increase in accounts payable		1,900,035		89,239	
Increase in accrued expenses  (Degraces) in deferred companyation		167,734		46,247	
(Decrease) in deferred compensation				(2,500)	
Net cash used in operating activities		(724,698)		(157,948)	
Cash flows from investing activities:					
Purchases of property and equipment		(29,355)		(36,276)	
Payment for patents rights		(67,350)		(76,986)	
Not each used in investing activities		(06.705)		(112.060)	
Net cash used in investing activities		(96,705)		(113,262)	
Cash flows from financing activities:					
Proceeds from sale of stock options				25,000	
Not such analysis de har financing activities				25,000	
Net cash provided by financing activities				25,000	
NET DECREASE IN CASH AND CASH EQUIVALENTS		(821,403)		(246,210)	
Cash and cash equivalents at beginning of period		1,029,129		743,665	
Cash and cash equivalents at end of period	\$	207,726	\$	497,455	
Supplemental disclosure of cash flow information:					
Income taxes paid	\$	4,357	\$	8,225	
Interest paid	\$	69,000	\$		

11

See Notes to Condensed Financial Statements (Unaudited)

7

#### **Table of Contents**

# 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. In June 2009 The Company moved its headquarters to 45 Knightsbridge Road in Piscataway, New Jersey. In June 2010, the Company cancelled the lease in Piscataway and moved to 220 South Orange Avenue, Livingston, New Jersey.

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, 2009 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, 2010 and December 31, 2009 and the results of its operations for the three and nine months ended September 30, 2010 and 2009.

The results reported for the three and nine months ended September 30, 2010 are not necessarily indicative of the results of operations which may be expected for a full year.

The Company has negative cash flows from operating activities of \$724,698 and \$157,948 for the nine months ended September 30, 2010 and September 30, 2009, respectively. At September 30, 2010, the Company had cash and cash equivalents and working capital of \$207,726 and \$1,958,242, respectively. The Company s working capital increased by \$332,169. The Company borrowed \$450,000 in 2008 from a shareholder, with a due date of January 2009. This borrowing was refinanced at December 31, 2008 and the due date was extended to June 30, 2012. The Company is continuing the pursuit of positive cash flows from operating activities. For the last several quarters, the Company has been in a program to reduce its operating expenses. The Company anticipates a higher level of marketing and sales which may require 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 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 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.

8

#### **Table of Contents**

#### **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.

#### **Patents**

Patents are recorded at actual cost to prepare and filed with the United States Patent Office, or internationally with the appropriate 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 its 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.

# **Revenue Recognition**

Revenue from product sales is recognized net of discounts and allowances to our domestic distributors on the date of arrival of the goods at the customer s location as shipments are FOB destination. Shipments to our international distributors are FOB our 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 sale installation, set-up or maintenance, these being the responsibility of the buyer. Customer acceptance is considered made at delivery. Our only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective instrument 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.

#### **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.

#### **Table of Contents**

The carrying amounts reported in the consolidated 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**

FASB ASC Topic 860 Accounting for Transfers of Financial Assets (SFAS 166) an amendment of FASB No. 140 was issued in June 2009. The purpose of this Statement was to address practices that developed subsequent to the issuance of SFAS No. 140, that were not consistent with the intent or key requirements of that Statement. This Statement must be applied as of the beginning of each entity s first annual reporting period that begins after November 15, 2009. The adoption of this Statement did not materially impact the financial statements of the Company.

In the second quarter of 2010, the FASB issued Accounting Standards Updates (ASU) 2010-09, *Fair Value Measurements and Disclosures: Improving Disclosures about Fair Value Measurements* (ASU 2010-06). ASU 2010-06 amends FASB ASC Topic 820, *Fair Value Measurements and Disclosures*, and requires reporting entities to make new disclosures about recurring or nonrecurring fair-value measurements. ASU 2010-06 also clarifies existing fair-value measurement disclosure guidance about the level of disaggregation, inputs and valuation techniques. Except for the detailed Level 3 rollforward disclosures, we adopted the provisions of ASU 2010-06 in the first quarter of 2010. This adoption did not affect our financial statements. We will adopt the provisions of ASU 2010-06 related to the new Level 3 rollforward disclosures in the first quarter of 2011. This adoption in 2011 will not affect our financial statements.

In the first quarter of 2010, the FASB issued ASU 2010-09, *Subsequent Events: Amendments to Certain Recognition and Disclosure Requirements* (ASU 2010-09). ASU 2010-09 amends ASC 855, *Subsequent Events*, so that SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in financial statements. We adopted the provisions of ASU 2010-09 in the first quarter of 2010.

#### Accounting Guidance Issued But Not Adopted as of September 30, 2010

In October 2009, the FASB issued ASU 2009-13, Revenue Recognition (Topic 605): Multiple-Deliverable Revenue Arrangements a consensus of the FASB Emerging Issues Task Force, which amends the criteria for when to evaluate individual delivered items in a multiple deliverable arrangement and how to allocate consideration received. This ASU is effective for fiscal years beginning on or after June 15, 2010, which is January 1, 2011 for the Corporation. The Corporation is currently evaluating the impact of adopting the guidance.

#### 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 net losses for the three and nine months ended September 30, 2010 and 2009, 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 1,644,474 and 175,000 at September 30, 2010 and 2009, respectively.

#### NOTE 3 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.

#### **Table of Contents**

A summary of option activity for employees under the plans as of September 30, 2010, and changes during the nine months ended, is presented below:

	Number of Options	Weighted Averaged Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value	
Outstanding, January 1, 2010	1,060,142	\$ 1.33	3.61	\$	
Granted	73,333	1.49	9.12		
Exercised					
Forfeited or expired	(159,000)	1.88			
Outstanding, September 30, 2010	974,475	1.26	3.62	136,549	
Exercisable, September 30, 2010	561,671	1.11	2.60	130,082	

Milestone recognizes compensation expense on a straight line basis over the requisite service period. During the nine months ended September 30, 2010, Milestone recognized \$219,941 of total compensation cost. As of September 30, 2010, there was \$220,885 of total unrecognized compensation cost related to non-vested options which Milestone expects to recognize over a weighted average period of 1.80 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, 2010, and changes during the nine months ended, is presented below:

	Number of Options		ghted raged ercise rice	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value	
Outstanding, January 1, 2010	414,999	\$	1.90	2.70	\$	
Granted	128,333		1.74	0.70		
Exercised						
Forfeited or expired	(8,333)		2.46			
Outstanding, September 30, 2010	534,999		1.85	1.69	113,950	
Exercisable, September 30, 2010	514,998		1.88	1.59	112,783	

During the nine months ended September 30, 2010, Milestone recognized \$61,647 of expenses related to non-employee options that vested during the period. The total unrecognized compensation cost related to non-vested options was \$42,102 as of September 30, 2010.

In March of 2010, the Company entered an agreement with a public relations firm to supply services to the Company over a three year (cancelable) agreement. The first year of the agreement required 120,000 options to be provided with immediate exercisability. The fair value of these options of approximately \$80,000 was recorded as an asset and an addition to additional paid in capital. The options continue to run through March 2011. The entire \$80,000 will be amortized to expense over the twelve month period. The Company canceled the agreement in September 2010.

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.

11

#### NOTE 4 CONCENTRATION OF CREDIT RISK

Milestone s financial instruments that are exposed to concentrations of credit risk consist primarily of cash, trade accounts receivable, and advances to contract manufacturers. 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 in 2004 with a vendor to supply Milestone with 5,000 instruments of *CompuDent*®. As part of this agreement, Milestone has a remaining advance of approximately \$341,320 with the vendor for purchase of materials at September 30, 2010. 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 at September 30, 2010.

In 2010, the Company entered into a three year agreement to purchase materials for the 12,000 instruments of the *STA Single Tooth Anesthesia System*<sup>®</sup>, for delivery to our distributor in China over the same period. As of September 30, 2010, the Company recorded an increase in advances to contract manufacturer of \$1,730,791 for the parts.

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 does not believe that significant credit risk exists with respect to accounts receivable at September 30, 2010.

#### NOTE 5 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. Three year warrants exercisable at \$5.00 per share, in an amount determined by dividing 50% of the amount borrowed by \$5.00 will be issued on each drawdown. There is no facility fee on the line. The warrants have been valued as of each draw down using the Black-Scholes model and are reflected as a discount against the debt incurred under this line of credit. 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 on the Line of Credit of aggregated \$110,409 was accrued as of September 30, 2010. This interest will be paid in equal quarterly payments of \$23,000 over the next two years. 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 borrowing includes a twelve percent 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, 2010, the discount was \$9,060.

Interest expense on this Line of Credit and long term loan for the nine months ended September 30, 2010 and 2009 is \$45,841 and \$115,619, respectively. Accrued interest related to these borrowings was \$219,721 and \$92,000 at September 30, 2010 and December 31, 2009, respectively. The charge for amortization of Debt Discount related to this Line of Credit is \$2,097 and \$23,625 for the nine months ended September 30, 2010 and September 30, 2009, respectively.

#### NOTE 6 STOCK ISSUANCE

During the nine months ended September 30, 2010, the Company issued 76,661 shares of common stock valued at \$104,000 to three parties owed in connection with public relations and consulting expenses. Additionally, 16,692 shares of common stock valued at \$25,855 were issued for payment of employee compensation and 34,614 shares of common stock valued at \$45,000 were issued for director s compensation.

#### NOTE 7 SIGNIFICANT CUSTOMERS

Milestone had net product sales to three customers (distributors) which in the aggregate accounted for approximately 63% and 72% of revenue for nine months ended September 30, 2010 and 2009, respectively. Milestone had sales to one of these major customers (a 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 three customers amounted to \$1,575,881 and \$174,311 representing 77% and 35% of gross accounts receivable as of September 30, 2010 and September 30, 2009, respectively.

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

	Three Months Ended September 30,			
		2010	,	2009
Instruments	\$	427,362	\$	511,531
Handpieces	\$	1,477,715	\$	1,373,255
Other	\$	21,812	\$	24,477
	\$	1,926,889	\$	1,909,263
United States	\$	865,967	\$	1,151,475
Canada	\$	97,954	\$	148,916
Other Foreign	\$	962,968	\$	608,872
	\$	1,926,889	\$	1,909,263
	Ni	ne Months Ende	ed Se	
7	ф	2010	Φ	2009
Instruments	\$ \$	2,851,614	\$	2,113,653
Handpieces Other	\$	4,781,987 74,535	\$ \$	3,968,836 68,495
	\$	7,708,136	\$	6,150,984
United States	\$	3,329,793	\$	4,038,306
Canada	\$	468,462	\$	441,366
Other Foreign	\$	3,909,881	\$	1,671,312
	\$	7,708,136	\$	6,150,984

Milestone continues to selectively expand its domestic distribution network in 2010. Further, Milestone is expanding and enhancing its reach to the dental community in Canada.

Milestone has also focused on expanding its global distribution network, granting exclusive rights to market, distribute and sell its products in certain key geographic markets around the world. In June 2008, the Company named Istrodent Pty Ltd AB as exclusive distributor of the *STA Single Tooth Anesthesia System*® (and ancillary products) in South Africa, and Unident AB as its exclusive distributor in Denmark, Sweden, Norway and Iceland. In April 2009, Milestone awarded exclusive distribution and marketing rights to China National Medicines Corporation, d/b/a Sinopharm, for the *STA Single Tooth Anesthesia System*® (and ancillary products).

As of July 1, 2009, Milestone established a direct path to its international distributors networks. Effectively, Milestone will sell directly to existing and new international distributors, rather than through its previous worldwide distributor in South Africa. As part of the change, Milestone agreed to pay a commission to the previous distributor, based on actual international sales, over the next six years. The commission is structured at two levels: Level One is based on historical sales volume, and Level Two is determined for incremental sales volume over the Level One plateau. The Company evaluated this event in September 2009 and continues to monitor the agreement through the date that the financial statements are issued. The commission paid to the previous distributor was \$476,633 for the nine months ended September 30, 2010 and is included in the accompanying financial statements within the selling, general and administrative expenses.

#### NOTE 8 COMMITMENTS AND OTHER

Contract Manufacturing Arrangement

Milestone has informal arrangements for the manufacture of its products. *CompuDent®*, *STA Single Tooth Anesthesia System®* and *CompuMed®* instruments are manufactured for Milestone by Tricor Systems, Inc. pursuant to specific purchase orders. *The Wand®* disposable handpiece without a needle is 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.

In January 2010, the Company issued a purchase order to Tricor Systems for the purchase of 12,000 *Tooth Anesthesia System*® 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.

13

#### **Table of Contents**

#### 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. See Risk Factors on Part II. ITEM 1A of this Form 10-Q.

Milestone Scientific, the Milestone logo, The Wand, The Safety Wand, Computational DPS Dynamic Pressure Sensing and STA Single Tooth Anesthesia System are registered trademarks; and C-CLAD is a trademark of Milestone Scientific, Inc.

#### **OVERVIEW**

In 2010, Milestone focused on advancing efforts to achieve our two primary objectives;

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

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

#### STA Single Tooth Anesthesia System® Awards Industry Recognition

In June 2010, the STA Single Tooth Anesthesia System® won further industry distinction, when it was honored as one of only 13 stand-out dental technologies to receive the Pride Institute s Best of Class Technology Award for 2010. In 2009 the STA Single Tooth Anesthesia System® was named by Dentistry Today as one of the Top 100 Products for the second time and again in 2010, marking three consecutive years the instrument has achieved this notable industry distinction.

In December 2008, the STA Single Tooth Anesthesia System® was recognized as one of the dental industry s best technological innovations, winning a Townie Choice Award from Dentaltown Magazine in the category Anesthetics: Technique System. This marked the second consecutive year that Milestone won a Townie Choice Award; in 2007, Milestone Scientific received the same award for our CompuDent®/The Wand® instrument. Also in December 2008, our STA Single Tooth Anesthesia System® 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 those 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 Single Tooth Anesthesia System® was recognized as a New Classic in the Technology category.

In July 2008, industry publication *Dentistry Today* featured the *STA Single Tooth Anesthesia System*® as one of the Top 100 Products in 2008, helping to promote broader recognition of the instrument and validating its value for dentists and patients alike. The *STA Single Tooth Anesthesia System*® went on to be named by *Dentistry Today* as one of the Top 100 Products for 2009 and 2010, marking three consecutive years the instrument has achieved this industry distinction.

14

#### **Table of Contents**

Since its market introduction in the spring of 2007, the STA Single Tooth Anesthesia System® has received very positive reviews and awards from the dental industry. In April 2008, Medical Device & Diagnostic Industry magazine distinguished the STA Single Tooth Anesthesia System® 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 Single Tooth Anesthesia System® was one of only two winning products that for dental practitioners.

#### Second Annual Symposium on C-CLAD®

In 2010, we broadly distributed more than 30,000 copies of a comprehensive monograph reflecting the topics discussed at the 2009 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.

On May 1 through May 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. The 2009 Symposium covered a broad range of *C-CLAD* related topics including:

The History of *C-CLAD* 

Treating with Connection

Heart Rate Study

STA Single Tooth Anesthesia System®: Compassionate Care in the 21st 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 Single Tooth Anesthesia System® 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 Single Tooth Anesthesia System® The Dental School s Perspective

Futuristic Vistas: The Dentist/Hygienist Partnership

In addition to winning noted acclaim among leading dental publications, our award winning STA Single Tooth Anesthesia System® has also been gaining the support of many of the world s leading dental practitioners and key opinion leaders. In February 2008, we hosted the First International Computer-Controlled Local Anesthesia Delivery (C-CLAD®)

The Symposium in New Orleans, welcomed a distinguished panel of dental experts who gathered to discuss advancements in the scientific and clinical practice communities toward the common goal of advancing the science, knowledge and art of *C-CLAD* in dentistry. The forum yielded a number of ideas on how we can integrate the *STA Single Tooth Anesthesia System*® not only into dental school curricula, but also publicizing its many unique benefits to the dental community and patients.

# STA Single Tooth Anesthesia System® Growth

Since its market introduction in early 2007, the STA Single Tooth Anesthesia System®, along with prior generations of Milestone s C-CLAD products (CompuDer The Wand® instruments) have been used to deliver tens of millions of safe, effective and comfortable injections. The STA Single Tooth Anesthesia System® has 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 instrument is proving to be a valuable and beneficial tool that is positively impacting the practice of dentistry worldwide. The utility and value of the STA Single Tooth Anesthesia System® is perhaps best summarized by Dr. Joe Blaes, who wrote in the December 2008 edition of Dental Economics, I tried the STA Single Tooth Anesthesia System® and my patients absolutely love it. This is a no brainer go get one ASAP!

#### **Table of Contents**

#### **Global Distribution Network**

The STA Single Tooth Anesthesia System® and related handpieces are marketed to the dental industry in the United States and Canada by many of the nation s leading dental supply companies.

On the global front, we also have granted exclusive marketing and distribution rights for the STA Single Tooth Anesthesia System® to select dental suppliers in various international regions in Asia, Africa 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. Sinopharm is also 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 Single Tooth Anesthesia Systems® to be delivered over 36 months, thereby marking the Company s initial penetration into China s emerging dental market. The first one thousand instruments were shipped during 2010. China National Medicine Corporation is currently in the process of finalizing the registration of the STA instrument with the China State Food and Drug Administration.

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 tooth decay 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 of 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 Single Tooth Anesthesia System*®, the *CompuDent*® instrument 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 named Shaul Koren, founder and CEO of Istrodent Pty Ltd AB and one of our strongest sales allies outside of the U.S., as our new International Sales Director. In collaboration with senior management, Mr. Koren will help manage product sales for us in all markets outside of North America.

In the second quarter of 2010, Milestone appointed Dale Johnson as Director of International Distribution. He is now responsible for overseeing the Company s network of independent dental distributors. In the third quarter, Milestone named Marvin Terrell as Director of Domestic Distribution, a newly created position responsible for all facets of domestic distribution and marketing of Milestone s dental products in the U.S. and Canada, including serving as the chief liaison between the Company and the dental supply companies who comprise its domestic distribution network.

16

# **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,					
		20	2010		2009	)
DOMESTIC						
Instruments	\$	177,387	20.5%	\$	263,451	22.9%
Handpieces		672,817	77.7%		865,508	75.1%
Other		15,763	1.8%		22,516	2.0%
		•				
Total Domestic	\$	865,967	100.0%	\$	1,151,475	100.0%
INTERNATIONAL						
Instruments	\$	249,975	23.6%	\$	248,080	32.7%
Handpieces		800,387	75.3%		507,747	67.0%
Other		10,560	1.0%		1,961	0.3%
Total International	\$	1,060,922	100.0%	\$	757,788	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS						
Domestic Domestic	\$	865,967	44.9%	\$	1,151,475	60.3%
International		1,060,922	55.1%	Ψ	757,788	39.7%
International		1,000,722	33.170		131,100	37.170
Total Product Sales	\$	1,926,889	100.0%	\$	1,909,263	100.0%
		N	Nine Months Ende	ed Se	eptember 30,	
		20			2009	)
DOMESTIC						
Instruments	\$	761,376	22.9%	\$	1,317,589	32.6%
Handpieces		2,511,426	75.4%		2,659,310	65.8%
Other		56,991	1.7%		61,407	1.6%
Total Domestic	\$ :	3,329,793	100.0%	\$	4,038,306	100.0%
INTERNATIONAL						
Instruments	\$ :	2,090,238	47.7%	\$	796,064	37.7%
Handpieces		2,270,561	51.9%		1,309,526	62.0%
Other		17,544	0.4%		7,088	0.3%
Total International	\$ 4	4,378,343	100.0%	\$	2,112,678	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS						
Domestic Domestic	•	3,329,793	43.2%	\$	4,038,306	65.7%
International		4,378,343	56.8%		2,112,678	34.3%
International	•	T,J / O,JTJ	30.670		2,112,070	34.370

Total Product Sales \$ 7,708,136 100.0% \$ 6,150,984 100.0%

The Company earned gross profits of 62% and 63% in for the three months ended September 30, 2010 and 2009, respectively. The Company earned gross profit of 64% and 60% for the nine months ended September 30, 2010 and 2009, respectively. However, our revenues and related gross profits have not been sufficient to fully support the expansion of our business efforts. Although the Company anticipates expending funds for research and development in 2010, these amounts will vary based on the operating results for each quarter. The Company has incurred operating losses since its inception. The Company is actively pursuing the generation of sustainable positive cash flows through increases in revenue, to be derived from a change in the business model in the US and Canada. This change in the business model incorporates a team of local dental hygienists training and educating the respective dentists in their territories. This change replaces the Company s sales force and a third party manufacturer s rep business system.

## New Product Development and Commercialization Utilizing CompuFlo® System 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 23 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.

17

#### **Table of Contents**

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 <u>all</u> 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, the Company has 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 it s a 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 the Company s STA Single Tooth Anesthesia System, the CompuDent® instrument and the CompuMed® instrument.

18

#### **Table of Contents**

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.

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 a total of 23 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 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*

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.

#### Impairment of Long-Lived Assets

The long lived assets of the Company, 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.

#### Revenue Recognition

Revenue from product sales is recognized net of discounts and allowances to our domestic distributors on the date of arrival of the goods at the customer's location as shipments are FOB destination. Shipments to our international distributor are FOB our 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. Our only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective instrument is returned within the warranty period.

19

#### **Results of Operations**

The consolidated results of operations for the three and nine months ended September 30, 2010 compared to the same three and nine month period in 2009 reflect our focus and development on the STA Single Tooth Anesthesia System®, 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 Mon 2010	nths Ended September 30, 2009			Nine Mon 2010	ths Ende	d September 30, 2009	
Products sales, net Cost of products sold	\$ 1,926,889 725,795	100% 38%	\$ 1,909,263 709,003	100% 37%	\$7,708,136 2,788,353	100% 36%	\$ 6,150,984 2,488,294	100% 40%
Gross Profit	1,201,094	62%	1,200,260	63%	4,919,783	64%	3,662,690	60%
Selling, general and administrative expenses Research and	1,704,896	88%	1,477,948	77%	5,024,791	65%	4,960,000	81%
development expenses  Total operating expenses	60,533 1,765,429	3% 91%	57,972 1,535,920	3% 80%	228,734 5,253,525	3% 68%	157,941 5,117,941	3% 84%
Loss from operations	(564,335)	-29%	(335,660)	-18%	(333,742)	-4%	(1,455,251)	-24%
Other income interest & expense		-1%	(37,610)	-2%	14,498	0%	(136,203)	-24%
Net loss	\$ (583,526)	-30%	\$ (373,270)	-20%	\$ (319,244)	-4%	\$ (1,591,454)	-26%

#### Three months ended September 30, 2010 compared to three months ended September 30, 2009

Total revenues for the three months ended September 30, 2010 and 2009 were \$1,926,889 and \$1,909,263, respectively. Domestic *STA Single Tooth Anesthesia System*® instrument sales decreased \$82,222 in 2010 over 2009. This decrease is due to a reduction in the sales force in 2010 from 2009, as management implemented a new sales strategy (deployment of hygienists in second quarter 2010) in the U.S. In the domestic market, handpiece sales decreased by \$192,691, or 22%. The major component of the decrease in handpiece sales is substantially due to reduced demand for CompuDent handpieces. The reduced demand for CompuDent handpieces is partially due to fewer patients visiting dentists due to a slower economy. On the international front, total revenue aggregated \$1,060,922 in 2010, a 40% increase over the same period in 2009. International instrument sales increased in the third quarter of 2010 over 2009 by \$1,895, or .7%. Internationally, handpieces increased by \$297,151 or 59% due to increased demand and sales force activities.

Cost of products sold for the three months ended September 30, 2010 and 2009 were \$725,795 and \$709,003, respectively. The \$16,792, or 2.4%, increase is attributable to an increase in sales volume.

For the three months ended September 30, 2010, Milestone generated a gross profit of \$1,201,094, or 62%, as compared to a gross profit of \$1,200,260, or 63%, for the three months ended September 30, 2009.

Selling, general and administrative expenses for the three months ended September 30, 2010 and 2009 were \$1,704,896 and \$1,477,948, respectively. The \$226,948, or 15.4%, net increase is described in the following sections of this paragraph. As the Company continues to focus on expense reductions, there are certain expenses that were required to initiate growth in product sales of the business. The comparative expenses for the same period in 2009 were substantially lower than historical expenses due to a conscious effort by management of the Company in 2009 to

reduce all cost centers. Therefore, the 2009 comparative expenses result in a substantial identified increase in comparing the same period in 2009 to 2010. The third quarter 2010 increase of \$226,948 is a product of increased Marketing Expenses of \$46,763, Sales Expenses of \$35,879 and Salary Expense of \$101,408, and an increase in General and Administrative (G&A) Expenses of \$57,264. Legal Expenses of \$14,367 decreased in 2010 over 2009. Other Expenses were impacted by reductions in Consulting Expense of \$178,844 and Royalty payments of \$45,393, while International Sales Commissions increased by \$129,530. While the reduction in Consulting expense was primarily a result of a decrease in consulting services, the International Commission increase was due to substantial increase in international sales volume, especially in handpiece sales, while the reduction in Royalty Expense is a result of lower STA System sales. The increase in salary expense increase is due to an increase in bonus potential for the employees of the Company.

20

#### **Table of Contents**

Research and development expenses for the three months ended September 30, 2010 and 2009 were \$60,533 and \$57,972 respectively.

The loss from operations for the three months ended September 30, 2010 was \$564,335 as compared to a loss from operations for the three months ended September 30, 2009 of \$335,660. The difference of \$228,675 or 68%, increase in loss from operations is explained above.

Interest income of \$60 was earned for the three months ended September 30, 2010 compared to \$495 for the same period in 2009.

Interest expense was \$18,553 and amortization of debt issuance was \$699 relating to the long term note payable for the third quarter of 2010 compared to interest expense of \$30,230 and amortization of debt issuance expense of \$7,875 for the same quarter in 2009. The decrease in interest expense \$11,677 is due to the conversion of the Line of Credit Note in December 2009 (as discussed in Note 5).

For the reasons explained above, net loss for the three months ended September 30, 2010 was \$583,526 as compared to a net loss of \$373,270 for the three months ended September 30, 2009. The \$210,256, or 56%, increase in net loss is primarily a result of the increased expenses in the category Marketing, Sales, Salary and Other General Expenses.

#### Nine months ended September 30, 2010 compared to the nine months ended September 30, 2009

Total revenues for the nine months ended September 30, 2010 and 2009 were \$7,708,136 and \$6,150,984, respectively. Total revenues increased by \$1,557,152, or 25%. All of this increase in revenue was generated by shipments to China. Contributing to this increase was *STA Single Tooth Anesthesia System*® instruments sales of \$763,707 and an increase in *STA Single Tooth Anesthesia System*® handpiece sales of \$659,135. *CompuDent*® instrument sales increased by \$86,910 and *CompuDent*® handpiece sales increased by \$193,647. International revenue increased \$2,265,665, or 107%, as compared to the 2009 period. Domestic product revenue decreased \$708,513, or 18% in 2010. The notable decrease is due to the reduction in both the advertising expenditures and domestic sales force in 2010 as compared to 2009, as management implement a new sales strategy focused on concentrated geographical sales efforts and support (deployment of hygienists) for our customers.

Gross profit for the nine months ended September 30, 2010 and 2009 was \$4,919,783, or 64%, and \$3,662,690, or 60%, respectively. Gross profit dollars in the first nine months of 2010 increased by \$1,257,093, 34% due to an increase in sales volume and gross profit percentage in 2010 over 2009. The gross profit percentage increase is due to a reduction in the manufacturing costs for the *STA Single Tooth Anesthesia System*® instruments in 2010.

Selling, general and administrative expenses for the nine months ended September 30, 2010 and 2009 were \$5,024,791 and \$4,960,000, respectively. The increase of \$64,791, or 1.3%, is primarily attributable to a net reduction in Marketing Expenses of \$527,045, Sales Expenses of \$61,841 and Salary Expenses of \$27,878, offset by increase in General and Administrative (G&A) Expense of \$659,951. Sales and marketing expense decreased by \$588,886, principally due to foregoing the Spring C-CLAD Symposium and other Marketing Consulting (savings of approximately \$309,000), reduction in the media spend of approximately \$214,000, a net reduction of printing (\$96,000) and a reduction in sales commissions (\$42,000) and domestic sales travel expenses (\$20,000) for the period ending September 30, 2010. The Company also realized a reduction in legal expense of \$34,000 as a result of resolution of litigation. In addition, this aggregate decrease is attributable to management s implementation of a new sales strategy in the U.S. with the implementation of a hygienist sales, education and support initiative. General and administrative expenses increased a net of \$659,951. Expense increases in this category that are directly related to sales volume increases was \$552,167. Expense increased in these categories are; international sales commissions \$423,643 (China \$64,800 and other countries \$358,843), international travel \$48,843 and royalty payments \$79,681. Stock based compensation expense increased by \$152,373, based on \$40,080 for an Investor Relation firm and \$165,697 for employee, stock based compensation and a decrease of \$53,404 for non-employee. Recruiting and Consulting Expenses decreased by \$145,720.

#### **Table of Contents**

Research and development expenses for the nine months ended September 30, 2010 and 2009 were \$228,734 and \$157,941, respectively. The increase of \$70,793 is due primarily to increased expenditures for the development of new medical devices (\$25,477) and foreign language enhancements for our *STA Single Tooth Anesthesia System*® instruments (\$26,000).

Other Income includes \$61,916 in 2010. This represents the balance of the sale of tax credits under the New Jersey Technology Tax Certificate Program.

Interest income of \$520 was earned for the nine months ended September 30, 2010 compared to \$3,041 for the same period in 2009.

Interest expense of \$45,841 as of September 30, 2010 decreased \$69,778, or 60%, over the same period in 2009. The decrease in interest expense is due to the conversion of the Line of Credit Note in December 2009 (as discussed in Note 5). Amortization of debt issuance cost of \$2,097 as of September 30, 2010 decreased by \$21,528, or 91%, over the same period in 2009.

For the reasons explained above, the net loss of \$319,244 for the nine months ended September 30, 2010, was an improvement over the net loss of \$1,591,454, for the nine month period ended September 30, 2009.

#### **Liquidity and Capital Resources**

As of September 30, 2010 we had cash and cash equivalents of \$207,726 and working capital of \$1,958,242, an increase in working capital from December 31, 2009 of \$332,169. Milestone incurred a net loss of \$319,244 and \$1,591,454 for the nine months ended September 30, 2010 and 2009, respectively. The improvement in the net loss for the nine months ended September 30, 2010 versus 2009 was generated in the first six months of 2010. The first six months of 2010 generated net income of \$264,282 as compared to a net loss of \$1,218,183 for the same period in 2009. There was a negative cash flow from operating activities of \$724,698 and \$157,948 for the nine months ended September 30, 2010 and September 30, 2009, respectively.

For the nine months ended September 30, 2010, our net cash used in operating activities was \$724,698. This was attributable primarily to a net loss of \$319,244, adjusted for noncash items of \$543,081, principally common stock and options issued for compensation, consulting and vendor services and changes in operating assets and liabilities of \$948,536. The changes in operating assets and liabilities are due to building up of inventory and the increase in advances and related liabilities for the expected sales growth in the fourth quarter of 2010.

The Company s increase in current asset of \$2,370,593 is primarily due to a build up of inventory (\$348,287) and increase in advances to contract manufacturer-current (\$1,796,326) principally for the 12,000 STA System instruments purchase order form China, and a net increase in accounts receivable (\$1,058,386) of which \$1,290,000 is for the sale to China. These increases are anticipated to continue in order to deliver the instruments on time and complete per the purchase order.

On a related basis, current liabilities increased by \$2,032,049 of which \$1,972,102 relates to the advance to contract manufactures and the purchases of handpieces for the China purchase order. Both the advance and payable to contract manufacturer are expected to continue to exist until the 12,000 instrument order is delivered to the distributor.

For the nine months ended September 30, 2010, Milestone used \$96,705 in investing activities. This was primarily attributable to \$67,350 of legal fees related to new patent application. Capital expenditures of \$29,355 were primarily for the leasehold improvement in the Livingston, New Jersey office.

As of September 30, 2010 and December 31, 2009, Milestone had recorded on the Balance Sheet a long term note payable of \$450,000 from a stockholder.

22

#### **Table of Contents**

The Company is actively pursuing the generation of sustainable positive cash flows from operating activities through an increase in revenue to be derived from a change in the business model in the US and Canada. This change in the business model incorporates a team of local dental hygienists training and educating the respective dentists in their territories. This change replaces the Company s sales force and a third party manufacturer s rep business system. If the Company is unable to maintain 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 sustainable positive operating cash flows or that traditional capital can be raised on terms and conditions satisfactory to the Company. If additional capital is required and 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 raises substantial doubt about its 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.

#### **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, 2010 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 that have materially affected, or that are reasonably likely to materially affect, the Company s internal controls over financial reporting.

23

# **Table of Contents**

# 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.

24

#### **Table of Contents**

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

Recent Sales of Unregistered Securities

In the quarter ended September 30, 2010, Milestone issued total 70,914 shares valued at \$85,500 as follows:

	Shares	\$ Value *		
Shares issued for employee compensation	6,250	\$	7,500	
Shares issued to directors	34,614		45,000	
Shares issued for services	30,050		33,000	
	70,914	\$	85,500	

\* Based on the closing market price and the date of grant.

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 SECURTIES

NONE.

ITEM 4. [Removed and Reserved]

NONE.

**ITEM 5. OTHER INFORMATION** 

NONE.

25

# **Table of Contents**

# **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 Financial 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 Financial Officer Certification pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

26

#### **Table of Contents**

#### **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 Financial Officer

Date: November 15, 2010

27