

MILESTONE SCIENTIFIC INC.

Form 10-Q

November 12, 2015

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, 2015

Or

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

For the transition period from _____ to _____

Commission File Number: 001-14053

MILESTONE SCIENTIFIC INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

13-3545623
(I.R.S. Employer
Identification No.)

220 South Orange Avenue, Livingston, New Jersey 07039

(Address of principal executive offices)

(973) 535-2717

(Registrant's telephone number, including area code)

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

Large accelerated filer

Accelerated filer

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

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

Yes No

As of November 12, 2015, the Issuer had a total of 21,478,248 shares of Common Stock, \$.001 par value, outstanding.

MILESTONE SCIENTIFIC INC

TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

Condensed Consolidated Balance Sheets September 30, 2015 (Unaudited) and December 31, 2014 (Audited) 4

Condensed Consolidated Statements of Operations Three and Nine months Ended September 30, 2015 and 2014 (Unaudited) 5

Condensed Consolidated Statement of Changes in Stockholders' Equity for the Nine months Ended September 30, 2015 (Unaudited) 6

Condensed Consolidated Statements of Cash Flows for the Nine months Ended September 30, 2015 and 2014 (Unaudited) 7

Notes to Condensed Consolidated Financial Statements (Unaudited) 8

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 15

Item 3. Quantitative and Qualitative Disclosures About Market Risk 19

Item 4. Controls and Procedures 19

PART II—OTHER INFORMATION

Item 1. Legal Proceedings 20

Item 1A. Risk Factors 20

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 20

Item 3. Defaults Upon Senior Securities 20

Item 4. Mine Safety Disclosures 20

Item 5. Other Information 20

Item 6. Exhibits 20

SIGNATURES 22

FORWARD-LOOKING STATEMENTS

When used in this Quarterly Report on Form 10-Q, the words “may”, “will”, “should”, “expect”, “believe”, “anticipate”, “cont”, “estimate”, “project”, “intend” and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) regarding events, conditions and financial trends that may affect Milestone Scientific’s future plans of operations, business strategy, results of operations and financial condition. Milestone Scientific 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 Scientific’s reports and registration statements filed with the Securities and Exchange Commission (the “SEC”). Milestone Scientific disclaims any intent or obligation to update such forward-looking statements.

Milestone Scientific has rights to the following trademarks: CompuDent®, CompuMed®, CompuFlo®, The Wand®, The Wand Plus®, The SafetyWand®, Dynamic Pressure Sensing Technology®, STA Single Tooth Anesthesia,TM (STA Instrument, instruments and handpieces), Ionic White® (light emitting diode), and Ionic WhiteTM (whitening toothpaste).

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014 (Audited)
ASSETS		
Current Assets:		
Cash and cash equivalents	\$4,390,783	\$10,367,993
Accounts receivable, net of allowance for doubtful accounts of \$5,000 as of September 30, 2015 and December 31, 2014	2,349,347	1,541,478
Due from related party	85,959	—
Note receivable-Milestone Medical Inc	2,000,000	—
Inventories	2,804,906	2,497,099
Advances on contracts	1,211,926	721,197
Prepaid expenses and other current assets	428,570	454,566
Total current assets	13,271,491	15,582,333
Investment in Milestone Medical Inc	—	888,720
Investment in Milestone Education LLC	18,700	24,192
Investment in Milestone China	161,588	348,651
Furniture, fixtures & equipment net of accumulated depreciation of \$437,024 as of September 30, 2015 and \$416,210 as of December 31, 2014	115,616	88,818
Patents, net of accumulated amortization of \$628,953 as of September 30, 2015 and \$576,960 as of December 31, 2014	480,021	530,029
Other assets	17,355	14,685
Total assets	\$14,064,771	\$17,477,428
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$780,934	\$1,453,908
Accrued expenses and other payables	1,350,853	981,168
Total current liabilities	2,131,787	2,435,076
Commitments and Contingencies		
Stockholders' Equity		
Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, 7,000 shares issued and outstanding, respectively	7	7
Common stock, par value \$.001; authorized 50,000,000 shares; 21,478,248 shares issued, 963,451 shares to be issued and 21,444,915 shares outstanding as of September 30, 2015; 21,404,494 shares issued, 974,953 shares to be issued and 21,371,161 shares outstanding as of December 31, 2014	22,442	22,380

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-Q

Additional paid-in capital	78,016,152	77,504,415
Accumulated deficit	(66,028,987)	(61,967,462)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total stockholders' equity	11,098,098	14,647,824
Noncontrolling interest	834,886	394,528
Total Equity	11,932,984	15,042,352
Total liabilities and stockholders' equity	\$14,064,771	\$17,477,428

See Notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Product sales, net	\$2,459,958	\$2,535,098	\$6,996,921	\$7,662,864
Cost of products sold	794,285	829,546	2,298,162	2,624,950
Gross profit	1,665,673	1,705,552	4,698,759	5,037,914
Selling, general and administrative expenses	2,480,354	1,838,388	6,969,332	4,749,112
Research and development expenses	20,676	29,370	49,616	74,254
Total operating expenses	2,501,030	1,867,758	7,018,948	4,823,366
(Loss) income from operations	(835,357)	(162,206)	(2,320,189)	214,548
Other income (expenses)	(632)	-	(632)	-
Interest income (expense)	(411)	755	(329)	916
Loss on earnings from Milestone Medical Inc.	(590,612)	(223,834)	(1,566,711)	(567,550)
Income (loss) on earnings from Education Joint Venture	2,343	(2,633)	(5,493)	(10,455)
Loss on earnings from China Joint Venture	(123,083)	29,428	(187,062)	29,428
Total other expenses, net	(712,395)	(196,284)	(1,760,227)	(547,661)
Loss before provision for income taxes	(1,547,752)	(358,490)	(4,080,416)	(333,113)
Provision for Income Tax	(27,105)	—	(40,751)	—
Net Loss	(1,574,857)	(358,490)	(4,121,167)	(333,113)
Net loss attributable to the noncontrolling interests	5,655	—	59,642	—
Net loss attributable to Milestone				
Scientific Inc.	\$ (1,569,202)	\$ (358,490)	\$ (4,061,525)	\$ (333,113)
Net loss per share applicable to common stockholders—				
Basic	\$ (0.07)	\$ (0.02)	\$ (0.19)	\$ (0)
Diluted	\$ (0.07)	\$ (0.02)	\$ (0.19)	\$ (0)
Weighted average shares outstanding and to be issued—				
Basic	21,418,145	21,189,245	21,375,317	19,621,471
Diluted	21,418,145	21,189,245	21,375,317	19,621,471

See Notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

NINE MONTHS ENDED SEPTEMBER 30, 2015

(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital		Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
	Shares	Amount	Shares	Amount	Capital	Deficit	interest	Stock		
Balance, January 1, 2015	7,000	\$7	22,379,447	\$22,380	\$77,504,415	\$(61,967,462)	\$394,528	\$(911,516)		\$15,042,352
Stock based compensation			—	—	334,049	—	—	—		334,049
Capital contribution from noncontrolling interest			—	—	—	—	500,000	—		500,000
Common stock to be issued to employee for bonuses			28,653	29	99,971	—	—	—		100,000
Common stock issued to employee for bonuses			7,407	7	19,993	—	—	—		20,000
Common stock issued for payment of consulting services			12,098	12	29,988	—	—	—		30,000
Common stock issued for payment of employee			5,761	6	14,994	—	—	—		15,000

compensation										
Exercise of stock options for										
consultants			8,333	8	12,742	—		—		12,750
Net loss			—	—	—	(4,061,525)	(59,642)	—		(4,121,167)
Balance, September 30, 2015	7,000	\$7	22,441,699	\$22,442	\$78,016,152	\$(66,028,987)	\$834,886	\$(911,516)		\$11,932,984

See Notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(4,121,167)	\$(333,113)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation expense	20,815	12,124
Amortization of patents	51,994	58,778
Common stock and options for compensation, consulting and vendor services	499,049	324,279
Equity loss on Milestone Medical Inc.	1,566,711	567,550
Equity loss on Education joint venture	5,493	10,455
Equity earning on China joint venture	187,062	(29,428)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(807,869)	(91,489)
Increase in related party	(85,959)	-
Increase in inventories	(307,807)	(919,814)
(Increase) decrease to advances on contracts	(490,729)	996,949
(Increase) decrease to prepaid expenses and other current assets	25,996	(114,807)
Increase in other assets	(2,670)	—
Decrease in accounts payable	(672,974)	(629,479)
Increase in customer advances	—	49,441
Increase in accrued expenses and other payables	369,685	95,194
Net cash used in operating activities	(3,762,370)	(3,360)
Cash flows from investing activities:		
Notes receivable to Milestone Medical Inc	(2,000,000)	—
Advances to related parties	(677,991)	(398,810)
Addition to intangible assets	(1,986)	-
Purchases of property and equipment	(47,613)	(66,130)
Net cash used in investing activities	(2,727,590)	(464,940)
Cash flows from financing activities:		
Proceeds from exercise of stock options	12,750	202,781
Net proceeds on Private Placement Offering in May 2014	—	9,449,683
Repayment of related party loan	—	(50,000)
Capital contribution from noncontrolling interest	500,000	—
Net cash provided by financing activities	512,750	9,602,464
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,977,210)	9,134,164
Cash and cash equivalents at beginning of period	10,367,993	1,147,198
Cash and cash equivalents at end of period	\$4,390,783	\$10,281,362
Supplemental disclosure of cash flow information:		
Shares issued to directors for the exercise of stock options	\$—	\$41,250
Shares issued to directors for compensation	\$—	\$55,200
Shares to be issued to employees for bonuses	\$100,000	\$—
Shares issued to employees for exercise of stock options	\$—	\$104,615
Shares issued to employees in lieu of cash compensations	\$42,500	\$35,624
Shares issued to consultants for exercise of stock options	\$60,000	\$199,500

Net proceeds on Private Placement Offering	\$—	\$56,916
--	-----	----------

See Notes to Condensed Consolidated Financial Statements

7

MILESTONE SCIENTIFIC INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Milestone Scientific Inc. and subsidiary (collectively “Milestone Scientific”, “our”, “us” or “we”) was incorporated in the state of Delaware in August 1989.

The unaudited consolidated financial statements of Milestone Scientific 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 consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2014 included in Milestone Scientific’s Annual Report on Form 10-K.

On June 1, 2015, Milestone Scientific up-listed to the NYSE MKT under the ticker symbol MLSS.

In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present Milestone Scientific’s financial position as of September 30, 2015 and the results of its operations for the three and nine months then ended.

The results reported for the three and nine months ended September 30, 2015 are not necessarily indicative of the results of operations which may be expected for a full year.

Milestone Scientific has incurred significant operating losses since its inception except for 2013 and the first quarter of 2014. Milestone Scientific had negative cash flows from operating activities for the nine months ending September 30, 2015 of \$3816,480 and a negative cash flow of \$3,360 for the nine months ended September 30, 2014. At September 30, 2015, Milestone Scientific had cash and cash equivalents of \$4,390,783 and a positive working capital of \$11,139,704 as compared to working capital of \$13,147,257 at December 31, 2014. The working capital decreased by \$2,007,553 as compared to December 31, 2014. The change in working capital is primarily due to a decrease in cash and cash equivalents, increase in accounts receivable, note receivable, inventories, and advances on contract and a decrease in current liabilities. Milestone Scientific’s management continues to examine all areas of the business to manage its cash flow. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue based upon management’s assessment of present contracts and current negotiations and reductions in operating expenses.

As of September 30, 2015, Milestone Scientific believes that it has sufficient cash reserves, collections of accounts and notes receivable to meet all of its anticipated obligations for the next twelve months. Milestone Scientific will continue to manage its cash position while taking strategic steps to expand its business in the medical and dental, business sectors.

NOTE -1 SUMMARY OF ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) and include the account of Milestone Scientific and its wholly owned subsidiary Wand Dental Inc. Additionally, the consolidated financial statements include the account of Milestone Scientific Advanced Cosmetic System, Inc. (“ACS”), a Delaware corporation that is seventy (70) percent owned by Milestone Scientific. The minority interest (thirty percent) in ACS is recorded in the equity section of the consolidated financial statements as noncontrolling interest. All significant intercompany transactions and balances have been eliminated in the consolidation.

ACS was organized in July 2014 by Milestone China (defined below) which is 40% owned by Milestone Scientific. ACS is owned fifty percent by Milestone China and fifty percent by Milestone Scientific. Milestone China has provided \$900,000 of cash and Milestone Scientific provided a royalty-free license to utilize its technology to develop a Botox instrument. Milestone Scientific will also provide the resources to design and commercialize the instrument at cost. Through attribution Milestone Scientific owns seventy percent of ACS.

Milestone Scientific Inc. Poland SP z.o.o. an inactive Polish company was formed in 2014. Milestone Scientific Inc. owns seventy-five percent of Milestone Scientific Inc. Poland SP z.o.o.

Accounts Receivable

The realization of accounts receivable will have a significant impact on Milestone Scientific. The criteria used by management to evaluate the adequacy of the allowance for doubtful accounts included, among others, credit worthiness of the customer, current trends, prior payment performance, the age of the receivables and Milestone Scientific's overall historical experience.

Inventories

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

Investment in Milestone Medical

In March 2011, Milestone Scientific entered into a joint venture (the "Medical Joint Venture") with Beijing 3H Scientific Technology Co., Ltd. ("Beijing 3H"), a People's Republic of China ("PRC") Company. Milestone Scientific contributed an exclusive worldwide royalty-free license for the development and commercialization of intra-articular and epidural drug delivery instruments, utilizing its patented CompuFlo technology to the Medical Joint Venture, and a group of individual investors including the controlling shareholders of Beijing 3H and a large shareholder of Milestone Scientific, who contributed \$1.5 million. Milestone Scientific, with the consent of the investors, organized a domestic research and development joint venture corporation, now known as Milestone Medical Inc. ("formally Medical Joint Venture"). In the fourth quarter of 2014, the joint venture agreement with Beijing 3H was terminated. However, Milestone Medical has continued to implement its business plan. As of September 30, 2015, Milestone Scientific owned 49.98% of the Milestone Medical and has recorded the investment using the equity method of accounting.

Investment in Milestone China

In July 2014, Milestone Scientific agreed to invest \$1.0 million through the contribution of 772 STA instruments for a 40% ownership in Milestone China Ltd., a Hong Kong based medical and dental distribution company ("Milestone China"). In 2014, 772 STA instruments were shipped and recorded at Milestone Scientific's cost in the investment account for Milestone China on the Balance Sheet. Milestone China will purchase STA instruments and handpieces on credit terms as required. Milestone China began operations in July 2014.

Impairment of Long-Lived Assets

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

Revenue Recognition

Revenue from product sales is recognized net of discounts and allowances to domestic distributors on the date of shipment for essentially all shipments, since the shipment terms are FOB warehouse. Milestone Scientific will recognize revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. Shipments to international distributors are FOB warehouse, therefore revenue is recognized on shipment of the goods. Milestone China is an exception, where only 60% of revenue is recognized on shipment, and the remaining balance is deferred until the goods have been sold to a third party by Milestone China. In all cases the price to the buyer is fixed

and the collectability is reasonably assured. Further, Milestone Scientific has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Recent Accounting Pronouncements

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. The new standard applies only to inventory for which cost is determined by methods other than last-in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new standard will be effective on

January 1, 2017. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

In September 2015, the FASB issued ASU No. 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. The new standard requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined and sets forth new disclosure requirements related to the adjustments. The new standard will be effective for us on January 1, 2016. The adoption of this standard is not expected to have an impact on our financial position or results of operations.

NOTE – 2 Basic and Diluted Net INCOME (Loss) Per Common Share

Milestone Scientific 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. (Fully diluted shares are only calculated if there is a net income.)

For the three and nine months ending September 30, 2015 and 2014, Milestone Scientific calculated basic and fully diluted earnings per common share as described in the previous paragraph.

NOTE – 3 ACCOUNTS RECEIVABLE

Milestone Scientific sells a significant amount of its product on credit terms to its major distributors. Milestone Scientific estimates losses from the inability of its customers to make payments on amounts billed. A majority of credit sales are due within ninety days from invoicing. There have not been any significant credit losses reported by the Company.

NOTE – 4 INVESTMENT IN UNCONSOLIDATED SUBSIDIARIES

Milestone Medical Inc

Milestone Medical had a zero net book value at September 30, 2015. In July 2013, Milestone Scientific entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare in the United States. This agreement was terminated in the second quarter of 2015.

Prior to the fourth quarter of 2014 Milestone Scientific had distribution responsibility in the U.S. and Canada, and Beijing 3H was responsible for distribution in Macao, Hong Kong and other regions of Asia. In the fourth quarter of 2014, the joint venture agreement with Beijing 3H was terminated and Milestone Medical contracted with Milestone China to become its new distributor in Asia for both the epidural and intra-articular instruments. In the fourth quarter of 2014, Milestone Scientific Inc. purchased an additional 995,000 shares of Milestone Medical from another shareholder for \$447,750 (\$0.45 per share), which increased its percentage of ownership to 49.98% of Milestone Medical

Milestone Scientific recorded a loss on its investment in Milestone Medical of \$590,612 and \$1,566,711 for the three and nine months ended September 30, 2015 and \$223,834 and \$567,550 for the three and nine months ended September 30, 2014, respectively. For the nine month September 30, 2015 Milestone Scientific offset advances to Milestone Medical by \$537,923 which is the excess loss of the Company's investment in Milestone Medical. Milestone Scientific has accounted for its investment in Milestone Medical using the equity method of accounting. The losses described represent the applicable losses reported by Milestone Medical during the three and nine months ended September 30, 2015 and 2014, respectively. Milestone Scientific utilizes the equity method of accounting to recognize its financial results of the Medical Joint Venture.

Milestone Scientific did not have any legal expense related to seeking U.S. Food and Drug Administration ("FDA") marketing clearance for the epidural and intra-articular instruments under section 510k for the three and nine months ended September 30, 2015. Milestone Scientific expensed \$44,415 and \$175,868 on behalf of Milestone Medical for the three and nine months ended September 30, 2014, respectively, for legal expenses related to seeking FDA marketing clearance for the epidural and intra-articular instruments under section 510K. As part of the joint venture agreement, Milestone Scientific agreed to pay all the legal fees related to the FDA clearance process.

Milestone Scientific had an investment in Milestone Medical of zero as September 30, 2015 and \$888,720 as of December 31, 2014.

Milestone Education LLC.

The Education Joint Venture has been providing training and education to our dentists throughout the world. Milestone Scientific accounted for its investment in the Education Joint Venture using the equity method of accounting. The Education Joint Venture earned a profit of \$4,686 and incurred a loss of \$10,986 for the three and nine months ended September 30, 2015, respectively. The Education Joint Venture incurred a loss of \$5,266 and \$20,910 for the three and nine months ended September 30, 2014, respectively. Fifty percent of these losses were recorded in the condensed consolidated statements of operations for the three and nine months ended September 30, 2015 and 2014.

Milestone China Inc

In September 2014, Milestone Scientific agreed to invest \$1. Million through the contribution of 772 STA instruments (at a distributor price of approximately \$1,295 per instrument) for a forty percent ownership in Milestone China. The instruments were shipped to the distributors over a period of two years. Milestone China will purchase additional STA handpieces as required. In 2014, 772 STA instruments were shipped and are recorded at Milestone Scientific's cost in the investment account for Milestone China on the Balance Sheet. Milestone China did not begin operations until July 2014. Milestone Scientific recognized a loss of \$123,083 and \$187,062 from Milestone China, for the three and nine months and ended September 30, 2015. These amounts represents 40% of the loss and profit of Milestone China for each period respectively. Milestone Scientific's investment in Milestone China is \$161,588 and \$348,651 as of September 30, 2015 and December 31, 2014, respectively. Milestone Scientific shipped \$938,304 of instruments and \$138,600 of handpieces in the nine months ended September 30, 2015. Milestone Scientific recognized 60% of the revenue on shipments of instruments and handpieces. The remaining 40% of revenue is recognized at the time the goods are sold to a third party. At September 30, 2015 there was no deferred revenue, all instruments and handpieces were sold to a third party.

NOTE – 5 Stock Option Plans

A summary of option activity for employees under the plans and changes during the nine months ended September 30, 2015, is presented below:

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Outstanding, January 1, 2015	1,472,130	1.33	3.23	1,430,231
Granted	157,306	3.01	4.48	57,000
Exercised	—	—	—	—
Forfeited or expired	—	—	—	—
Outstanding, September 30, 2015	1,629,436	1.49	2.50	2,620,771
Exercisable, September 30, 2015	1,077,520	1.14	1.95	2,093,571

Milestone Scientific recognizes stock compensation expense on a straight line basis over the requisite service period. During the three months ended September 30, 2015, and 2014 Milestone Scientific recognized \$107,205 and \$39,877 of total stock compensation cost. During the nine months ended September 30, 2015 and 2014, Milestone Scientific recognized \$334,049 and \$119,630 of total stock compensation cost. As of September 30, 2015 and September 30,

2014, there was \$881,765 and \$272,946, respectively, of total unrecognized compensation cost related to non-vested options which Milestone Scientific expects to recognize over a weighted average period of 3.59 years and 2.0 years at September 30, 2015 and 2014, respectively. A 6% rate of forfeitures is assumed in the calculation of the compensation cost for the period in 2015 and 2014.

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

A summary of option activity for non-employees under the plans and changes during the nine months ended September 30, 2015, is presented below:

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-Q

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Outstanding, January 1, 2015	16,666	1.27	0.62	17,166
Granted	—	—	—	—
Expired	—	—	—	—
Exercised	8,333	1.53	—	—
Outstanding, September 30, 2015	8,333	1.01	0.19	17,166
Exercisable, September 30, 2015	8,333	1.01	0.19	17,166

During the nine months ended September 30, 2015 and September 30, 2014, Milestone Scientific had no expenses related to non-employee options that vested during the period. There was no unrecognized compensation cost related to non-vested options as of September 30, 2015. A six percent rate of forfeitures is assumed in the calculation of the compensation cost for the period.

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 Scientific 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 Scientific had paid cash for the goods or services.

NOTE – 6 CONCENTRATION OF CREDIT RISK

Milestone Scientific's consolidated financial instruments that are exposed to concentrations of credit risk consist primarily of cash, trade accounts receivable, and advances on contracts. Milestone Scientific 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 Scientific 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 Scientific to credit risk consist principally of trade accounts receivable, as Milestone Scientific does not require collateral or other security to support customer receivables, and advances on contracts. Milestone Scientific entered into a purchase agreement with a vendor to supply Milestone Scientific with 12,000 STA Instruments and this commitment was completed in September 2015. Milestone Scientific does not believe that significant credit risk exists with respect to this advance to the contract manufacturer.

Milestone Scientific closely monitors the extension of credit to its customers while maintaining allowances, if necessary, for potential credit losses. On a periodic basis, Milestone Scientific evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit

conditions. Management has provided a reserve that it believes is sufficient to record accounts receivable at net realizable value as of September 30, 2015 and December 31, 2014.

NOTE – 7 ADVANCES ON CONTRACTS

The advances on contracts represent funding of future STA inventory purchases. The balance of the advances as of September 30, 2015 and December 31, 2014 is \$1,211,926 and \$721,197, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE – 8 INCOME TAXES

For the three and nine months ending September 30, 2015, state tax liability was approximately \$27,000 and \$41,000. Such expense was recognized in the accompanying consolidated financial statements as of September 30, 2015. Due to Milestone Scientific's history of past operating losses, which required a full valuation allowances for all of Milestone Scientific's deferred tax assets at September 30, 2015 and 2014, no recognition was given to the utilization of the remaining Federal net operating loss carryforwards.

NOTE – 9 COMMON STOCK ISSUANCES

As of September 30, 2015 Milestone Scientific issued 40,155 shares to a former employee based on a deferred compensation agreement. In addition Milestone Scientific Inc. issued 13,168 shares of common stock valued at \$35,000 for the payment of employee compensation and 12,098 share of common stock valued at \$30,000 was issued for payment of services. Milestone Scientific Inc. also issued 8,333 shares of common stock on the exercise of certain stock options valued at \$12,750.

NOTE – 10 PREFERRED STOCK ISSUANCE

In May 2014, Milestone Scientific completed a \$10 million private placement pursuant, which raised \$3 million, from the sales of 2 million shares of common stock at \$1.50 per share, and \$7 million from the sale of 7,000 shares of Series A Convertible Preferred Stock (the “Series A Stock”), with a stated value of \$1,000 per share. The Series A Stock votes together with the Common Stock on a converted basis and as a single class. However, those shares have class voting rights as to amendments to the Certificate of Incorporation adversely affecting the Series A Stock and increasing in the number of authorized shares of Series A Stock. Issuances of additional shares of Series A Stock, and increases in the size of the board, prior to the time for the holders of the Series A Stock, no longer have a right to nominate a designee for election to the board or issuance of “senior stock” or “parity stock.” The Series A Stock is entitled to a liquidation preference in an amount equal to the greater of 100% of its \$1,000 per share stated value plus an amount equal to any then accrued and unpaid dividends, or the amount the Series A Stock would receive if all the outstanding shares of Series A Stock had been converted into common stock at \$2.545 per share, subject to adjustment in accordance with the terms and provisions of the Certificate of Incorporation (the “base conversion price”). The Series A Stock is convertible into common stock at the base conversion price at the option of the holder or mandatorily convertible into common stock on May 13, 2019, at the base conversion price provided that certain “threshold” prices have been achieved during the 360 calendar day period prior to such date. If those threshold prices have not been achieved, the Series A Stock will convert at \$1.50 per share on May 13, 2019.

NOTE – 11 RELATED PARTY

Milestone Scientific has a manufacturing agreement with a related party. The related party manufactures products under specific purchase orders but without minimum purchase commitments. Milestone Scientific purchased \$447,817 and \$325,628 from the supplier for the three months ended September 30, 2015 and 2014, respectively. Milestone Scientific purchased \$1,801,449 and \$2,069,546 from the supplier for the nine months ended September 30, 2015 and 2014, respectively. Milestone Scientific owed \$427,231 and \$502,167 to this supplier as of September 30, 2015 and December 31, 2014, respectively.

On July 1, 2013, Milestone Scientific and Milestone Medical signed an agreement for the reimbursement of specific expenses incurred by Milestone Scientific specifically for the benefit of Milestone Medical. At September 30, 2015, the expenses due from Milestone Medical are \$623,881, which were offset by \$537,923 which is the excess loss of the company investment in Milestone Medical.

In December 2014, Milestone Scientific entered into a bridge financing to Milestone Medical while waiting approval of the capital raise, Milestone Scientific (49.98% owners) entered into a line of credit agreement allows Milestone Medical to borrow up to \$2 million from Milestone Scientific through January 2016, if needed, to assist in paying for the capital raise. The loan provides for interest at a rate of 3.25% per annual, the prime rate at the inception of the line of credit. The agreement terminates at April 15, 2016. In September 2015 Milestone Scientific increased the line of credit to \$2.5 million at the request of Milestone Medical Inc., due to the delay in obtaining regulatory approval to proceed with the additional capital raise. All other contractual conditions of the line of credit remain unchanged. \$2,000,000 was borrowed by Milestone Medical as of September 30, 2015 and is recognized as notes receivable on the condensed consolidated balance sheet.

A wholly-owned subsidiary (Wand Dental) of Milestone Scientific shipped approximately \$938,304 of instruments and \$150,600 of handpieces in the nine months ended September 30, 2015 to Milestone China. Milestone China owes

\$1,088,904 Wand Dental for handpieces and instruments shipped in 2015. The receivable is included within the accounts receivable balance within the balance sheet.

NOTE – 12 SIGNIFICANT CUSTOMERS & GEOGRAPHICAL INFORMATION

Milestone Scientific had two customers (distributors) for the three months ended September 30, 2015, that had approximately 33% (15% and 18 %), of its net product sales and two customers (distributors) that had approximately 47% (21% and 26 %), of its net product sales for three months ended September 30, 2014. Milestone Scientific had two customers (distributors) for the nine months ended September 30, 2015 that had approximately 40% (22%, and 18 %) of the net product sales and two customers (distributors) that had approximately 46% (21% and 25 %) of its net product sales for the nine months ended September 30, 2014.

Milestone Scientific had accounts receivable for three major customers that amounted to \$1,571,782 (\$1,088,904, \$306,221 and \$176,657) representing 69% (47%, 13% and 9%) of accounts receivable as of September 30, 2015, and accounts receivable for two major customers of \$1,099,804, or 69% as of December 31, 2014, respectively.

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

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-Q

	Three Months Ended			Nine Months Ended	
	September 30, 2015	2014		September 30, 2015	2014
Instruments	\$901,213	\$413,914	Instruments	\$2,317,547	\$1,938,293
Handpieces	1,533,936	2,090,580	Handpieces	4,610,592	5,608,776
Other	24,809	30,604	Other	68,782	115,795
	\$2,459,958	\$2,535,098		\$6,996,921	\$7,662,864
United States	\$700,879	\$1,039,153	United States	\$2,410,054	\$3,434,171
Canada	145,808	30,548	Canada	189,164	100,321
Other Foreign	1,613,271	1,465,397	Other Foreign	4,397,703	4,128,372
	\$2,459,958	\$2,535,098		\$6,996,921	\$7,662,864

NOTE – 13 PENSION PLANS

Milestone Scientific have a defined contribution plan that allows eligible employees to contribute part of their salary through payroll deductions. Milestone Scientific does not contribute to this plan but does pay the administrative costs of the plan, which are not significant.

In March 2014, the Board of Directors approved the Compensation Committee’s request to amend the Chief Executive Officer of Milestone Scientific’s employment agreement to provide benefits to make payments of \$203,111 per year for five years to the Executive, or as he directs such payments to a third party, to fund his acquisition of, or contribution to an annuity, pension, or deferred distribution plan or for an investment for the Executive and his family. For the three and nine months ended September 30, 2015, approximately \$51,000 and \$102,000, was expensed.

NOTE – 14 COMMITMENTS AND OTHER

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

The termination of the manufacturing relationship with any of the above manufacturers could have a material adverse effect on Milestone Scientific’s ability to produce and sell its products. Although alternate sources of supply exist and new manufacturing relationships could be established, Milestone Scientific 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 Scientific.

The technology underlying the SafetyWand and CompuFlo, and an improvement to the controls for CompuDent were developed by the Director of Clinical Affairs and assigned to us. Milestone Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director will receive additional payments of 2.5% of the total sales of products using certain of these technologies, and 5% of the total sales of products using certain other of the

technologies. In addition, the Director is granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant, 8,333 shares of the common stock upon the issuance of each additional patent relating to these technologies. If products produced by third parties use any of these technologies (under license from us) then the Director will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license. Milestone Scientific expensed the Director's royalty fees of \$117,320 and \$89,600 for the three months ended September 30, 2015 and 2014, respectively. Milestone Scientific expensed the Director's royalty fee of \$313,751 and \$291,714 for the nine months ended September 30, 2015 and 2014, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of zero and \$39,390 for the nine months ended September 30, 2015 and 2014, respectively.

In January 2010, Milestone Scientific issued a purchase order to Tricor Systems Inc for the purchase of 12,000 STA Instruments to be delivered over the next three years. The purchase order is for \$5,261,640. Wand Dental Inc, a wholly-owned subsidiary of Milestone Scientific was assigned this commitment on October 1, 2014. As of September 30, 2015, this commitment was completed. In the second quarter of 2015, Wand Dental Inc entered into a new purchase commitment for 3,000 STA instruments, (\$1,785,750) for the delivery of these instruments beginning October 2015 and into 2016. The balance of the advances as of September 30, 2015 and December 31, 2014 is \$1,211,926 and \$721,197, respectively.

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

Subsequent Events

Milestone Scientific has evaluated subsequent events and has determined that there are no other events to be disclosed.

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

The following discussions of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Form 10-Q. Certain statements in this discussion and elsewhere in this report constitute forward-looking statements, within the meaning of section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements.

OVERVIEW

Milestone Scientific was officially listed on the NYSE MKT on June 1, 2015.

In 2015, Milestone Scientific remains focused on advancing efforts to achieve our two primary objectives; those being:

- Enhancing our global reach by partnering with distribution companies in the medical sector and
 - Optimizing our tactical approach to product sales and marketing in order to materially increase penetration of the global dental and medical markets with our proprietary, patented Computer-Controlled Local Anesthesia Delivery (C-CLAD) solution, the STA Single Tooth Anesthesia Instrument (STA Instrument)
- STA Instrument Growth

Since its market introduction in early 2007, the STA Instrument and a prior computerized controlled local anesthesia delivery product have been used to deliver over 60 million safe, effective and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

Global Distribution Network

United States and Canadian Market

In September 2015, Milestone Scientific received official notification that a consortium led by, Milestone Scientific Inc. Poland, SP z.o.o. had been awarded a \$4.2 million grant from The Natural Centre for Research and development in Poland of which Milestone Scientific's subsidiary will receive approximately \$1.5 million in funding.

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

In July 2013, Milestone Scientific entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare. Pursuant to the strategic partnership, the distributor will hold, for a period of three years with the FDA market, the exclusive rights to market, resell, label and distribute Milestone Scientific's CompuFlo injection technology for use in epidural applications for childbirth and other pain management needs in the U.S. hospital sector. This partnership was terminated in June 2015, due to delays in receiving FDA clearance on the instrument at that time.

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

International Market

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

In early October 2012, the State Food and Drug Administration (SFDA) of the People's Republic of China approved Milestone Scientific's Single Tooth Anesthesia System® (STA System). In May 2014, the CFDA, (previously the SFDA), granted registration approval of the STA handpieces in China.

Shortly before the end of the second quarter 2009, we announced that we were refining our international marketing strategy to gain greater access to and penetration of the international dental markets for the STA Instrument, CompuDent and related disposable handpieces. 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 Scientific added in the spring of 2010 an International Sales Director to focus on the growth of our products outside the USA and Canada. The position was eliminated in 2014 and subsidized with a consultant in Central and South America, while our new CEO of Wand Dental has focused his efforts in developing distributors in Europe and South America.

In March 2011, Milestone Scientific entered into a joint venture (the “Medical Joint Venture”) with Beijing 3H Scientific Technology Co., Ltd. (“Beijing 3H”), a People’s Republic of China (“PRC”) Company. Milestone Scientific contributed an exclusive worldwide royalty-free license for the development and commercialization of intra-articular and epidural drug delivery instruments, utilizing its patented CompuFlo technology to the Medical Joint Venture. A group of individual investors including the controlling shareholders of Beijing 3H and a large shareholder of Milestone Scientific contributed \$1.5 million. Milestone Scientific, with the consent of the investors, organized a domestic research and development joint venture corporation, now known as Milestone Medical Inc. (“Milestone Medical”). In the fourth quarter of 2014, the joint venture agreement with Beijing 3H was terminated. However, Milestone Medical has continued to implement its business plan. As of September 30, 2015, Milestone Scientific owned 49.98% of Milestone Medical and has recorded the investment using the equity method of accounting.

Subsequent to the termination of the distribution agreement with Beijing 3H, Milestone Medical contracted with Milestone China to become the new distributor in Asia for both the epidural and intra-articular instruments while Milestone Scientific continues to have distribution responsibility in the U.S. and Canada. Milestone Scientific owns forty percent of Milestone China. As of September 30, 2015, Milestone Medical’s development of the two medical instruments is ongoing and nearing the completion. In September 2014, Milestone Medical received CE certification to distribute their instruments in European Community (EU). Milestone Scientific is actively pursuing medical distributors for the instrument in the EU community. In March 2015, Milestone Medical signed a distribution agreement with a Polish Medical distributor for the distribution of the epidural instrument. Shipment of instruments and disposables began in September 2015. In September 2015, Milestone Medical signed a distribution agreement with an Italian distributor for distribution of the epidural instrument in Italy. During the third quarter of 2015, the company shipped its first instruments to the Italian distributor.

Segmented Sales Performance

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

	Three Months Ended September 30,				Nine Months Ended September 30,				
	2015		2014		2015		2014		
DOMESTIC	DOMESTIC								
Instruments	\$9,555	1.0 %	\$178,623	17.2 %	Instruments	\$611,845	25.4 %	\$687,501	20.0 %
Handpieces	672,425	96.0 %	846,420	81.5 %	Handpieces	1,777,548	73.7 %	2,685,360	78.2 %
Other	18,898	3.0 %	14,110	1.3 %	Other	20,661	0.9 %	61,310	1.8 %
Total Domestic	700,878	100.0%	1,039,153	100.0%	Total Domestic	2,410,055	100.0%	3,434,171	100.0%
INTERNATIONAL	INTERNATIONAL								
Instruments	\$891,657	40.0 %	\$235,291	15.7 %	Instruments	\$1,705,703	37.2 %	\$1,250,792	29.6 %
Handpieces	861,512	60.0 %	1,244,160	83.2 %	Handpieces	2,833,043	61.8 %	2,923,417	69.1 %
Other	5,910	0.0 %	16,494	1.1 %	Other	48,120	1.0 %	54,484	1.3 %
Total International	1,759,079	100.0%	1,495,945	100.0%	Total International	4,586,866	100.0%	4,228,693	100.0%

DOMESTIC/INTERNATIONAL ANALYSIS					DOMESTIC/INTERNATIONAL ANALYSIS				
Domestic	\$700,878	32.0 %	\$1,039,153	41.0 %	Domestic	\$2,410,055	34.4 %	\$3,434,171	44.8 %
International	1,759,080	68.0 %	1,495,945	59.0 %	International	4,586,866	65.6 %	4,228,693	55.2 %
Total Product Sales	\$2,459,958	100.0%	\$2,535,098	100.0%	Total Product Sales	\$6,996,921	100.0%	\$7,662,864	100.0%

In 2015, Milestone Scientific planned to further support increased sales and marketing activity through our current distributors and through newly appointed distributors of the STA Instruments in the international market. In the U.S. and Canada, Milestone Scientific will continue the utilization of independent hygienists for training individual practitioners and group practices, continue to, refined and directed advertising to dental professionals, and continue to support and broaden our global distribution network.

Results of Operations

The consolidated results of operations for the three and nine months ended September 30, 2015 compared to the same three and nine month periods in 2014 reflect our focus and development on the Wand/STA Instrument, as well as continuing efforts on

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-Q

identifying collaborative partners which will allow for new product development utilizing our CompuFlo technology.

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2015		2014		2015		2014	
Total revenue	\$2,459,958	100 %	\$2,535,098	100 %	\$6,996,921	100 %	\$7,662,864	100 %
Cost of products sold	794,285	32 %	829,546	33 %	2,298,162	33 %	2,624,950	34 %
Gross Profit	1,665,673	68 %	1,705,552	67 %	4,698,759	67 %	5,037,914	66 %
Selling, general and administrative expenses	2,480,354	99 %	1,838,388	73 %	6,969,332	99 %	4,749,112	62 %
Research and development expenses	20,676	1 %	29,370	1 %	49,616	1 %	74,254	1 %
Operating expenses	2,501,030	100 %	1,867,758	74 %	7,018,948	99 %	4,823,366	62 %
(Loss) income from operations	(835,357)	-34 %	(162,206)	-6 %	(2,320,189)	-33 %	214,548	3 %
Other expenses - interest & expenses	(712,395)	-29 %	(196,284)	-8 %	(1,760,227)	-25 %	(547,661)	-7 %
Loss before Provision for Tax	(1,547,752)	-64 %	(358,490)	-10 %	(4,080,416)	-59 %	(333,113)	7 %
Provision for Income Tax	(27,105)	-1 %	—	0 %	(40,751)	-2 %	—	0 %
Net loss	(1,574,857)	-64 %	(358,490)	-14 %	(4,121,167)	-58 %	(333,113)	-4 %
Less: Net loss attributable to the noncontrolling interests	5,655	0 %	—	0 %	59,642	0 %	—	0 %
Net loss attributable to Milestone Scientific Inc.	\$(1,569,202)	-64 %	\$(358,490)	-14 %	\$(4,061,525)	57 %	\$(333,113)	-4 %

Three months ended September 30, 2015 compared to Three months ended September 30, 2014

Total product sales for the three months ended September 30, 2015 and 2014 were \$2,459,958 and \$2,535,098, respectively, a decrease of \$75,140, from 2014. Domestic sales decreased by \$338,275 or 33% from 2014. In the domestic market, the total handpiece sales decreased by \$173,995, or 21%, in 2015 over 2014. The decrease in domestic handpiece sales is primarily due to a price increase in January 2015 that is slowly being adopted by our distributor in the USA. We have adjusted our training and field support to increase handpiece usage. On the international front, revenue increased by \$263,134 in 2015 over 2014. This increase is primarily due to the recognition of instruments revenue for sales to Milestone China. Handpiece sales decreased by \$382,648, or 31%, due to international price increase at the beginning of 2015 and a strengthening of the US dollar as compared to the Euro and other currencies throughout the world. We believe that Wand Plus users in Europe will continue to own, utilize and purchase handpieces. We are adjusting our pricing strategy for both instruments and handpieces in light of the strengthened US dollar.

Cost of products sold for the three months ended September 30, 2015 and 2014 were \$794,285 and \$829,546, respectively.

For the three months ended September 30, 2015, Milestone Scientific generated a gross profit of \$1,665,673 or 68% of total revenues, as compared to a gross profit of \$1,705,552, or 67% of total revenues, for the three months ended September 30, 2014. The total decrease in gross profit dollars of \$39,879 is primarily due to a decrease in sales.

Selling, general and administrative expenses (“SG&A Expenses”) for the three months ended September 30, 2015 and 2014 were \$2,480,354 and \$1,838,388, respectively, an increase of \$641,966. Milestone Scientific continues to focus on controlling expenses in all categories. In the third quarter of 2015, Milestone Scientific continued the process of building its marketing and sales efforts to increase revenues in the medical and dental business sectors. As such, a large portion of the increase in SG&A expenses is in the area, of personnel costs. Payroll, bonus, and business consulting cost increased by \$405,974 partially offset by the reduction of International sales commission of \$344,000 as the agreement with this provider ended in the second quarter 2015, in the third quarter of 2015 as compared to the same period of 2014. Additionally, legal fees increased for ongoing business activity and for the litigation settlement with a distributor increased by \$113,856. Also marketing expenses increased by \$116,004 in the quarter to support or sales effort.

Research and development expenses for the three months ended September 30, 2015 and 2014 were \$20,676 and \$29,370.

The loss from operations for the three months ended September 30, 2015 and 2014 was \$835,357 and \$162,206, respectively. The \$673,151 increase in loss from operations is explained above.

For the quarter ended September 30, 2015, we recognized a loss of \$590,612 (non-cash) attributable to Milestone Medical compared to a loss of \$223,834 (non-cash) for the same prior year period. We recognized a loss of \$123,083 (non-cash) (40% percent of Milestone China's loss) attributable to Milestone China compared to \$29,428 income for the same prior year period. Milestone China began operations in July 2014.

For the reasons explained above, net loss for the three months ended September 30, 2015 and 2014 was \$1,569,202 and \$358,490, respectively. The \$1,210,712 increase in net loss is primarily a result of an increase in SG&A Expenses of \$641,966 and a net increase of non-cash losses on the unconsolidated subsidiaries of \$516,111.

Nine months ended September 30, 2015 compared to the nine months ended September 30, 2014

Total product sales for the nine months ended September 30, 2015 and 2014 were \$6,996,921 and \$7,662,864, respectively, a decrease of \$665,943, or 9% due mainly a decrease in domestic handpieces sales, compared to the same period in 2014. The domestic handpiece sales decreased by \$907,812 for the nine months ended September 30, 2015 as compared to the same period in 2014. The decrease in handpiece sales is due to a price increase in the beginning of 2015 that is taking time for the distributors to pass on to their customers along with sell thru of handpieces purchased by the distributor in late 2014 to avoid the price increase in 2015. International revenue increased by \$358,173. The increase is primarily attributable to an increase in international instruments revenue of \$454,911 for the nine months ended September 30, 2015 as compared to the same period in 2014. However, as noted in the three month period comparison the nine month period continues to be negatively impacted (international) by the strengthened US dollar. As such, we have Milestone Scientific has modified our pricing strategy for the remainder of the year.

Cost of products sold for the nine months ended September 30, 2015 and 2014 were \$2,298,162 and \$2,624,950, respectively, a decrease of \$326,788, or 12% due to a reduction in units sold.

Gross profit for the nine months ended September 30, 2015 and 2014 was \$4,698,759 or 67% of total revenues, and \$5,037,914 or 66% of total revenues, respectively. Gross profit dollars in the first nine months of 2015 decreased by \$339,155 or 7% due to a decrease in sales volume offset by an increase in gross profit margin in 2015 over 2014.

SG&A Expenses for the nine months ended September 30, 2015 and 2014 were \$6,969,332, and \$4,749,112, respectively, an increase of \$2,220,220 in 2015 as compared to 2014. Milestone Scientific continues to focus on controlling expenses in all categories. However, as we continue the process of building a marketing and sales management staff to grow our existing business and initiate new medical instruments in various sectors: these costs to continue to rise. Since January 1, 2015, Milestone Scientific has added a President and Wand Dental Inc. (subsidiary of Milestone Scientific) has added a CEO. In late 2014 Wand Dental also added a Director of Marketing. During the nine month period ended September 30, 2015, the increase in SG&A Expenses was primarily attributable to the following: (i) approximately \$800,000 of the increase was attributable to the increase in compensation and travel expenses, (ii) approximately \$200,000 of the increase was attributable to additional legal expenses in the area of regulatory for Patents, (iii) approximately \$500,000 of the increase was attributable to general legal expenses as a result of increased legal procedures and distributor litigation expense that was settled in 2015, and (iv) approximately \$425,000 of the increase was attributable to a commission paid to a consultant for obtaining a Polish government grant for development of a new instrument for delivery of stem cells for diabetes treatments. In addition, investor relations expense increased in 2015 over 2014 due to the expansion of the investor relations beyond the USA.

Research and development expenses for the nine months ended September 30, 2015 and 2014 were \$49,616 and \$74,254, respectively.

The loss from operations for the nine months ended September 30, 2015 was \$2,320,189 compared to income from operations of \$214,548 for the comparable period in 2014. The \$2,534,737 increase in operating loss is explained above.

For the nine months ended September 30, 2015, we recognized a loss of \$1,566,711 (non-cash) attributable to Milestone Medical compared to a loss of \$567,550 (non-cash) for the same prior year period. We recognized a loss \$187,062 (non-cash) (40% percent of Milestone China's loss) attributable to Milestone China compared to income of \$29,428 or for the same prior year period. Milestone China began operations in July 2014.

For the reasons explained above, net loss for the nine months ended September 30, 2015 and 2014 was \$4,061,525 and \$333,113 respectively. The \$3,728,412 increase in net loss is primarily a result of an increase in SG&A Expenses of \$2,220,220 and a net increase of non-cash losses on the unconsolidated subsidiaries of \$1,212,566.

Liquidity and Capital Resources

As of September 30, 2015, Milestone Scientific had cash and cash equivalents of \$4,390,783 and positive working capital of \$11,139,704.

The working capital at September 30, 2015 was \$11,139,704 as compared to the working capital at December 31, 2014 of \$13,147,257. The decrease of \$2,007,553 in working capital was primarily attributable to a decrease in cash and cash equivalents of \$5,977,210 offset by an increase in account receivable of \$807,869, increase in inventory of \$307,807, increase in advances to contractors of \$490,729 an increase to the note receivable of \$2,000,000 coupled with a net decrease in current liabilities of \$303,289.

The \$2 million note receivable is pursuant to the \$2.5 million line of credit Milestone Scientific entered into with Milestone Medical in December 2014. This line of credit was increased from \$2 million to \$2.5 million in September 2015. Milestone Scientific expects that this note receivable will be repaid in the fourth quarter of 2015, or in the first quarter of 2016 by means of capital raise in Poland by Milestone Medical.

Milestone Scientific continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements.

For the nine months ended September 30, 2015, the net cash used in operating activities was \$3,762,370. This was attributable primarily to a net loss of \$4,061,525 for the nine months ended September 30, 2015.

. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through increases in revenues based upon management's assessment of present contracts and current negotiations and reductions in operating expenses. With the \$10 million Private Placement (net \$9.4 million) in May 2014, Milestone Scientific believes that carefully controlling expenses, collection of current accounts receivable and repayment of the \$2 million note receivable it does have sufficient cash reserves to meet all of its anticipated obligations for the next twelve months.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Milestone Scientific's management, including the Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of Milestone Scientific'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 (the "Evaluation Date"). Based upon that evaluation, Milestone Scientific's Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of the Evaluation Date are effective to ensure that information required to be disclosed in the reports Milestone Scientific files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Milestone Scientific's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding disclosure.

There were no changes in Milestone Scientific's internal control over financial reporting identified in connection with the evaluation that occurred during Milestone Scientific's last fiscal quarter ended September 30, 2015 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific's internal controls over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

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

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

In the nine months ended September 30, 2015, Milestone Scientific issued a total of 33,599 shares of its common stock for aggregate consideration of \$77,750. In September 2015, 40,155 shares were issued to a previous employee as part of a deferred compensation agreement. These shares were classified as shares to be issued, previously included in outstanding shares, and therefore not included in this schedule.

	Shares	\$
Shares issued to employee as compensation	13,168	35,000
Shares issued for services	12,098	30,000
Exercise of stock options by consultants	8,333	12,750
	33,599	\$77,750

All of the foregoing shares of common stock were issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended (the “Act”) pursuant to Section 4(a)(2) of the Act. The stock certificates for all of the foregoing shares were each imprinted with an appropriate restrictive legend.

ITEM 3. DEFAULT UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

- 101.INS XBRL Instance Document.*
- 101.SCH XBRL Taxonomy Extension Schema Document.*
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.*

101.LABXBRL Taxonomy Extension Label Linkbase Document.*

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.*

101.DEF XBRL Taxonomy Extension Definition Linkbase Document.*

20

*Filed herewith.

**Furnished, not filed, in accordance with Item 601(32)(ii) of Regulation S-K.

SIGNATURES

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

MILESTONE SCIENTIFIC INC.

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

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

Date: November 12, 2015