

MILESTONE SCIENTIFIC INC/NJ

Form 10-Q

November 12, 2009

Table of Contents

**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, 2009

or

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

For the transition period from _____ to _____

Commission File Number: 001-14053

MILESTONE SCIENTIFIC INC.

(Exact name of registrant as specified in its charter)

Delaware

13-3545623

(State or other jurisdiction of incorporation or
organization)

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

45 Knightsbridge Road Piscataway, New Jersey 08854

(Address of principal executive offices)

(973) 535-2717

(Registrant's telephone number, including area code)

220 South Orange Avenue Livingston, New Jersey 07039

Former name, former address and former fiscal year

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

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

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

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

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of November 10, 2009, the Issuer had a total of 13,939,461 shares of Common Stock, \$.001 par value outstanding.

**MILESTONE SCIENTIFIC INC
INDEX**

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Condensed Balance Sheets

September 30, 2009 (Unaudited) and December 31, 2008 4

Condensed Statements of Operations

Three Months and Nine Months Ended September 30, 2009 and 2008 (Unaudited) 5

Condensed Statements of Changes in Stockholders' Equity

Nine Months Ended September 30, 2009 (Unaudited) 6

Condensed Statements of Cash Flows

Nine Months Ended September 30, 2009 and 2008 (Unaudited) 7

Notes to Condensed Financial Statements (Unaudited) 8

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 16

Item 3. Quantitative and Qualitative Disclosures about Market Risk 24

Item 4T. Controls and Procedures 24

PART II OTHER INFORMATION

Item 1. Legal Proceedings 25

Item 1A. Risk Factors 25

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 25

Item 3. Defaults Upon Senior Securities 26

Item 4. Submission of Matters to a Vote of Security Holders 26

Item 5. Other Information 26

Item 6. Exhibits 27

SIGNATURES 28

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**ITEM 1. Financial Statements.**MILESTONE SCIENTIFIC INC.
CONDENSED BALANCE SHEETS

	September 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 497,455	\$ 743,665
Accounts receivable, net of allowance for doubtful accounts of \$5,000 in 2009 and 2008	500,880	925,742
Stock Subscription Receivable	112,500	
Inventories	888,641	719,902
Advances to contract manufacturer	148,960	250,110
Prepaid expenses and other current assets	136,134	218,296
Total current assets	2,284,570	2,857,715
Advances to contract manufacturer	324,235	415,780
Investment in distributor, at cost	76,319	76,319
Furniture, Fixtures & Equipment net of accumulated depreciation of \$384,407 as of September 30, 2009 and \$345,377 as of December 31, 2008	149,820	152,574
Patents, net of accumulated amortization of \$191,580 as of September 30, 2009 and \$135,406 as of December 31, 2008	921,858	901,045
Other assets-including advance payment for consulting services \$127,772 in 2009	143,645	7,317
Total assets	\$ 3,900,447	\$ 4,410,750
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	\$ 880,869	\$ 829,130
Accrued expenses and other payable	539,645	495,897
Line of credit-net of discount of \$28,976	1,271,024	
Total current liabilities	2,691,538	1,325,027
Long-term Liabilities:		
Line of credit-net of discount of \$52,530		1,247,470
Notes Payable-net of discount of \$11,856 and \$11,927, respectively	438,144	438,073
Total long-term liabilities	438,144	1,685,543
Commitments and Contingencies		
Stockholders Equity		

Edgar Filing: MILESTONE SCIENTIFIC INC/NJ - Form 10-Q

Common stock, par value \$.001; authorized 50,000,000 shares;
13,928,832 shares issued 550,093 shares to be issued and 13,895,499
shares outstanding as of September 30, 2009; 12,695,685 shares issued,
504,639 shares to be issued, and 12,662,352 shares outstanding as of
December 31, 2008

	14,478	13,200
Additional paid-in capital	60,492,626	59,531,865
Accumulated deficit	(58,824,823)	(57,233,369)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total stockholders' equity	770,765	1,400,180
Total liabilities and stockholders' equity	\$ 3,900,447	\$ 4,410,750

See Notes to Condensed Financial Statements (unaudited)

Table of Contents

MILESTONE SCIENTIFIC INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Product sales, net	\$ 1,909,263	\$ 1,813,103	\$ 6,150,984	\$ 4,741,976
Royalty income		5,112		28,282
Total revenue	1,909,263	1,818,215	6,150,984	4,770,258
Cost of products sold	709,003	740,398	2,488,294	1,798,758
Gross profit	1,200,260	1,077,817	3,662,690	2,971,500
Selling, general and administrative expenses	1,477,948	1,199,353	4,960,000	4,039,137
Research and development expenses	57,972	35,181	157,941	119,500
Total operating expenses	1,535,920	1,234,534	5,117,941	4,158,637
Loss from operations	(335,660)	(156,717)	(1,455,251)	(1,187,137)
Interest expense	(30,230)	(23,863)	(115,619)	(73,455)
Interest-Amortization of debt issuance	(7,875)	(7,926)	(23,625)	(21,622)
Interest income	495	1,773	3,041	6,479
Net loss applicable to common stockholders	\$ (373,270)	\$ (186,733)	\$ (1,591,454)	\$ (1,275,735)
Loss per share applicable to common stockholders basic and diluted	\$ (0.03)	\$ (0.02)	\$ (0.12)	\$ (0.10)
Weighted average shares outstanding and to be issued basic and diluted	13,486,513	12,709,260	13,139,276	12,631,311

See Notes to Condensed Financial Statements (unaudited)

Table of Contents

MILESTONE SCIENTIFIC INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
NINE MONTHS ENDED SEPTEMBER 30, 2009
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Treasury Stock	Total
Balance, January 1, 2009	13,200,324	\$ 13,200	\$ 59,531,865	\$ (57,233,369)	\$ (911,516)	\$ 1,400,180
Options issued to employees and consultants			129,214			129,214
Common stock issued for payment of consulting services to settle accounts payable	502,660	503	481,997			482,500
Common stock issued for payment of employee compensation	312,371	312	150,013			150,325
Common stock issued in advance of services-Chairman	84,783	85	(85)			
Common stock to be issued for settlement of deferred compensation	45,454	45	24,955			25,000
Sale of common stock	333,333	333	149,667			150,000
Proceeds on the sale of stock option agreement			25,000			25,000
Net loss				(1,591,454)		(1,591,454)
Balance, September 30, 2009	14,478,925	\$ 14,478	\$ 60,492,626	\$ (58,824,823)	\$ (911,516)	\$ 770,765

See Notes to Condensed Financial Statements (unaudited)

Table of Contents

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

	Nine Months Ended September 30, 2009	2008
Cash flows from operating activities:		
Net loss	\$ (1,591,454)	\$ (1,275,735)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	39,030	54,367
Amortization of patents	56,174	37,869
Amortization of debt discount	23,625	21,622
Common stock and options issued for compensation, consulting and vendor services	787,040	312,252
Loss on sale/disposal of equipment		2,255
Changes in operating assets and liabilities:		
Decrease (Increase) in accounts receivable	424,862	(397,416)
Decrease in royalty receivable		10,247
(Increase) Decrease in inventories	(168,739)	791,447
Decrease to advances to contract manufacturer	192,695	350,183
Decrease to prepaid expenses and other current assets	82,162	126,042
(Increase) Decrease in other assets	(136,329)	18,029
Increase (Decrease) in accounts payable	89,239	(922,463)
Increase in accrued expenses	46,247	171,095
(Decrease) Increase in deferred compensation	(2,500)	7,042
Net cash used in operating activities	(157,948)	(693,164)
Cash flows from investing activities:		
Purchases of property and equipment	(36,276)	(5,738)
Proceeds on sale of equipment		7,750
Payment for patents rights	(76,986)	(267,831)
Net cash used in investing activities	(113,262)	(265,819)
Cash flows from financing activities:		
Notes Payable-Short Term borrowing		200,000
Line of credit borrowing		300,000
Proceeds from sale of stock options	25,000	
Net cash provided by financing activities	25,000	500,000
NET DECREASE IN CASH AND CASH EQUIVALENTS	(246,210)	(458,983)
Cash and cash equivalents at beginning of period	743,665	745,003
Cash and cash equivalents at end of period	\$ 497,455	\$ 286,020

Supplemental disclosure of cash flow information:

Interest paid in cash	\$		\$	3,000
Income taxes paid	\$	8,225	\$	
Stocks issued to employees in lieu of cash compensation	\$	150,325	\$	92,544
Shares issued to officer in advance of services	\$	97,500	\$	
Warrants issued in connection with line of credit	\$		\$	21,575
Shares issued to settle accounts payable	\$	482,500	\$	548,845

See Notes to Condensed Financial Statements (unaudited)

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. The Company leased additional office space in June 2009 and moved its headquarters to 45 Knightsbridge Road in Piscataway, 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, 2008 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, 2009 and December 31, 2008 and the results of its operations for the three and nine months ended September 30, 2009 and 2008.

The results reported for the three and nine months ended September 30, 2009 are not necessarily indicative of the results of operations which may be expected for a full year.

The Company has incurred operating losses and negative cash flows from operating activities since its inception, including a net loss of \$1,591,454 and \$1,275,735 for the nine months ended September 30, 2009 and 2008, respectively. At September 30, 2009, the Company had cash and cash equivalents of \$497,455 and negative working capital of \$406,968. The working capital is negative by the inclusion in current liabilities as of September 30, 2009 of the \$1,300,000 line of credit, due on June 30, 2010. As discussed in Note 5, the Company secured a revolving line of credit in the aggregate amount of \$1.3 million from a stockholder, which was fully borrowed at December 31, 2008. All borrowings and interest thereon must be repaid by June 30, 2010, and after the expiration date of the line, may be repaid by Milestone in cash or, at its option, in shares of common stock. As mentioned above, this borrowing is classified as a current liability as of September 30, 2009. Additionally, the Company borrowed \$450,000 in 2008 from the same shareholder, with an original due date of January 2009. This additional borrowing was refinanced at December 31, 2008 and the due date was extended to June 30, 2012 (as discussed in Note 5). The Company, at September 30, 2009, expects to have sufficient cash reserves to meet all of its anticipated obligations through December 31, 2009. Additionally, 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. If the Company is unable to generate positive cash flows from its operating activities, it will need to raise additional capital. There is no assurance that the Company will be able to achieve positive operating cash flows or that additional capital can be raised on terms and conditions satisfactory to the Company, if at all. If additional capital is required and it cannot be raised, then the Company would be forced to curtail its development activities, reduce marketing expenses for existing dental products or adopt other cost saving measures, any of which might negatively affect the Company's operating results.

The Company's recurring losses and negative operating cash flows raises 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.

Table of Contents

NOTE 1 SUMMARY OF ACCOUNTING POLICIES

Cash and Cash Equivalents

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

Inventories

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or market.

Patents

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

Revenue Recognition

Revenue from product sales is recognized net of discounts and allowances to the Company's domestic distributors on the date of arrival of the goods at the customer's location as shipments are FOB destination. Shipments to the Company's international distributors are FOB Milestone's 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, the Company has no obligation on these sales for any post sale installation, set-up or maintenance, these being the responsibility of the buyer. Customer acceptance is considered made at delivery. The Company's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Royalty income was recognized as earned based on reports received from the licensee, and related royalty expense is accrued during the same 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 evaluations for impairment of long-lived assets and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

Recent Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168 (SFAS 168), Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles . The FASB Accounting Standards Codification (Codification) has become the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in accordance with GAAP. All existing accounting standard documents are superseded by the Codification and any accounting literature not included in the Codification will not be authoritative. However, rules and interpretive releases of the Securities Exchange Commission (SEC) issued under the authority of federal securities laws will continue to be sources of authoritative GAAP for SEC registrants.

Table of Contents

SFAS 168 is effective for interim and annual reporting periods ending after September 15, 2009. Therefore, beginning with our quarter ending September 30, 2009, all references made by it to GAAP in its consolidated financial statements now use the new Codification numbering system. The Codification does not change or alter existing GAAP and, therefore, it is not having an impact on the Company's financial position, results of operations and cash flows.

FASB ASC Topic 350-30-65-2, formerly, Emerging Issue Task Force (EITF) No 08-7 Accounting for Defensive Intangible Assets, issued in November 2007, provides accounting and reporting guidance when an intangible acquired through a business combination or an asset acquisition that an entity does not intend to use but does intend to prevent others from using, commonly called a defensive asset or a locked up asset, because while the asset is not being actively used, it is likely contributing to an increase in the value of the other assets owned by the entity. This issue is effective for intangible assets acquired on or after the beginning of the first annual period beginning on or after December 15, 2008. This Statement does not currently impact the financial statements of the Company.

FASB ASC Topic 808-10-05, Accounting for Collaborative Agreements, issued in November 2007, defines a Collaborative Arrangement and establishes the reporting requirements for transactions between participants in a collaborative arrangement and between participants in an arrangement with third parties. This issue shall be effective beginning after December 15, 2008 and interim periods within those fiscal years. This Statement does not currently impact the financial statements of the Company.

FASB ASC Topic 805-10-65-1, *Summary No. 141 (revised 2007)*. SFAS No.141 (revised) provides for improving the relevance, representational faithfulness, and comparability of the information that an entity provides in its financial reports about a business combination and its effects. SFAS No.141 (revised) applies prospectively to business combinations for which the acquisition date is on or after December 15, 2008. This statement does not currently impact the financial statements of the Company.

FASB ASC Topic 810, *Non controlling Interests in Consolidated Financial Statements- an amendment of ARB No. 51*. SFAS No.160 establishes accounting and reporting standards for non-controlling interests, sometimes called minority interests for the portion of equity in a subsidiary not attributable, directly or indirectly, to a parent. SFAS No.160 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2008. This statement does not currently impact the financial statements of the Company.

FASB ASC Topic 815-10-20, *Disclosure about Derivative Instruments and Hedging Activities* an amendment of FASB No. 133. This Statement requires enhanced disclosure about an entity's derivative and hedging activities. The effective date for this Statement is for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. This Statement does not currently impact the financial statements of the Company.

In May 2008, the FASB issued FSP Accounting Principles Board (APB) Opinion 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FASB ASC 470-20-65-3) which applies to all convertible debt instruments that have a net settlement feature; which means that such convertible debt instruments, by their terms, may be settled either wholly or partially in cash upon conversion. FASB ASC 470-20-65-3 requires issuers of convertible debt instruments that may be settled wholly or partially in cash upon conversion to separately account for the liability and equity components in a manner reflective of the issuer's nonconvertible debt borrowing rate. Previous guidance provided for accounting for this type of convertible debt instrument entirely as debt. FASB ASC 470-20-65-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years. This statement does not currently impact the financial statements of the Company.

FASB ASC Topic 944, *Accounting for Financial Guarantee Insurance Contracts*. The Statement requires that an insurance enterprise recognize a claim liability prior to an event of default, when there is evidence that credit deterioration has occurred in an insured financial obligation. This Statement is effective for fiscal years beginning after December 15, 2008, and interim periods within the fiscal year. This Statement does not currently impact the financial statements of the Company.

Table of Contents

FASB ASC Topic 855, *Subsequent Events* (SFAS No. 165) a statement that requires disclosure of events that occur after the balance sheet date, but before the financial statements are issued. The effective date of this statement is for interim or annual financial periods after June 15, 2009. In accordance with the ASC, the Company reviewed the events for inclusion in the financial statements through the filing date.

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. This Statement does not currently impact the financial statements of the Company.

Statement No.167 *Amendment to FASB Interpretation No.46(R)* was issued in June 2009 by the Financial Accounting Standards Board. The purpose is to improve financial reporting by enterprises involved with variable interest entities. The Statement is effective as of the beginning of each reporting entity's first annual reporting period that begins after November 15, 2009. This Statement does not currently impact the financial statements of the Company.

Reclassifications

Certain reclassifications have been made to the 2008 balances to conform to the presentation used in 2009. These reclassifications had no effect on operating results previously reported.

NOTE 2 BASIC AND DILUTED NET LOSS PER COMMON SHARE

Milestone presents basic 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, 2009 and 2008, 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 1,316,997 at September 30, 2009 and 3,537,079 at September 30, 2008. The major reduction in the total outstanding options and warrants is due to the expiration of 2,227,946 warrants in the first and second quarter of 2009. Outstanding warrants totaled 175,000 at September 30, 2009 and 2,357,946 at September 30, 2008.

Additionally, the Company has an existing Line of Credit and related accrued interest that is convertible into 5,594,613 share of common stock at its option by June 30, 2010.

NOTE 3 STOCK OPTION PLANS

FASB ASC Topic 505, *Share-Based Payment*, under the modified-prospective transition method whereby prior periods will not be restated for comparability. Topic 505 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. Pro-forma disclosure is no longer an alternative. Milestone recognizes as compensation expense in its financial statements the unvested portion of existing options granted prior to the effective date and the cost of stock options granted to employees after the effective date based on the fair value of the stock options at grant date.

Table of Contents

A summary of option activity for employees under the stock option plans as of September 30, 2009, 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, 2009	570,832	\$ 1.51	3.01	\$ 75
Granted	528,056	0.62	4.59	194,122
Exercised				
Forfeited or expired	(371,890)	0.88		
Outstanding, September 30, 2009	726,998	1.19	3.16	106,766
Exercisable, September 30, 2009	464,330	1.40	2.37	45,433

The weighted average grant date fair value of options granted to employees during the nine months ended September 30, 2009 was \$0.69. The fair value of the options was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions: expected life of five years, volatility of 227% and a risk free interest rate of 1.580%. A six percent rate of forfeitures is assumed in the calculation of the compensation costs for the period.

Milestone recognizes compensation expense on a straight line basis over the requisite service period. During the nine and three months ended September 30, 2009, Milestone recognized \$54,244 and \$8,022, respectively, of total compensation cost related to options that vested during the period. As of September 30, 2009, there was \$180,006 of total unrecognized compensation cost related to non-vested options which Milestone expects to recognize over a weighted average period of three and one quarter years.

The expected volatilities are based on historical volatility of Milestone's common stock over a period commensurate with the anticipated term. Milestone uses historical data to estimate option exercise and employee termination within the valuation model. The expected term of the options granted was estimated using the simplified method as the average of the contractual term and vesting term of the option.

A summary of option activity for non-employees under the stock option plans as of September 30, 2009, 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, 2009	627,467	\$ 3.14	1.61	\$
Granted	140,000	0.32	2.91	35,250
Exercised				
Forfeited or expired	(352,468)	3.45		
Outstanding, September 30, 2009	414,999	1.93	2.69	87,900
Exercisable, September 30, 2009	347,499	1.97	2.80	87,900

During the three and nine months ended September 30, 2009, Milestone recognized \$12,835 and \$74,970, respectively, of expenses related to non-employee options that vested during the period. The total unrecognized compensation cost related to non-vested options was \$22,428 as of September 30, 2009.

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.

Table of Contents**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 a contract manufacturer. Milestone entered into a purchase agreement in 2004 with a vendor to supply Milestone with 5,000 units of *CompuDent*. As part of this agreement, Milestone has a remaining advance of approximately \$473,195 with the vendor for purchase of materials at September 30, 2009. The advance will be reduced 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, 2009.

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, 2009.

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. Borrowings bear interest at 6% per annum, with one year's interest at 1% payable in advance on each draw. Monies may be drawn by Milestone under the line in multiples of \$100,000 upon five days written notice to the stockholder from either Milestone's Chief Executive Officer or Chief Financial Officer. Monies under the line in excess of \$1,000,000 may be drawn in multiples of \$25,000. Borrowings may be prepaid at any time in multiples of \$100,000, without penalty. All borrowings and interest thereon must be repaid by June 30, 2010, and after the expiration date of the line, may be repaid by Milestone in cash or, at its option, in shares of common stock valued at the lower of \$2.00 per share or 80% of the average closing price of its shares during the 20 trading days ending with December 31, 2008. After December 31, 2008, and before June 30, 2010 the lender may convert all or any part of the then outstanding balance and interest thereon into shares of common stock at \$4.00 per share. 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. At September 30, 2009, the remaining balance of Debt Discount was \$28,976. The full amount of the line of credit and amendment, \$1.3 million, had been drawn at September 30, 2009 and December 31, 2008. As of September 30, 2009, this line of credit is classified as a current liability on the Condensed Balance Sheet. 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 12 percent interest rate, interest compounded quarterly, with interest and principle due at the maturity. Further, the note has warrants attached, 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, 2009, the discount was \$11,856.

Interest expense on this line of credit and note payable for the three and nine months ended September 30, 2009 and 2008 was \$30,230 and \$115,619, respectively, and \$23,863 and \$73,455, respectively. Accrued interest related to this line of credit and note payable was \$207,868 at September 30, 2009. The charge for amortization of debt discount related to this line of credit and note payable was \$23,625 and \$21,622 for the nine months ended September 30, 2009 and 2008, respectively.

Table of Contents**NOTE 6 STOCK ISSUANCE**

During the nine months ended September 30, 2009, the Company issued 502,660 shares of common stock valued at \$482,500 to pay off outstanding accounts payable at December 31, 2008. Additionally, 397,154 shares of common stock valued at \$247,825 were issued for payment of employee compensation and 333,333 shares were sold for \$150,000, which is recorded as stock subscription receivable. The stock subscription receivable is reduced by offsetting inventory purchased in the third and fourth quarter of 2009. The 45,454 shares of common stock valued at \$25,000 are to be issued in settlement of deferred compensation.

Included in the amount above are shares issued to the Company's Chairman of the Board of Directors (84,783 shares) at a value of \$97,500 in advance of services performed per her employment agreement. Additionally, a consultant to the Company was issued 173,913 shares valued at \$200,000 in advance of the performance of his services over a three year period. Of this \$200,000, \$66,672 is included in the prepaid expenses as current assets and \$127,772 is included in other non-current assets on the condensed Balance Sheet. Such amounts will be amortized to expense over the contract period.

NOTE 7 SIGNIFICANT CUSTOMERS

Milestone had net product sales to major customers (distributors) which in the aggregate accounted for approximately 72% and 77% of revenue for the nine months ended September 30, 2009 and 2008, respectively. Milestone had sales to one customer (a worldwide distributor of Milestone's products based in South Africa) of \$813,570 or 13% for the nine months ended September 30, 2009. Accounts receivable from these major customers amounted to \$174,311 and \$642,584 representing 35% and 87% of gross accounts receivable as of September 30, 2009 and September 30, 2008, respectively.

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

	Three Months Ended September 30,	
	2009	2008
<i>Instruments</i>	\$ 511,531	\$ 498,879
Handpieces	\$ 1,373,255	\$ 1,297,654
Other	\$ 24,477	\$ 16,570
	\$ 1,909,263	\$ 1,813,103
United States	\$ 1,151,475	\$ 1,322,665
Canada	\$ 148,916	\$ 111,570
Other Foreign	\$ 608,872	\$ 378,868
	\$ 1,909,263	\$ 1,813,103
	Nine Months Ended September 30,	
	2009	2008
<i>Instruments</i>	\$ 2,113,653	\$ 846,558
Handpieces	\$ 3,968,836	\$ 3,840,723
Other	\$ 68,495	\$ 54,695
	\$ 6,150,984	\$ 4,741,976
United States	\$ 4,038,306	\$ 3,209,683

Canada	\$	441,366	\$	429,077
Other Foreign	\$	1,671,312	\$	1,103,216
	\$	6,150,984	\$	4,741,976

In January 2007, Milestone finalized an Exclusive Distribution and Supply Agreement with Henry Schein, Inc. Henry Schein, Inc. served as the exclusive distributor of *STA* and *CompuDent* systems (and ancillary products) in North America for a one year period. In June 2008, Milestone implemented a change to its domestic distribution strategy and signed Henry Schein, Inc. as a non-exclusive distributor of *STA* and *CompuDent* systems (and ancillary products) in North America. That same month, the Company also signed Patterson Dental Supply as an additional non-exclusive partner to promote sales of the Company's products in North America. Early in the third quarter of 2008, the Company added four more non-exclusive distributors to its domestic sales network, including Benco Dental, Burkhard Dental, Goetze Dental and Atlanta Dental. Milestone continued to expand its domestic distribution network during the first nine months of 2009, welcoming Darby Dental Supply, Dental Health Products, Nashville Dental and Parkway Dental.

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 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 System* (and ancillary products).

Table of Contents

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 nine 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 to the previous distributor was \$117,790 for the quarter ending September 30, 2009.

NOTE 8 COMMITMENTS AND OTHER

Contract Manufacturing Arrangement

Milestone has informal arrangements for the manufacture of its products. *CompuDent*, *STA* and *CompuMed* units are manufactured for Milestone by Tricor Systems, Inc. pursuant to specific purchase orders. *The Wand* disposable hand piece without a needle is manufactured for Milestone in Mexico pursuant to scheduled production requirements. *The Wand* and *STA* hand pieces (with and without needles) are 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.

NOTE 9 SUBSEQUENT EVENTS

Subsequent to the end of the third quarter, Milestone received a blanket purchase order from Sinopharm for 12,000 *STA Systems*, deliverable of the next 36 months.

The Company, subsequent to September 30, 2009, agreed to offer a bonus program to its Chief Executive Officer that will allow for an issuance of up to \$300,000 in restricted stock and/or stock options upon the achievement of specified revenues generated from the business with Sinopharm over a four year period. Such compensation will be recorded under this plan annually, upon successful achievement of the bonus program revenue targets as included in the agreement.

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.

OVERVIEW

During the third quarter of 2009, we remained focused on advancing efforts to achieve our two primary objectives; those being:

- Optimizing our tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with our proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, the *STA Single Tooth Anesthesia System (STA System)*; and
- Identifying and pursuing strategic collaborations with third parties to jointly develop new products utilizing our patented *CompuFlo* pressure force technology for novel new medical applications.

STA System Awards Industry Recognition

Since its market introduction in the spring of 2007, the *STA System* has received rave reviews and awards from the dental industry. In July 2007, noted industry publication *Dentistry Today* featured the *STA System* as one of the Top 100 Products in 2007, helping to promote much broader recognition of the instrument and validating the *STA System's* value proposition for dentists and patients alike. In April 2008, *Medical Device & Diagnostic Industry* magazine distinguished the *STA 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 System* was one of only two winning products that serve dental practitioners.

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

Second Annual Symposium on C-CLAD

In addition to winning noted acclaim among leading dental publications, our award winning *STA 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 C-CLAD Symposium in New Orleans, welcoming 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 System* not only into dental school curricula, but also extend messaging regarding its many unique benefits to the dental community and patients alike.

Table of Contents

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

- The History of C-CLAD
- Treating with Connection
- Heart Rate Study
- STA Compassionate Care in the 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 for Tots and Teens
- Computerized Local Anesthesia in Dentistry: A Review
- Today's Technology
- Managing a Successful Dental Practice: Why People Keep Coming Back
- STA – The Dental School's Perspective
- Futuristic Vistas: The Dentist/Hygienist Partnership

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

STA System Growth

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

Global Distribution Network

The *STA System* and related hand pieces are marketed to the dental industry in the United States and Canada by many of the nation's leading dental supply companies, including Henry Schein, Inc., Patterson Dental Supply, Benco Dental, Burkhart Dental, Goetze Dental, Atlanta Dental, Darby Dental Supply, Dental Health Products, Nashville Dental and Parkway Dental.

Collectively, our domestic network has more than 2,500 independent sales representatives trained to sell the *STA System* and related hand pieces to dentists throughout North America.

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

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.

Shortly before the end of the second quarter, 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 System*, *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 named Shaul Koren, founder and CEO of Istrodent Pty Ltd AB and one of our strongest marketing 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.

Table of Contents

As a result of growing market awareness and appreciation of the *STA System*, coupled with our active worldwide marketing efforts, sales of the instrument (and related hand pieces) yielded four consecutive quarters of growth in 2008. In the first nine months of this year, we saw no indication that this trend is slowing or reversing. Sales of the *STA System* and related recurring sales from disposable hand pieces helped increase total revenues by \$1,380,726 during the nine months ended September 30, 2009, when compared to the same nine month period in the prior year.

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,			
	2009		2008	
DOMESTIC				
<i>Instruments</i>	\$ 263,451	22.9%	\$ 365,887	27.6%
Handpieces	865,508	75.1%	942,613	71.3%
Other	22,516	2.0%	14,165	1.1%
Total Domestic	\$ 1,151,475	100.0%	\$ 1,322,665	100.0%
INTERNATIONAL				
<i>Instruments</i>	\$ 248,080	32.7%	\$ 132,992	27.1%
Handpieces	507,747	67.0%	355,041	72.4%
Other	1,961	0.3%	2,405	0.5%
Total International	\$ 757,788	100.0%	\$ 490,438	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS				
Domestic	\$ 1,151,475	60.3%	\$ 1,322,665	73.0%
International	757,788	39.7%	490,438	27.0%
Total Product Sales	\$ 1,909,263	100.0%	\$ 1,813,103	100.0%

	Nine Months Ended September 30,			
	2009		2008	
DOMESTIC				
<i>Instruments</i>	\$ 1,317,589	32.6%	\$ 420,028	13.0%
Handpieces	2,659,310	65.8%	2,743,031	85.5%
Other	61,407	1.6%	46,625	1.5%
Total Domestic	\$ 4,038,306	100.0%	\$ 3,209,684	100.0%
INTERNATIONAL				
<i>Instruments</i>	\$ 796,064	37.7%	\$ 426,530	27.8%
Handpieces	1,309,526	62.0%	1,097,692	71.7%
Other	7,088	0.3%	8,070	0.5%
Total International	\$ 2,112,678	100.0%	\$ 1,532,292	100.0%

DOMESTIC/INTERNATIONAL ANALYSIS

Domestic	\$ 4,038,306	65.7%	\$ 3,209,684	67.7%
International	2,112,678	34.3%	1,532,292	32.3%
Total Product Sales	\$ 6,150,984	100.0%	\$ 4,741,976	100.0%

We achieved gross profit margin of 63% and 60% for the three and nine months ended September 30, 2009, respectively. However, our revenues and related gross profits have not been sufficient to support our overhead, new product introduction and research and development expenses. Although we anticipate expending funds for research and development in 2009, these amounts will vary based on the operating results for each quarter. We have incurred operating losses and negative cash flows from operating activities since its inception. The Company is actively pursuing the generation of positive cash flows from operating activities through increases in revenue, assessment of current contracts and current negotiations and reductions in operating expenses. At September 30, 2009, we expect to have sufficient cash reserves to meet all of our anticipated obligations through December 31, 2009.

New Product Development and Commercialization Utilizing CompuFlo Technology

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

Table of Contents

In keeping with our stated goal for leveraging our patented *CompuFlo* technology in new medical applications, our management team has continued to identify and pursue opportunities to form strategic collaborations in the areas of self-administered drug delivery, injections for osteoarthritis pain management and epidurals. The response to our proprietary technology with whom we have engaged in meaningful teaming discussions has continued to be encouraging. Throughout 2008, we have met with healthcare companies who expressed interest in potential applications of the *CompuFlo* technology. As we progress through 2009, the Company maintains its pursuit of *CompuFlo*-based product development prospects that are deemed the most promising and commercially viable, and offer the greatest potential for allowing us to fully realize the product development and commercialization opportunities.

Executive Management Change

On March 27, 2009, we accepted the resignation of our Chief Executive Officer, who chose to leave Milestone to pursue a new career opportunity. Our Chairman of the Board, Leonard Osser, temporarily assumed the post of Chief Executive Officer. However, on September 1, 2009, Leslie Bernhard, an independent member of our Board of Directors, was named Chairman, succeeding Mr. Osser who had led the Company as its Chairman since 1991. Mr. Osser now serves as our Chief Executive Officer.

Technology Rights

The technology underlying our *SafetyWand* and *CompuFlo* technology and an improvement to the controls for *CompuDent* were developed by our Director of Clinical Affairs and assigned to us. We purchased this technology pursuant to an agreement dated January 1, 2005 for 43,424 shares of restricted common stock and \$145,000 in cash, paid on April 1, 2005. In addition, our Director of Clinical Affairs will receive additional contingent payments of 2.5% of our total sales of *CompuDent* and *Wand Plus* units using some of these technologies, and 5% of our total sales of *STA* units and hand pieces using some of our other technologies. If products produced by third parties use any of these technologies, under a license from Milestone, then he will also receive the corresponding percentage of the consideration received by us for such sale or license.

Intellectual Property

In August 2009, we were issued a Notice of Allowance by the U.S. Patent and Trademark Office for its U.S. patent application directed to the use of its disposable hand piece for fluid administration. Our award-winning hand piece is an instrument currently utilized in conjunction with the Company's *STA*, *CompuDent* and *CompuMed* systems. Subsequent to the end of the third quarter of 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.

To date, we have been awarded a total of 23 U.S. utility and design patents relating to our Computer-Controlled Local Anesthesia Delivery (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.

Table of Contents*Accounts Receivable*

The realization of Accounts Receivable will have a significant impact on the Company. Consequently, we estimate 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, 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 unit is returned within the warranty period.

Results of Operations

The consolidated results of operations for the three and nine months ended September 30, 2009 compared to the same three and nine month period in 2008 reflect our focus and development on the *STA System*, as well as our continuing efforts on identifying collaborative partners for new product development utilizing our *CompuFlo* technology.

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2009		2008		2009		2008	
Products sales, net	\$ 1,909,263	100%	\$ 1,813,103	100%	\$ 6,150,984	100%	\$ 4,741,976	99%
Royalty income		0%	5,112	0%		0%	28,282	1%
Total revenue	1,909,263	100%	1,818,215	100%	6,150,984	100%	4,770,258	100%
Cost of products sold	709,003	37%	740,398	41%	2,488,294	40%	1,798,758	38%
Gross Profit	1,200,260	63%	1,077,817	59%	3,662,690	60%	2,971,500	62%
Selling, general and administrative expenses	1,477,948	77%	1,199,353	66%	4,960,000	81%	4,039,137	85%
Research and development expenses	57,972	3%	35,181	2%	157,941	3%	119,500	3%
Total operating expenses	1,535,920	80%	1,234,534	68%	5,117,941	83%	4,158,637	88%

Edgar Filing: MILESTONE SCIENTIFIC INC/NJ - Form 10-Q

Loss from operations	(335,660)	-18%	(156,717)	-9%	(1,455,251)	-24%	(1,187,137)	-25%
Other income interest & expense	(37,610)	-2%	(30,016)	-2%	(136,203)	-2%	(88,598)	-2%
Net loss	\$ (373,270)	-20%	\$ (186,733)	-11%	\$ (1,591,454)	-26%	\$ (1,275,735)	-27%

Table of Contents

Three months ended September 30, 2009 compared to three months ended September 30, 2008

Total revenues for the three months ended September 30, 2009 and 2008 were \$1,909,263 and \$1,818,215, respectively. The total increase in product sales of \$96,160, or 5%, in 2009 over 2008 is primarily the result of the continued *STA* product sales growth. Domestic *STA* unit sales decreased \$75,333 in 2009 over 2008. This decrease represented a slower sell through of the *STA System* during the summer of this year. In the domestic market, hand piece sales were lower, decreasing by \$77,105 or 8.2%. On the international front, unit sales increased in the third quarter of 2009 over 2008 by \$115,088, or 87%, principally due to increased market penetration for the *STA System*. Internationally, hand pieces increased by \$152,706, or 43% due to an increased demand. Our international business is an area of growth potential for us.

Cost of products sold for the three months ended September 30, 2009 and 2008 were \$709,003 and \$740,398 respectively. The \$31,395, or 4%, decrease is primarily attributable to a change in sales mix.

For the three months ended September 30, 2009, we generated a gross profit of \$1,200,260, or 63%, as compared to a gross profit of \$1,077,817, or 59%, for the three months ended September 30, 2008. The total increase in gross profit dollars of \$122,443 is due to an increase in sales dollar volume attributable to a change in our international sales process. Effective July 1, 2009, we began selling our products directly to international distributors. As a result of this change, we recorded a higher selling price of the product to our international distributor and pay a commission to our former master international distributor based on our agreement. This commission for the quarter is \$117,790 and is included in Selling, General and Administrative Expenses in the third quarter.

Selling, general and administrative expenses for the three months ended September 30, 2009 and 2008 were \$1,477,948 and \$1,199,353, respectively. The \$278,595, or 23%, increase is described in the following sections of this paragraph. Although we continue to focus on reducing expenses, the 2009 third quarter increase was due to higher expenses relating to promoting continued sales growth and increased consulting expenses. Personnel and related expenses remained relatively unchanged. Marketing (\$133,053) and sales (\$195,430) expenses increased principally due to increased attendance at trade shows and various sales promotions. Sales and trade show expenses increased by \$18,798, as we increase participation and presence at trade shows. Additionally, international sales commission increased by \$117,790 due to a change in our international sales agreement with our former master international distributor, while our third party sales representative commissions decreased based on decreased domestic sales of the *STA Systems*. Other variable sales expenses for the *STA System* and hand pieces increased in the third quarter of 2009 due to higher royalty payments (\$75,058). On the positive side of the ledger, professional services decreased by \$20,715 in the third quarter of 2009 over the same period in 2008. However, there was a significant increase in consulting services of \$201,284 in the third quarter of 2009, paid in stock, to professionals that have assisted in our continuous growth.

Research and development expenses for the three months ended September 30, 2009 and 2008 were \$57,972 and \$35,181, respectively. This increase is due to expenses related to new prototype equipment in the medical field.

The loss from operations for the three months ended September 30, 2009 and 2008 was \$335,660 and \$156,717, respectively. The \$178,943 increase in loss from operations is explained above.

Interest expense was \$30,230 and amortization of debt issuance relating to the line of credit and long term note payable was \$7,875 for the third quarter of 2009 compared to interest expense of \$23,863 and amortization of debt issuance expense of \$7,926 for the same quarter in 2008. The increase in interest expense of \$6,367 is due to the \$450,000 long term note, initiated in the fourth quarter of 2008 (as discussed in Note 5).

For the reasons explained above, net loss for the three months ended September 30, 2009 was \$373,270 as compared to a net loss of \$186,733 for the three months ended September 30, 2008. The \$186,537 increase in net loss is primarily a result of the increase in sales and gross margin dollars, offset by increases in market and sales costs and an increase in consulting and other selling, general and administrative expenses.

Table of Contents***Nine months ended September 30, 2009 compared to the nine months ended September 30, 2008***

Total revenues for the nine months ended September 30, 2009 and 2008 were \$6,150,984 and \$4,770,258, respectively. Total revenues increased by \$1,380,726 or 29%. Contributing to this increase was *STA* unit sales of \$1,268,728 and an increase in *STA* hand piece sales of \$434,451. *CompuDent* unit sales remained relatively unchanged and *CompuDent* hand piece sales decreased by \$333,782. The breakdown of the change is as follows. International revenue increased \$580,386, or 38%, as compared to the 2008 period. Domestic product revenue increased by \$828,622 in 2009, or 26%, as a result of a change in our distribution business model to a non-exclusive distributor base. This change was initiated in the second quarter of 2008. Domestic disposable hand piece sales decreased \$83,721 and international disposable hand piece sales increased \$211,834 or 19%. International unit sales increased by \$369,534 or 87% for the nine months ending September 30, 2009 as compared to the same period in 2008. Our international business continues to be a substantial growth area for us.

Gross profit for the nine months ended September 30, 2009 and 2008 was \$3,662,690, or 60%, (net of a write-down of returned defective merchandise of \$36,066) and \$2,971,500 or 62%, respectively. Gross profit dollars increased by \$691,190 due to an increase in sales volume in 2009 over 2008. The gross profit percentage decrease was due principally to the change in product mix with a substantially larger proportion of *STA* unit sales and the write down of legacy returned defective merchandise in the nine months of 2009 over the same period in 2008. A portion of the increase in gross profit dollars (\$117,790) is due to an increase in sales volume attributable to a change in how we record international sales. Effective July 1, 2009, the Company began selling our products directly to international distributors. As a result of this change, the Company records a higher selling price of the product to our international distributor and pays a commission to our former master international distributor based on our agreement. This commission is included in Selling, General and Administrative Expenses.

Selling, general and administrative expenses for the nine months ended September 30, 2009 and 2008 were \$4,960,000 and \$4,039,137, respectively. The increase of \$920,863, or 23%, is primarily attributable to an increase in several expense categories. Sales and marketing expense increased by \$614,654 for the period ending September 30, 2009. This increase was due to media and production spending of \$145,281; trade shows and travel expense of \$162,977; and cost relating to the C-CLAD Symposium, Key Opinion Leaders and sales promotions of \$187,560, offset by savings in employee relocation of \$23,869 and printing cost of \$46,102. Commission expense increased by \$49,703 for third party sales representatives due to sales volume increases and by \$117,790 for international sales commissions (effective July 1, 2009). General and administrative expenses increased a net of \$306,209. Expense increases in this category were consulting expenses of \$108,103 paid in stock to professionals that have assisted in the growth of the Company, patent annuity expenses of \$39,970, royalties of \$155,560 (based on increased *STA* unit and hand piece sales), a business consultant study of \$150,000, and an international business consultant of \$39,068. On a positive note, we reduced expenses for accounting costs by \$97,397 (audit, review and Sarbanes-Oxley), proxy costs by \$23,516 (electronic filing, Notice and Access System), warehousing fees by \$21,206 and reduced insurance costs by \$29,531.

Research and development expenses for the nine months ended September 30, 2009 and 2008 were \$157,941 and \$119,500, respectively.

Interest expense totaled \$115,619 as of September 30, 2009, an increase of \$42,164, or 57%, over the same period in 2008. The increase in this expense is due to the \$450,000 long term note that was initiated in the fourth quarter of 2008. Amortization of debt issuance costs of \$23,625 is related to the long term debt outstanding as of September 30, 2009 (as discussed in Note 5).

For the reasons explained above, net loss for the nine months ended September 30, 2009 of \$1,591,454 increased by \$315,719 or 25%, over the net loss for the nine month period ended September 30, 2008.

Working capital as of September 30, 2009 is negative \$406,968. Current assets declined by \$573,145 in all current asset categories (principally in cash, accounts receivable and advances to a contract manufacturer) from December 31, 2008. Current liabilities increased by \$1,366,511, principally due to the classification of the \$1.3 million line of credit, due June 30, 2010, as a current liability at September 30, 2009. The line of credit was classified as a long-term liability as of December 31, 2008. All borrowings and interest thereon must be repaid by June 30, 2010, and after the expiration date of the line, may be repaid by us in cash or, at its option, in shares of common stock (as discussed in

Note 5). Other increases in current liabilities are accounts payable for inventory purchases and a consultant business project. We are making every effort to maintain a viable lower level of inventory and to keep control of operating costs.

Table of Contents

Liquidity and Capital Resources

As of September 30, 2009, we had cash and cash equivalents of \$497,455 and working capital of negative \$406,968. The negative working capital is due to the classification of the \$1.3 million line of credit as a current liability as of September 30, 2009. All borrowings and interest thereon must be repaid by June 30, 2010, and after the expiration date of the line, may be repaid by us in cash or, at its option, in shares of common stock (as discussed in Note 5). We incurred net losses of \$1,591,454 and \$1,275,735 and negative cash flows from operating activities of \$157,948 and \$693,164 for the nine months ended September 30, 2009 and 2008, respectively.

Our working capital at September 30, 2009 was a negative \$406,968 compared to a positive working capital of \$1,532,688 as of December 31, 2008. The significant reduction in working capital as of September 30, 2009 is due to the classification of the \$1.3 million line of credit classified as a current liability at September 30, 2009 as compared to a classification as a long term liability at December 31, 2008. All borrowings and interest thereon must be repaid by June 30, 2010 and may be repaid by us in cash or at our option in shares of common stock. Current assets decreased by \$573,145, principally due to a decrease in cash by \$246,210 and accounts receivable by \$424,862. Inventory and stock subscription receivable increased by \$281,239. Current liabilities increased by \$1,366,511, principally due to the classification of the line of credit. We continue to strive to maintain a reasonable level of inventory and to keep control of operating cost.

Additionally, as of September 30, 2009, we had cash and cash equivalents of \$497,455 as compared to \$498,576 as of June 30, 2009, a decrease of \$1,121. Our working capital on June 30, 2009 as compared to September 30, 2009 improved by \$167,418. This continued effort is well under way to provide a cash flow neutral position in the future.

For the nine months ended September 30, 2009, our net cash used in operating activities was \$157,948. This was attributable primarily to a net loss of \$1,591,454 adjusted for noncash items of \$905,869, which was comprised principally of common stock and options issued for compensation and consulting services and changes in operating assets and liabilities of \$527,637.

For the nine months ended September 30, 2009, we used \$113,262 in investing activities. This was primarily attributable to \$76,986 of legal fees related to new patent applications. We have capital expenditures of \$36,276, primarily for the purchase of trade show booths for the purpose of showcasing the *STA System*.

For the nine months ended September 30, 2009, we received \$25,000 in financing activities.

We have incurred operating losses and negative cash flows from operating activities since its inception. We are 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. The Company, at September 30, 2009, expects to have sufficient cash reserves to meet all of its anticipated obligations through December 31, 2009. If we are unable to generate positive cash flows from its operating activities it will need to raise additional capital. There is no assurance that we will be able to achieve 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 we 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 our operating results.

Our recurring losses and negative operating cash flows raised 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.

Table of Contents

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 4T. Controls and Procedures.

Our 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, 2009 are effective to ensure that information required to be disclosed in the reports we filed 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 our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding disclosure.

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

Table of Contents**PART II OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

NONE

ITEM 1A. RISK FACTORS

The following factors may affect the growth and profitability of Milestone and should be considered by any prospective purchaser or current holder of our securities:

We have no history of profitable operations. Continuing losses could exhaust our capital resources and force us to discontinue operations.

For the nine months ended September 30, 2009 and 2008 our revenues were approximately \$6.2 million and \$4.8 million, respectively. In addition, we have had losses for each year since the commencement of operations, including net losses of approximately \$1.7 million and \$1.3 million for the nine months ended September 30, 2009 and 2008, respectively. At September 30, 2009, we had an accumulated deficit of approximately \$58.9 million. At September 30, 2009, we had cash and cash equivalents \$497,455 and working capital of a negative \$406,968. Additionally, we secured a line of credit in the aggregate amount of \$1.3 million from a stockholder. This line of credit of \$1.3 million is classified as a current liability as of September 30, 2009. All borrowings and interest thereon must be repaid by June 30, 2010, and after the expiration date of the line, may be repaid by us in cash or, at its option, in shares of common stock (as discussed in Note 5). Additionally, the Company borrowed \$450,000 in 2008 from the same shareholder, with an original due date of January 2009. This additional borrowing was refinanced at December 31, 2008 and the due date was extended to June 30, 2012, as discussed in Note 5. At September 30, 2009, we expect to have sufficient cash reserves to meet all of its anticipated obligations through December 31, 2009. Additionally, we are actively pursuing the generation of positive cash flows from operating activities through increases in revenues based upon management's assessment of present contracts and current negotiations and reductions in operating expenses. If we are unable to generate positive cash flows from its operating activities it will need to raise additional capital. There is no assurance that we will be able to achieve positive operating cash flows or that additional capital can be raised on the terms and conditions satisfactory to us if at all. If additional capital is required and it cannot be raised, then we would be forced to curtail its development activities, reduce marketing expenses for existing dental products or adopt other cost savings measures, any of which might negatively affect the our operating results.

Our recurring losses and negative operating cash flows raise substantial doubt about its ability to continue as a going concern.

There are no other changes to our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**Recent Sales of Unregistered Securities**

In the quarter ended September 30, 2009, we issued a total of 811,258 shares valued at \$676,500 as follows:

	Shares	\$
Shares issued for employee compensation	112,562	\$ 110,000
Shares issued for services	365,363	416,500
Shares sold	333,333	150,000
	811,258	\$ 676,500

Table of Contents

ITEM 3. DEFAULT UPON SENIOR SECURITIES

NONE

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

NONE

ITEM 5. OTHER INFORMATION

NONE

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. |

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 12, 2009