MILESTONE SCIENTIFIC INC.
Form 10-Q
November 09, 2016

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, 2016

Or

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

For the transition period from _____ to _____

Commission File Number: 001-14053

MILESTONE SCIENTIFIC INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3545623**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

220 South Orange Avenue, Livingston, New Jersey 07039

(Address of principal executive offices)

(973) 535-2717

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $.001 per share	NYSE MKT LLC

Securities registered pursuant to section 12(g) of the Act: NONE

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 November 9, 2016, the Issuer had a total of 28,054,670 shares of Common Stock, and $.001 par value, outstanding.

MILESTONE SCIENTIFIC INC

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FORWARD-LOOKING STATEMENTS

When used in this Quarterly Report on Form 10-Q, the words "may", "will", "should", "expect", "believe", "anticipate", "continue", "estimate", "project", "intend" and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") regarding events, conditions and financial trends that may affect Milestone 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*®, and *STA Single Tooth Anesthesia*™(STA Instrument, instruments and handpieces).

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

NINE MONTHS ENDED SEPTEMBER 30, 2016

(Unaudited)

	September 30, 2016 (unaudited)	**December 31, 2015 (audited)**
ASSETS		
Current Assets:		
Cash and cash equivalents	$2,322,705	$4,194,384
Accounts receivable, net of allowance for doubtful accounts of $10,000 as of September 30, 2016 and $5,000 as of December 31, 2015	2,553,186	1,863,582
Other receivable	-	58,140
Inventories	4,319,255	4,258,094
Advances on contracts	1,268,694	1,215,128
Prepaid expenses and other current assets	276,903	304,604
Total current assets	10,740,743	11,893,932
Investment in Milestone Education LLC	-	16,346
Furniture, fixtures & equipment net of accumulated depreciation of $636,265 as of September 30, 2016 and $566,477 as of December 31, 2015	181,906	235,935
Patents, net of accumulated amortization of $699,405 as of September 30, 2016 and $646,388 as of December 31, 2015	678,139	715,540
Other assets	17,355	17,355
Total assets	$11,618,143	$12,879,108
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$2,273,585	$2,088,268
Accrued expenses and other payables	1,741,806	1,555,567
Other liabilities	381,113	69,781
Total current liabilities	4,396,504	3,713,616
Commitments and Contingencies		
Stockholders' Equity		
Series A convertible preferred stock, par value $.001, authorized 5,000,000 shares, 33,333 shares held in the treasury, and 7,000 shares issued and outstanding as September 30, 2016 and December 31, 2015	7	7
Common stock, par value $.001; authorized 50,000,000 shares; 28,066,666 shares issued, 1,145,481shares to be issued and 28,033,333 shares outstanding as of September 30, 2016; 21,720,497 shares issued, 963,451 shares to be issued and 21,687,164 shares outstanding as of December 31, 2015	29,213	22,685
Additional paid-in capital	79,477,418	78,632,383
Accumulated deficit	(71,642,654)	(67,434,984)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)

Total Milestone Scientific Inc. stockholders' equity	6,952,468	10,308,575
Noncontrolling interest	269,171	(1,143,083)
Total Equity	7,221,639	9,165,492
Total liabilities and stockholders’ equity	$11,618,143	$12,879,108

See Notes to Unaudited Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS

NINE MONTHS ENDED SEPTEMBER 30, 2016

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Product sales, net	$ 3,186,596	$ 2,459,958	$ 8,973,726	$ 6,996,921
Cost of products sold	1,517,561	794,285	3,675,552	2,298,162
Gross profit	1,669,035	1,665,673	5,298,174	4,698,759
Selling, general and administrative expenses	2,933,950	2,480,354	9,226,062	6,969,332
Research and development expenses	303,268	20,676	756,045	49,616
Total operating expenses	3,237,218	2,501,030	9,982,107	7,018,948
Loss from operations	(1,568,183)	(835,357)	(4,683,933)	(2,320,189)
Interest expense	(846)	(1,043)	(2,782)	(961)
Loss before provision for income tax and equity in net earnings of equity investments	(1,569,029)	(836,400)	(4,686,715)	(2,321,150)
Provision for income tax	(16,522)	(27,105)	(80,147)	(40,751)
Loss before equity in net earnings of equity investments	(1,585,551)	(863,505)	(4,766,862)	(2,361,901)
Loss on earnings from Milestone Medical	-	(590,612)	-	(1,566,711)
Income (Loss) on earnings from Education Joint Venture	-	2,343	-	(5,493)
Loss on earnings from China Joint Venture	(253,451)	(123,083)	(554,766)	(187,062)
Loss in equity investments	(253,451)	(711,352)	(554,766)	(1,759,266)
Net Loss	(1,839,002)	(1,574,857)	(5,321,628)	(4,121,167)
Net loss attributable to noncontrolling interests	(137,752)	(5,655)	(1,113,958)	(59,642)
Net loss attributable to Milestone Scientific Inc.	$ (1,701,250)	$ (1,569,202)	$ (4,207,670)	$ (4,061,525)
Net loss per share applicable to common stockholders—				
Basic	$ (0.05)	$ (0.07)	$ (0.16)	$ (0.19)
Diluted	$ (0.05)	$ (0.07)	$ (0.16)	$ (0.19)
Weighted average shares outstanding and to be issued—				
Basic	29,155,712	21,418,145	25,965,566	21,375,317
Diluted	29,155,712	21,418,145	25,965,566	21,375,317

See Notes to Unaudited Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

NINE MONTHS ENDED SEPTEMBER 30, 2016

(Unaudited)

	Preferred Stock		Common Stock						
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance, January 1, 2016	7,000	$ 7	22,683,948	$ 22,685	$ 78,632,383	$ (67,434,984)	$ (1,143,083)	$ (911,516)	$ 9,165,492
Consolidation of Milestone Education	-	-	-	-	-	-	16,346	-	16,346
Stock based compensation	-	-	-	-	357,934	-	-	-	357,934
Common stock to be issued to employee for bonuses	-	-	182,030	182	389,318	-	-	-	389,500
Common stock to be issued to employee for compensation			10,709	11	22,489				22,500
Common stock issued for payment of consulting services			196,218	196	366,299				366,495
Common Stock exchanged for MMD			5,035,042	5,035	(2,514,901)		2,509,866		-
Sale of Common Stock - Private Placement			1,104,200	1,104	2,223,896				2,225,000
Net loss	-	-	-	-	-	(4,207,670)	(1,113,958)	-	(5,321,628)
Balance, September 30, 2016	7,000	$ 7	29,212,147	$ 29,213	$ 79,477,418	$ (71,642,654)	$ 269,171	$ (911,516)	$ 7,221,639

See Notes to
Unaudited Condensed
Consolidated
Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	For the Nine Month Ended September 30,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (5,321,628)	$ (4,121,167)
Adjustments to reconcile net cash used in operating activities:		
Depreciation expense	69,345	20,815
Amortization of patents	53,017	51,994
Common stock and options for compensation, consulting and vendor services	1,136,430	499,049
Equity loss on Milestone Medical	-	1,566,711
Equity loss on Education joint venture	-	5,493
Equity loss on China joint venture	545,950	187,062
Changes in operating assets and liabilities:		
Increase in accounts receivable	(759,385)	(807,869)
Decrease (Increase) in other receivable	58,140	(85,959)
Increase in inventories	(225,998)	(307,807)
Increase to advances on contracts	(53,566)	(490,729)
Increase to prepaid expenses and other current assets	27,701	25,996
Increase in other assets	-	(2,670)
Increase (decrease) in accounts payable	169,388	(672,974)
Increase in accrued expenses and other payables	181,324	369,685
Net cash used in operating activities	(4,119,282)	(3,762,370)
Cash flows from investing activities:		
Notes receivable from Milestone Medical	-	(2,000,000)
Due from related party	-	(677,991)
Investment in Treasury Bills	-	-
Purchases of intangible assets	(15,616)	(1,986)
Purchases of property and equipment	(14,945)	(47,613)
Cash acquired from variable interest entity	50,621	-
Net cash provided by (used in) investing activities	20,060	(2,727,590)
Cash flows from financing activities:		
Capital contribution from noncontrolling interest	2,543	-
Proceeds from exercise of stock options	-	12,750
Net Proceeds on Private Placement Offering	2,225,000	-
Capital contribution from noncontrolling interest	-	500,000
Net cash provided by investing activities	2,227,543	512,750
Net decrease in cash and cash equivalents	(1,871,679)	(5,977,210)
Cash and cash equivalents at beginning of period	4,194,384	10,367,993
Cash and cash equivalents at end of period	$ 2,322,705	$ 4,390,783
Supplemental disclosure of cash flow information:		
Net assets acquired from variable interest entity	$ 14,076	$ -

Shares issued to employees in lieu of cash compensations	$ 22,489	$ 42,500
Shares issued to employees for bonus	$ 389,318	$ 100,000
Shares issued to consultants in lieu of cash payment	$ 366,299	$ 60,000

See Notes to Unaudited Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Milestone Scientific Inc. and Subsidiaries, (collectively "Milestone Scientific", "our", "us" or "we") was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery instrument, through the use of *The Wand®,* a single use disposable handpiece. The instrument is marketed in dentistry under the trademark *CompuDent®, Wand Plus® and STA (Single Tooth Anesthesia)™* and in medicine under the trademark *CompuMed®. CompuDent®* is suitable for all dental procedures that require local anesthetic. *CompuMed®* is suitable for many medical procedures regularly performed in Plastic Surgery, Hair Restoration Surgery, Podiatry, Colorectal Surgery, Dermatology, Orthopedics and a number of other disciplines. The dental instruments are sold in the United States and in over 47 countries abroad. There have been no medical instruments sold in the United States and limited amounts sold internationally as of the reporting date, although certain medical instruments have obtained CE mark approval and now can be marketed and sold in most European countries. Milestone Scientific's products are manufactured by a third-party contract manufacturer.

In July 2014, Milestone Scientific acquired all of the 750,000 outstanding shares of an inactive Florida corporation and changed its name to Wand Dental, Inc. ("Wand Dental"). In September 2014, that corporation was merged into a Delaware corporation, retaining the same name and capitalization. On July 1, 2014, Wand Dental was capitalized with cash and received Milestone Scientific's dental business and related dental assets including the exclusive license of Milestone Scientific's, patents, trademarks, and technology for use in the dental marketplace. Wand Dental is consolidated into Milestone Scientific.

The unaudited consolidated financial statements of Milestone Scientific have been prepared in accordance with accounting principles generally accepted in the United States 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 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, 2015 included in Milestone Scientific's Annual Report on Form 10-K.

In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present Milestone Scientific's financial position as of September 30, 2016 and the results of its operations for the three and nine months then ended.

The results of operations reported for the three and nine months ended September 30, 2016 are not necessarily indicative of the results of operations which may be expected for a full year.

In June 2016, a group of investors that participated in our May 2014 financing invested an additional $2.0 million in Milestone Scientific through a private placement of one million restricted shares of our common stock, $.001 par value per share ("common stock"), at a price of $2.00 per share.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which we would exchange one share of common stock for every two outstanding shares of Milestone Medical (described below) common stock, a consolidated variable interest entity. As of September 30, 2016, 5,035,042 shares of common stock have been issued in exchange for 9,005,000 shares of Milestone Medical common stock. As a result of these exchanges, at September 30, 2016 Milestone Scientific owns approximately 91% of Milestone Medical.

In July 2016, Milestone Scientific filed for 510(K) marketing clearance with the US Food and Drug administration (FDA) for marketing clearance of Milestone Medical's (described below) epidural instrument. This clearance is necessary to begin commercialization of this medical instrument in the United States.

In July 2016, Milestone Scientific raised $250,000 in additional capital from the sale of 104,200 shares of common stock at $2.40 per share. The Company incurred placement agent fees equal to ten percent of the gross proceeds, or $25,000, which are reflected as an offset against additional paid-in capital as of September 30, 2016.

Milestone Scientific has incurred operating losses and negative cash flows from operating activities since its inception, except for 2013. Milestone Scientific is actively pursuing the generation of revenue, positive operating income and net income. The capital raised in May 2014 and June and July 2016 provided Milestone Scientific with the opportunity to continue to develop and commercialize additional medical instruments and aggressively market its dental instruments throughout the world. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue and management believes its cash on hand and remaining net current assets are sufficient to meet its obligations over the next twelve months. Milestone Scientific may need to raise additional capital prior to management's expected generation of sustainable positive cash flow from operating activities.

NOTE – 1 SUMMARY OF ACCOUNTING POLICIES

1. 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 accounts of Milestone Scientific and its wholly owned and majority owned subsidiaries, including Wand Dental, Milestone Advanced Cosmetic Systems, Inc., as well as Milestone Medical Inc. (“Milestone Medical”) and Milestone Education LLC (“Milestone Education”), both variable interest entities for which Milestone Scientific is the primary beneficiary. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

2. Reclassifications

Certain reclassifications have been made to the 2015 financial statements to conform to the consolidated 2016 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

3. Variable Interest Entities

A variable interest entity (“VIE”) is an entity that either (i) has insufficient equity to permit the entity to finance its activities without additional subordinated financial support or (ii) has equity investors who lack the characteristics of a controlling financial interest. A VIE is consolidated by its primary beneficiary. The primary beneficiary has both the power to direct the activities that most significantly impact the entity's economic performance and the obligation to absorb losses or the right to receive benefits from the entity that could potentially be significant to the VIE.

If Milestone Scientific determines that it has operating power and the obligation to absorb losses or receive benefits, Milestone Scientific consolidates the VIE as the primary beneficiary. Milestone Scientific’s involvement constitutes power that is most significant to the entity when it has unconstrained decision making ability over key operational functions within the entity.

Milestone Scientific is the primary beneficiary of Milestone Medical through December 31, 2015 (see Note 3) and Milestone Education, as VIEs. Accordingly, the assets and liabilities of Milestone Medical and Milestone Education are included in the accompanying consolidated financial statements. See Note 3 for further details regarding the treatment of the VIE.

Because Milestone Scientific had an increasing variable interest in Milestone China, it further considered the guidance in Accounting Standard Codification ("ASC") 810 as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. As Milestone China’s equity at risk and voting rights were not proportional to their economic interest, Milestone China was determined to be a VIE. Milestone Scientific would be considered the primary beneficiary of the VIE if it has both of the following characteristics:

- Power Criterion: The power to direct the activities that most significantly impact the entity's economic performance;
- Losses/Benefits Criterion: The obligation to absorb losses that could potentially be significant or the right to receive benefits that could potentially be significant to the VIE.

Milestone management does not have the ability to control the activities that most significantly impact China's economics and, therefore, the power criterion has not been met. Management placed the most weight on the relationship and significance of activities of China to the majority shareholder/CEO of Milestone China. As majority shareholder, majority holder of voting rights, and the active CEO, the 53% investor has the power to direct the activities that most significantly impact the economic performance of China. Management has concludes that Milestone Scientific is not the primary beneficiary under ASC 810. Accordingly, Milestone China has not been consolidated into the financial statements of Milestone Scientific and continues to be accounted for under the equity method (see Note 4).

4. Cash

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

5. 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 incurred by Milestone Scientific.

6. Product Return and Warranty

Milestone Scientific does not accept non-defective returns from its customers. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Warranty Policy. Returns not within the Warranty Policy are evaluated and the customer is charged for the repair.

7. Inventories

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

8. Equity Method Investments

Investments in which we have the ability to exercise significant influence, but do not control, are accounted for under the equity method of accounting and are included in the long term assets on the Condensed Consolidated Balance Sheets. Under this method of accounting, our share of the net earnings or losses of the investee is presented below the income tax line on the Condensed Consolidated Statements of Operations. We evaluate our equity method investments whenever events or changes in circumstance indicate that the carrying amounts of such investments may be impaired. If a decline in the value of an equity method investment is determined to be other than temporary, a loss is recorded in earnings in the current period.

9. Furniture, Fixture and Equipment

Equipment is recorded at cost, less accumulated depreciation. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets, which range from five to seven years. The costs of maintenance and repairs are charged to operations as incurred.

10. Intangible Assets - Patents

Patents are recorded at 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 Milestone Scientific receives notice of such rejection. Patent defense costs, to the extent applicable are expensed as incurred. 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 Milestone Scientific. Milestone Scientific also attempts to protect the proprietary information through the use of confidentiality agreements and by limiting access to its facilities. There can be no assurance that the program of patents, confidentiality agreements and restricted access to the facilities will be sufficient to protect the proprietary technology.

11. Impairment of Long-Lived Assets

Milestone Scientific reviews long-lived assets for impairment whenever events or circumstances (i.e. a triggering event) indicate that the carrying amounts may not be recoverable. The carrying value of the assets is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets. Milestone Scientific adjusts the net book value of an underlying asset if its fair value is determined to be less than its net book value. There have been no impairment indicators or triggering events and therefore, no impairment reviews have been performed in the period ending September 30, 2016.

12. 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. 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.

13. Shipping and Handling Costs

Milestone Scientific includes shipping and handling costs in cost of goods sold. These costs are billed to customers at the time of shipment for domestic shipments. International shipments are FOB warehouse, therefore no costs are incurred by Milestone Scientific.

14. Research and Development

Research and development costs, which consist principally of new product development costs payable to third parties, are expensed as incurred. Advance payments for the research are amortized to expense either as services are performed or over the relevant service period using the straight line method.

15. Income Taxes

Milestone Scientific accounts for income taxes pursuant to the asset and liability method which requires deferred income tax assets and liabilities to be computed for temporary differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

16. Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. The FASB continues to release guidance clarifying certain aspects of the revenue guidance. We do not believe that this new accounting pronouncement will have a material impact on our financial statements.

In August 2014, the FASB issued a new standard Accounting Standards Update ("ASU") No.2014-15, "Presentation of Financial Statements – Going Concern" (Subtopic 205-40).The new standard is intended to increase the disclosure as it relates to management's assessment of the abilities to continue as a going concern. The standard will be effective for the annual period ending after December 15, 2016. Milestone Scientific will be adopting this standard with its annual reporting of December 31, 2016 to include enhanced disclosures as it relates to management's considerations.

In November 2015, the FASB issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented.

In February 2016, the FASB issued a new standard ASU No.2016-02, "Leases"(Topic 842). The new standard is intended to increase transparency and comparability among organizations to recognize lease assets and liabilities on the balance sheet and disclose key information about leasing arrangements. It will be effective for fiscal years beginning after December 15, 2019 and for interim periods within fiscal years beginning after December 15, 2020. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In March 2016, the FASB issued a new standard ASU No.2016-07, “Investments - Equity Method and Joint Ventures” (Topic 323): The new standard is intended to eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an in increase in the level of ownership or degree of influence, results of operations and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect all of the previous periods that the investment was held. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2016. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In March 2016, the FASB issued a new standard ASU No.2016-09, “Compensation – Stock Compensation” (Topic 718). The new standard is intended to clarify certain reporting aspects relating to stock based compensation, relating primarily to forfeitures, tax impacts and cash flow presentation. Certain attributes will be treated prospectively, while others will require a retroactive application. Generally, the changes will be effective for fiscal years and interim periods, beginning after December 15, 2016. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In June 2016, the FASB issued a new standard ASU No.2016-13, “Financial Instruments – Credit Losses” (Topic 326).: The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2019. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In August 2016, the FASB issued a new standard ASU No.2016-15, “Statement of Cash Flows – Classification of Certain Cash Receipts and Cash Disbursements” (Topic 230). The new standard provides guidance as to the conformity of presentation of certain cash receipts and disbursements. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017. Milestone Scientific is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

We have evaluated all other issued and unadopted ASUs and believe the adoption of these standards will not have a material impact on its results of operations, financial position, or cash flows of its common stock.

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

Milestone Scientific 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 Statement of Financial Accounting Standards 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, warrants, and the conversion of debt were issued during the period.

Since Milestone Scientific had net losses for 2016 and 2015, the assumed effects of the exercise of potentially dilutive outstanding stock options of 1,885,010 were not included in the calculation as their effect would have been anti-dilutive.

NOTE – 3 CONSOLIDATION OF VARIABLE INTEREST ENTITY

Milestone Medical

Milestone Medical is approximately 91% owned by Milestone Scientific as of September 30, 2016. Milestone Medical was established to develop and commercialize intra-articular and epidural drug delivery instruments, utilizing an exclusive royalty-free license to Milestone Scientific's CompuFlo technology. The license was contributed by Milestone Scientific for our initial ownership in Milestone Medical.

Since our initial investment in Milestone Medical we have accounted for the investment in accordance with the equity method of accounting. However, during 2015, Milestone Scientific provided short term bridge financing to Milestone Medical in anticipation of the completion of a secondary stock offering in Poland. In December 2015, Milestone Medical suspended this capital raise efforts meriting re-consideration of the initial accounting for the investment as an equity method investment. In April 2016, Milestone Medical cancelled the uplisting of its shares to the Poland Warsaw Stock Exchange.

As a result of the change in circumstances around the proposed offering in December 2015 by Milestone Medical, we reevaluated our relationship and Milestone Medical's status as a VIE and determined that Milestone Medical does not have sufficient capital at risk to support its activities without additional financial support from us. Since the factors giving rise to concluding that Milestone Medical is a VIE happened so close to the end of fiscal year 2015, the date for measuring the consolidation of Milestone Medical has been deemed to be December 31, 2015.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which we would exchange one share of common stock for every two outstanding shares of Milestone Medical common stock. As there was no change in control, the acquisition of the non-controlling interest is reflected as an equity transaction with the carrying value of the non-controlling interest adjusted to reflect Milestone Scientific's increased ownership interest in the subsidiary. As of September 30, 2016, 5,035,042 shares of common stock have been issued in exchange for 9,005,000 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owns approximately 91% of Milestone Medical at September 30, 2016.

As a result of our increased ownership in Milestone Medical, we have determined that we continue to have control of Milestone Medical and have consolidated Milestone Medical in the accompanying condensed consolidated financial statements.

Milestone Education LLC

Milestone Education is a 50% owned subsidiary of Milestone Scientific which began operations in 2013 to provide training and education to dentists throughout the world. Milestone Scientific accounted for its investment in Milestone Education using the equity method of accounting through December 31, 2015. Approximately 83% of the revenue earned by Milestone Education is from services performed for Milestone Scientific. As a result of this relationship, we determined that we have the power to direct the activities that most significantly impact Milestone Education's economic performance, and that it is a VIE and should be consolidated in the financials of Milestone Scientific.

The financial information in the table below summarizes the combined results of operations of Milestone Scientific and its subsidiaries, including Milestone Medical and Milestone Education, on a pro forma basis as though the companies had been combined as of the beginning of the earliest period presented. The pro forma financial information is presented for informational purposes only and is not indicative of the result of operations that would have been achieved if the consolidation had taken place at the beginning of the period presented.

The financial statements of Milestone Education have been consolidated in the accompanying condensed consolidated financial statements.

The financial information in the table below summarizes the combined results of operations of Milestone Scientific and its subsidiaries, including Milestone Medical and Milestone Education, on a pro forma basis as though the companies had been combined as of the beginning of the earliest period presented. The pro forma financial information is presented for informational purposes only and is not indicative of the result of operations that would have been achieved if the consolidation had taken place at the beginning of the period presented.

	Three Months Ended September 30, 2015	**Nine Months Ended September 30, 2015**
	Pro Forma	**Pro Forma**
Total revenue	$ 2,509,096	$ 7,099,164
Cost of products sold	805,429	2,312,980
Gross Profit	1,703,667	4,786,184
Selling, general and administrative expenses	3,481,703	9,609,318
Research and development expenses	217,138	621,870
Operating expenses	3,698,841	10,231,188
Loss from operations	(1,995,174)	(5,445,004)
Interest expense	(18,237)	(21,655)

Loss before provision for income tax and equity in net earnings of equity investments	(2,013,411	)	(5,466,659	)
Provision for Income Tax	(27,105	)	(40,751	)
Loss before equity in net earnings of equity investments	(2,040,516	)	(5,507,410	)
Loss on earnings from China Joint Venture	(123,083	)	(187,063	)
Loss in equity investments	(123,083	)	(187,063	)
Net loss	(2,163,599	)	(5,694,473	)
Less: Net loss attributable to the noncontrolling interests	(594,397	)	(1,632,948	)
Net loss attributable to Milestone Scientific Inc.	$ (1,569,202	)	$ (4,061,525	)

NOTE – 4 INVESTMENT INUNCONSOLIDATED SUBSIDIARIES

Advance Ocular Science SA

Advanced Ocular Sciences SA (“Advanced Ocular”) is an entity organized to develop an instrument that delivers injections into the eyes. Advanced Ocular is a shell company as of September 30, 2016. Milestone Scientific owns 25% of this entity. As of the balance sheet date, no equity has been contributed to Advanced Ocular by Milestone Scientific. During 2015, Milestone Scientific advanced $78,798 for marketing and strategy planning to Advanced Ocular and they, or their organizers, are obligated to repay this advance once a public offering of Advanced Ocular equity is approved and funded in Poland during 2016. No public offering was completed in Poland as of September 30, 2016. As such, Milestone Scientific has written-off the $78,798 advanced to Advanced Ocular as of September 30, 2016. Advance Ocular was not included in the consolidated financial statements at September 30, 2016 as no investment has been made by Milestone Scientific. The suspended losses approximated $19,700 at September 30, 2016.

Milestone China Ltd.

In June 2014, Milestone Scientific invested $1 million through the contribution of 772 STA instruments (at a distributor price of approximately $1,296 per instrument) for a forty percent (40%) ownership in Milestone China Ltd. (“Milestone China”). In 2014, the instruments were shipped and were recorded as an investment in Milestone China at the cost of the inventory contributed. In January 2016, Milestone Scientific contributed 308 STA instruments with a retail value of approximately $400,000 ($1,296 per instrument) to Milestone China which increased Milestone Scientific’s investment by approximately $165,000 which represents the cost of the instruments. This did not increase Milestone Scientific’s percentage of ownership since the contribution was proportionate to contributions from other shareholders.

Milestone Scientific recorded a loss on its investment in Milestone China of $253,451 and $554,766 for the three and nine months ended September 30, 2016, respectively, and $123,083 and $187,062 for the three and nine months ended

September 30, 2015, respectively. Milestone Scientific's investment in Milestone China was $0 as of September 30, 2016 and December 31, 2015. Milestone Scientific had suspended losses on its investment in Milestone China of $405,205, as of September 30, 2016.

Milestone Scientific sold $3,203,466 in instruments and handpieces during the nine months ended September 30, 2016 to Milestone China. Milestone China owes $1,850,200 to Milestone Scientific for STA instruments and handpieces shipped in 2016, which is included in accounts receivable at September 30, 2016. Milestone China payment terms are ninety days from receipt of goods.

Milestone Scientific recognizes the total revenue and costs of goods sold at the time the shipment of instruments and handpieces to Milestone China. However, due to timing differences of when the inventory is sold to Milestone China and when Milestone China sells the acquired inventory to third parties, elimination of the intra-entity profit is required as of the balance sheet date. In accordance with ASC 323 – *Equity Method and Joint* Ventures, Milestone Scientific has deferred the gross profit associated with inventory shipped to Milestone China that has not been sold to third parties. The deferred profit of $381,113 is included in the loss from Milestone China within the Condensed Consolidated Statements of Operations and presented in other liabilities in the Condensed Consolidated Balance Sheets.

The following table includes summarized financial information for Milestone China the unconsolidated subsidiary:

	September 30, 2016 (unaudited)	December 31, 2015 (unaudited)
Assets:		
Current Assets	$ 6,523,902	$ 772,999
Non-Current Assets	1,745,764	903,766
Total Assets:	$ 8,269,666	$ 1,676,765
Liabilities		
Current Liabilities	4,406,577	580,613
Stockholders' equity	3,863,089	1,096,152
Total liabilities and stockholders' equity	$ 8,269,666	$ 1,676,765

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016 (unaudited)	2015 (unaudited)	2016 (unaudited)	2015 (unaudited)
Net Sales	$ 329,617	$1,193,234	$ 2,645,119	$ 2,226,434

Cost of Good Sold	444,255	1,161,983	2,529,374	1,830,272
Gross Profit	(114,638)	31,251	115,745	396,162
Other Expenses	(305,742)	(338,963)	(1,002,484)	(863,819)
Net Loss	$ (420,380)	$ (307,712)	$ (886,739)	$ (467,697)

NOTE – 5 Stock Option Plans

Milestone Scientific recognizes compensation expense on a straight line basis over the requisite service period and in the case of performance based options over the period of the expected performance. For the three months ended September 30, 2016 and 2015, Milestone Scientific recognized $81,678 and $107,205 of total employee compensation cost, respectively. For the nine months ended September 30, 2016 and 2015, Milestone Scientific recognized $357,934 and $334,049 of total employee compensation cost, respectively. As of September 30, 2016 and 2015, there was $580,331 and $881,765 respectively, of total unrecognized compensation cost related to non-vested options. Milestone Scientific expects to recognize these cost over a weighted average period of 2.49 years and 3.59 years as of September 30, 2016 and 2015, respectively.

A summary of option activity for employees under the plans and changes during the nine months ended September 30, 2016, is presented below:

	Number of Options	Weighted Averaged Exercised Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Outstanding January 1, 2016	1,419,436	$ 1.56	2.78	$1,220,338
Granted	348,908	1.72	4.35	376,821
Forfeited or Expired	(100,000)	2.50		-
Exercised	-	-	-	-
Outstanding September 30, 2016	1,668,344	$1.54	2.44	$1,147,015
Exercisable September 30, 2016	1,170,718	$1.36	1.95	$999,904

A summary of option activity for non-employees under the plans and changes during the nine months ended September 30, 2016, is presented below:

	Number of Options	Weighted Averaged Exercised Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value $
Outstanding January 1, 2016	8,333	$2.70	4.83	$-
Granted	208,333	2.55	0.00	-
Forfeited or Expired	-	0.00	0.00	-
Exercised	-	-	-	-
Outstanding September 30, 2016	216,666	$2.55	5.58	$-
Exercisable September 30, 2016	555	$2.52	4.51	$-

The fair value of the non-employee options was estimated on the date of grant using the Black Scholes option-pricing model at the date of grant. In accordance with the provisions of FASB ASC 505 Milestone Scientific will re-measure the value of the grant at each presentation date unless there is a significant disincentive for non-performance or until performance is completed. For the three and nine months ended September 30, 2016, Milestone Scientific recognized $2,807 and $8,421 expense related to non-employee options. During the three and nine months ended September 30, 2015, Milestone Scientific had no expense related to non-employee options. As of September 30, 2016, there was a total of $359,485 unrecognized compensation cost related to non-vested options which the company expects to recognize over a weighted average period of 5.5 years.

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 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 re-measured at each reporting period whether 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.

Milestone Scientific closely monitors the extension of credit to its customers while maintaining allowances, if necessary, for potential credit losses. 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, 2016 and December 31, 2015, respectively.

NOTE – 7 ADVANCES ON CONTRACTS

Milestone Scientific has informal arrangements with the manufacturer of the STA, CompuDent® and CompuMed® instruments, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. Milestone Scientific has open purchase orders with a contract manufacturer to manufacture STA instruments. The contract manufacturer bills Wand Dental as the work progresses and it is Wand Dental's policy to record these payments as advances on contracts. These advances are reclassified into inventory when the contract manufacturer ships the product and title passes to Wand Dental. The advances on contracts represent funding of future STA inventory purchases. The balance of the advances as of September 30, 2016 and December 31, 2015, is $1,268,694 and $1,215,128 respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE – 8 INCOME TAXES

For the nine months ended September 30, 2016 and 2015, state tax credit $29,300 and liability was $40,751, respectively. 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, 2016 and 2015, no recognition was given to the utilization of the remaining Federal net operating loss carryforwards.

NOTE – 9 CONCENTRATIONS & GEOGRAPHICAL INFORMATION

Milestone Scientific has a manufacturing agreement with one of the principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders but without minimum purchase commitments. A five percent shareholder of Milestone Scientific is also a shareholder of this vendor. Purchases from this supplier were $2,088,229 and $1,801,449 during nine months ended September 30, 2016 and 2015, respectively. Milestone Scientific owed $984,286 and $716,520 to this supplier as of September 30, 2016 and December 31, 2015, respectively.

For the nine months ended September 30, 2016 and 2015 (i) two customers (distributors), one of which is a related party, accounted for approximately 70% (62% and 8%), and approximately 33% (15% and 18%), of Milestone Scientific's net product sales, respectively; and (ii) two customers accounted for approximately $1,995,000 ($1,850,000 and $145,000) representing approximately 78% (72% and 6%), and three customers accounted for approximately $1,572,000 ($1,089,000, $306,000 and $177,000) representing 69% (47%, 13% and 9%), of accounts receivable, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
DOMESTIC				
Instruments	$-	$9,555	$852,149	$611,845
Handpieces	106,908	672,425	1,860,593	1,777,548
Other	12,508	18,899	46,634	20,661
Total Domestic	$119,416	$700,879	$2,759,376	$2,410,054
INTERNATIONAL				
Instruments	$1,909,030	$891,657	$3,468,080	$1,705,703
Handpieces	1,070,166	861,512	2,558,224	2,833,043
Other	87,984	5,910	188,046	48,121
Total International	$3,067,180	$1,759,079	$6,214,350	$4,586,867
Total Product Sales	$3,186,596	$2,459,958	$8,973,726	$6,996,921

NOTE – 10 PENSION PLANS

Milestone Scientific has 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 were not significant.

NOTE – 11 COMMITMENTS AND OTHER

(1) Lease Commitments

The headquarters for Milestone Scientific is located at 220 South Orange Ave, Livingston, New Jersey. Milestone Scientific leases approximately 7,625 square feet of office space. The lease term expires January 31, 2020 at a monthly cost of $12,522. Additionally, Milestone Scientific has other smaller insignificant leases ending through 2017. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a

month-to-month basis. For the three and nine months ended September 30, 2016 rent expense amounted to $25,031 and $95,019, respectively. For the three and nine months ended September 30, 2015, rent expense amounted to $18,941 and $56,693, respectively.

(2) Contract Manufacturing Arrangement

Milestone Scientific has informal arrangements for the manufacture of its product, The STA (single tooth anesthesia) instrument is 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.

(3) Other Commitments and Subsequent Events

Other Commitments

The Chief Executive Officer's employment agreement with Milestone Scientific provides for 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 benefit of the executive and his family. For the three and nine months ended September 30, 2016, approximately $50,777 and $152,000 was charged to expense, respectively. For the three and nine months ended September 30, 2015, approximately $50,778 and $152,000 was charged to expense, respectively.

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. The Director of Clinical Affairs was granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant 8,333 shares of 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 of Clinical Affairs will receive the corresponding percentage of the consideration received by

Milestone Scientific for such sale or license. The Director of Clinical Affairs' royalty fee was $148,185 and $449,875 during the three and nine months ended September 30, 2016, respectively and $117,320 and $313,751, during the three and nine months ended September 30, 2015, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $68,751 and $206,253 for the three and nine months ended September 30, 2016. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of $39,300 and $117,900 for the three and nine months ended September 30, 2015, respectively.

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. In June 2016 Milestone Scientific established a new exclusive distribution arrangement for its dental products for the United States and Canada with Henry Schein Inc. ("Henry Schein"), a global leader of distribution in the dental supplies. Under the new arrangement Milestone Scientific will, for the first time, have a dedicated independent sales force visiting dentists.

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 Inc. ("Milestone Scientific", "our", "us" or "we") was officially listed on the NYSE MKT on June 1, 2015 and "MLSS" is its trading symbol. We are a medical research and development company that designs and patents innovative injection technology. Our computer-controlled injection systems make injections precise, efficient and virtually painless.

In 2016, 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)

Our Injection Technology

Since our inception we have engaged in pioneering proprietary, innovative, computer-controlled injection technologies and solutions for the medical and dental markets. We have focused our energy and resources on redefining the worldwide standard of care for injection techniques by making the experience more comfortable for the patient and by reducing the anxiety and stress of administering injections for the healthcare provider.

We believe that we and our technology are widely recognized by key opinion leaders (i.e. academics and practicing dentists whose opinions are widely respected), industry experts and medical and dental practitioners as a leader in the emerging, high growth, computer-controlled injection industry; and we remain intent on expanding the use and application of our proprietary, patented technologies to achieve greater operational efficiencies, enhanced patient

safety and therapeutic adherence, and improved quality of care within a broad range of medical disciplines.

We have developed and commercialized of proprietary, innovative, computer controlled injection instruments and related disposable, single-use handpieces for the medical and dental markets. We believe our dental instruments have set a new standard of care for dental injections. As of September 30, 2016, the Company has not yet obtained U.S. Food and Drug Administration ("FDA") regulatory clearance for our new epidural anesthetic injections and intra-articular injections instruments However, as of September 2014, the company did receive European Union (CE) clearance to market the instruments in the European Market. Our technology is proven and well established and our dental instruments have been used to administer millions of injections worldwide. Each of our instruments has a related single use disposable leading to a continuing revenue stream following sale of the instrument.

***CompuDent*® and the *Wand*®**

Our first commercial product, the *CompuDent*®, and its associated disposable *Wand*® handpiece for the dental market is intended to allow the dentist to provide painless injections for virtually all dental procedures, including routine cleanings and fillings, as well as more sophisticated implants, root canals and crowns. New injections made possible by the *CompuDent*® eliminate collateral numbness of the tongue, lips and facial muscles and often hasten the onset of anesthesia by eliminating the need for preliminary mandibular blocks. The pencil grip used with the *Wand*® handpieces provides the practitioner with unprecedented tactile sense and accurate control and allows bi-directional rotation eliminating needle deflection, resulting in a greater success rate. Since the *Wand*® handpiece does not look like a typical syringe it also reduces patient anxiety and offers the possibility of curing dental phobia of which 40 million Americans suffer (see the Colgate Oral Care website). The *CompuDent*® instrument is considered one of the major advances in dentistry in the 20th Century and has been favorably evaluated in more than 50 peer reviewed or independent clinical research reports, which we have reviewed.

CompuFlo®

Our next significant intellectual property advancement was the development of our proprietary patented *CompuFlo*® technology for the precise delivery of anesthetics and other medicaments into various tissues and bodily cavities. The *CompuFlo*® technology has been U.S. Food and Drug Administration ("FDA") approved and allows the practitioner to precisely regulate and control the flow rate of the injectable material while receiving visual and audible in-tissue pressure feedback, allowing the practitioner to determine the tissue into which the injectable material is being delivered. The *CompuFlo*® technology encompasses the painless delivery benefits of the *CompuDent*® while allowing the practitioner to know which tissues have been penetrated and to inject medicaments precisely into the desired location. With *CompuFlo*®, the injection of chemotherapeutics and other toxic substances outside the targeted area can be avoided. The instruments developed using the *CompuFlo*® also provide a digital record of the time and amount of anesthetic or medicament injected.

Our first system utilizing the *CompuFlo*® technology was our *STA*® instrument and related handpiece for the dental market. The *STA*® instrument and handpiece continue to provide all of the benefits of the *CompuDent*® system while better facilitating single tooth anesthesia (now generally performed with a high pressure spring loaded gun-like instrument) by allowing the practitioner to monitor and precisely control pressure, rate and volume. Instruments using the *CompuFlo*® technology can be used to inject a wide variety of liquid medicaments as well as anesthetics. We believe *CompuFlo*® avoids the negative side effects from the use of traditional hypodermic drug delivery injection instruments, which are well documented in dental and medical literature and include risk of death, transient or permanent paralysis, pain, tissue damage and post-operative complications. Pain and tissue damage often result from uncontrolled flow rates and pressure created during the administration of drug solutions into human tissue. While several technologies have been capable of controlling flow rate, we believe the ability to accurately and precisely control pressure has been unobtainable until the development of *CompuFlo*®.

The next systems utilizing the *CompuFlo*® technology were instruments for administering epidural injections and related disposable and an instrument for administering hyaluronic acid and other medicaments into both major and minor joints for the alleviation of pain associated with arthritis and other deleterious joint conditions.

Our epidural injection instrument using *CompuFlo*® pressure sensing technology provides an objective tool that we believe consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the extraligamentary tissue. In studies utilizing the *CompuFlo*® technology the epidural space has been correctly identified 100% of the time. Knowing the precise location of a needle during an epidural injection procedure provides a measure of safety not presently available to doctors using conventional syringes, in the absence of fluoroscopy, who identify the epidural space by relying on the subjective perception of loss of resistance to saline.

Precisely controlling in-tissue pressure increases patient safety by reducing the risk of tissue damage and post-treatment pain related to excessive pressure that may occur during certain injections. Identification of the tissue, in which the needle tip is imbedded, is believed to be highly important in epidural injections, intra-articular injections and numerous organ, subcutaneous and intramuscular injections.

Our intra-articular injection instrument we believed to be particularly efficacious for arthritis patients who are obliged to endure multiple painful injections annually for a lifetime. Often these injections are not efficacious because the doctor using a syringe fails to locate the intra-articular space or does not inject the appropriate volume of hyaluronic acid or other medicament into that space. The *CompuFlo*® technology has been successful in administering hyaluronic acid and other medicaments into the intra-articular space in both small and large joints using its computer-controlled pressure sensing capabilities in an independent animal study.

Both the epidural and intra-articular instruments have obtained CE mark approval and may now be marketed and sold in most European countries and many other countries accepting CE approved instruments. In the United States, we have completed required testing for the epidural instrument for birthing and pain management and have submitted the favorable results of these tests to the FDA. We expect to receive FDA approval of our epidural instrument by the end of the first quarter 2017 and of our intra-articular instrument in the same time frame. Given the fact that the speed of approval depends on the FDA it is impossible for any company to correctly predict the timely. The development of an international marketing network of independent distributors awaits the receipt of FDA approval, although a limited number of European and near-east distributors have already been appointed.

At earlier stages of development are our products using our *CompuFlo*® technology for less painful injections into the eye and for the subcutaneous injection of fillers and other substances in the dermatology market. In the self-injectable market there are a number of injectable drugs routinely self-administered in a home or office setting using spring loaded automatic injection devices by people who suffer from long term chronic conditions such as Multiple Sclerosis, Rheumatoid Arthritis, and other diseases of the auto immune system. We believe the *CompuFlo*® technology, using pressure sensing capabilities, can serve as a painless subcutaneous injection method for these self-administered drugs. A significant reduction in pain during delivery should have a positive impact on compliance, which is a major consideration when physicians are treating patients. In addition, the ability to record the injection will allow for significantly enhanced monitoring of the patient.

Distribution and Marketing Arrangements

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein, Inc. (“Henry Schein”). In June 2016 we established new distribution arrangements for our dental products for the United States and Canada with Henry Schein. Under these arrangements we will, for the first time, have a semi-dedicated independent sales force visiting dentists. We believe that these arrangements will be more effective than previous arrangements relying on appearances at dental shows and catalog sales.

In China, where the dental market lags behind other health care services and has largely been neglected in the past, a CS Market Research report indicates that 50% of adults and 70% of children out of China’s estimated 1.3 billion plus population have tooth decay problems and over 90% have periodontal disease. *See Shuyu Sun & Seth Pierrepont*, *The Dental Equipment Market Over in China*, CS Market Research (Sept. 20, 2005) and *Opportunities Abound for Dental Care in China, CHINA BRIEFING (February 27, 2015)*. With increasing affluence and increasing attention towards personal care, the provision of dental services has been growing rapidly. We have established exclusive distribution arrangements with Milestone China, Ltd, a 40% owned affiliate, which has placed our dental instruments in clinics serving major cities in China. We expect this initial limited distribution of instruments will lead to both increased sales of dental instruments and our single-use handpieces.

Competition

Milestone Scientific faces intense competition from many companies in the medical and dental device industry, possessing substantially greater financial, marketing, personnel, and other resources. In dentistry the main competition is the syringe, a product that has been in use and virtually unchanged for more than 150 years. For epidurals, we face competition from the established method of providing epidurals with the use of two medical practitioners, one to insert and place the needle and the other to inject the anesthesia and potentially from a computer controlled injection instrument that claims to be able to reliably identify the epidural space but has had limited success in the marketplace.

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,			
	2016		2015		2016		2015	
DOMESTIC								
Instruments	$-	—	$9,555	1.4 %	$852,149	30.9 %	$611,845	25.4 %
Handpieces	106,908	89.5 %	672,425	95.9 %	1,860,593	67.4 %	1,777,548	73.8 %
Other	12,508	10.5 %	18,899	2.7 %	46,634	1.7 %	20,661	0.9 %
Total Domestic	$119,416	100.0%	$700,879	100.0%	$2,759,376	100.0%	$2,410,054	100.0%
INTERNATIONAL								
Instruments	$1,909,030	62.2 %	$891,657	50.7 %	$3,468,080	55.8 %	$1,705,703	37.2 %
Handpieces	1,070,166	34.9 %	861,512	49.0 %	2,558,224	41.2 %	2,833,043	61.8 %
Other	87,984	2.9 %	5,910	0.3 %	188,046	3.0 %	48,121	1.0 %
Total International	$3,067,180	100.0%	$1,759,079	100.0%	$6,214,350	100.0%	$4,586,867	100.0%
DOMESTIC/INTERNATIONAL ANALYSIS								
Domestic	$119,416	3.7 %	$700,879	28.5 %	$2,759,376	30.7 %	$2,410,054	34.4 %
International	3,067,180	96.3 %	1,759,079	71.5 %	6,214,350	69.3 %	4,586,867	65.6 %
Total Product Sales	$3,186,596	100.0%	$2,459,958	100.0%	$8,973,726	100.0%	$6,996,921	100.0%

Milestone Scientific earned gross profit of approximately $1.7 million and $5.3 million in the three and nine months ended September 30, 2016. Milestone Scientific earned gross profit of approximately $1.7 million and $4.7 million in the three and nine months ended September 30, 2015. However, the revenues and related gross profits have not been sufficient to support overhead, new product introduction and research and development expenses. Although Milestone Scientific anticipates expending funds for research and development in 2016, these amounts will vary based on the operating results for each quarter. Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception, except for 2013. At September 30, 2016, Milestone Scientific has sufficient cash reserves to meet all of its anticipated obligations for at least the next twelve months, including a limited amount of financing for the operation of Milestone Medical until additional financing is consummated in late 2016 and 2017. Milestone Scientific is actively pursuing the continued generation of positive cash flows from operating activities through increase in revenue, assessment of current contracts and current negotiations.

At December 31, 2015, Milestone Scientific determined that Milestone Medical was a variable interest entity (VIE), as such Milestone Medical was consolidated with Milestone Scientific. Previous to this determination Milestone Medical was accounted for under the equity method and the results of their operation were shown as a separate line on the Statement of Operation for periods prior to December 31, 2015. Accordingly, in comparison with 2016 consolidated financial statements certain amounts may a not appear to be comparable to the corresponding results in 2015.

Results of Operations

The following table sets forth for the consolidated results of operations for the three and nine months ended September 30, 2016 compared to 2015 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,			
	2016		2015		2016		2015	
Product sales, net	$ 3,186,596	100%	$ 2,459,958	100%	$ 8,973,726	100%	$ 6,996,921	100%
Cost of products sold	1,517,561	48 %	794,285	32 %	3,675,552	41 %	2,298,162	33 %
Gross profit	1,669,035	52 %	1,665,673	68 %	5,298,174	59 %	4,698,759	67 %
Selling, general and administrative expenses	2,933,950	91 %	2,480,354	99 %	9,226,062	92 %	6,969,332	99 %
Research and development expenses	303,268	9 %	20,676	1 %	756,045	8 %	49,616	1 %
Total operating expenses	3,237,218	100%	2,501,030	100%	9,982,107	100%	7,018,948	100%
Loss from operations	(1,568,183)	(49)%	(835,357)	(34)%	(4,658,933)	(52)%	(2,320,189)	(33)%
Interest expense	(846)	(0)%	(1,043)	(0)%	(2,782)	(0)%	(961)	(0)%
Loss before provision for income tax and equity in net earnings of equity investments	(1,569,029)	(49)%	(836,400)	(34)%	(4,686,715)	(52)%	(2,321,150)	(33)%
Provision for income tax	(16,522)	(1)%	(27,105)	3 %	(80,147)	(2)%	(40,751)	2 %
Loss before equity in net earnings of equity investments	(1,,581,551)	(46)%	(863,505)	(35)%	(4,766,862)	(53)%	(2,361,901)	(34)%
Loss on earnings from Milestone Medical	-	0 %	(590,612)	(24)%	-	0 %	(1,566,711)	(22)%
Income (Loss) on earnings from Education Joint Venture	-	0 %	2,343	0 %	-	0 %	(5,493)	(0)%
Loss on earnings from China Joint Venture	(253,451)	16 %	(123,083)	15 %	(554,766)	12 %	(187,062)	8 %
Loss in equity investments	(253,451)	(8)%	(711,352)	(29)%	(554,766)	(6)%	(1,759,266)	(25)%
Net Loss	(1,839,002)	(58)%	(1,574,857)	(64)%	(5,321,628)	(59)%	(4,121,167)	(59)%
Net loss attributable to noncontrolling interests	(137,752)	(4)%	(5,655)	(0)%	(1,113,958)	(12)%	(59,642)	(1)%
Net loss attributable to Milestone Scientific Inc.	$ (1,701,250)	(53)%	$ (1,569,202)	(64)%	$ (4,207,670)	(47)%	$ (4,061,525)	(58)%

The three months ended September 30, 2016 compared to the three months ended September 30, 2015

The following paragraphs describe the 2016 results compared to 2015.

Total revenues for the three months ended September 30, 2016 and 2015 were approximately $3.2 and $2.5 million, respectively. The total revenue increased by approximately $727,000 or 28%, which was principally related to the

increase in instrument and handpieces sales to China. Domestic sales in the United States decreased by approximately $582,000 in 2016. In the third quarter of 2016 Henry Schein did not purchase instruments and handpieces as they continued to introduce our instrument to the market and sell down their current inventory. International Instruments sales increased by approximately $1 million over the same period in 2015 principally due to a shipment of STA instruments and handpiece to China. Handpieces sales increased by approximately $209,000 compared to the comparable period in 2015. International sales increased in total by approximately $1.3 million. In the USA, Milestone Scientific did not renew its non-exclusive distribution and marketing agreement with Aseptico Inc. after March 2016. Instead, Milestone Scientific chose to continue our distribution and marketing effort in the USA and Canada pursuant to the non-exclusive distribution agreement with Henry Schein. In June 2016, Milestone Scientific entered into an exclusive distribution agreement with Henry Schein pursuant to which Henry Schein agreed to have a dedicated independent sales force to market our dental products in the USA and Canada. We believe that this agreement with Henry Schein will lead to increased domestic sales of STA instruments and handpieces in the fourth quarter of 2016 and into 2017.

The gross margin in 2016 decreased to 52% versus 68% in 2015. This decrease in gross profit margin is due to a special price reduction given to a distributor in a key international market for instruments in an effort to stimulate growth in the 2016 sales volume. This distributor is a related party of the Company. Although the gross margin percentage decreased 16%, gross profit dollars in 2016 was approximately the same as 2015, or approximately $1.7 million.

Selling, general and administrative expenses for the three months ended September 30, 2016 were approximately $2.9 million versus $2.5 million in 2015. This net increase of approximately $428,000 is predominantly due to the consolidation of Milestone Medical commencing on December 31, 2015. In 2015, Milestone Medical was accounted for under the equity method, as such their line item expenses were recorded as a one line entry in the Statement of Operations as a Loss on Earnings from Milestone Medical of approximately $591,000. The total operating expense for Milestone Scientific for the quarter ending September 30, 2016 and 2015 was $3.1 million and $2.8 million, respectively, after giving effect to proforma consolidation of Milestone Medical in 2015, which resulted in a net increase of $300,000.

On a consolidated basis, giving effect to the consolidation of Milestone Medical, Milestone Education, LLC (“Milestone Education”), Milestone Advanced Cosmetic Systems, Inc. (“Milestone Cosmetic”) and Wand Dental, Inc. (“Wand Dental”), each a subsidiary of Milestone Scientific, selling, general and administrative expenses net increased by approximately $300,000 for the three months ended September 30, 2016 as compared to the same prior year period. The increase in selling, general and administrative expenses include a decrease of $100,000 in salaries and other compensation expense for the three months ended September 30, 2016 as compared to the same prior year period due to a temporary decrease in personnel. Salary expense is expected to increase in future quarters as we fill existing open positions to grow our business. The hiring of a replacement Senior Brand Manager, and an increase in our Clinical Hygienist staff to train our current and new customers is anticipated in the future.

Research and development expenses for the three month ended September 30, 2016 and 2015 were $300,000 and $20,000, respectively. The increase is due to research and development projects within Advanced Cosmetic Systems, Inc that relates to the Botox instrument.

The loss from operations for the three months ended September 30, 2016 and 2015 was approximately $1.6 million and $835,000, respectively, an increase of approximately $732,000. The increase in loss from operations in 2016 is primarily the result of the consolidation Milestone Medical in 2016.

The loss on earnings from the China Joint Venture was approximately $253,000 and $123,000 for the three months ended September 30, 2016 and 2015, respectively, an increase of approximately $130,000. The increase in loss on earning from the China Joint Venture is primarily due to the China Joint Venture being in its initial operating and expansion cycle in China. As such, we expect the China Joint Venture to continue to have losses in 2016.

Nine months ended September 30, 2016 compared to Nine months ended September 30, 2015

Total revenues for the nine months ended September 30, 2016 and 2015 were approximately $8.9 and $7.0 million, respectively. The total dental revenue increased by approximately $2 million or 28% which was primarily related to the increase in instrument sales worldwide. Domestic sales in the United States increased by approximately $349,000 in 2016. This increase in revenue relates to sales of both STA instruments and handpieces. It is important to note that in the first half of 2016 Henry Schein a global leader in the distribution of medical, and dental supplies continued to purchased instruments and handpieces as a non-exclusive distributor in United States and Canada. In the third quarter Henry Schein continued to sell through their previously purchased dental inventory and increase their marketing base for the instruments and handpieces. International Instruments sales increased approximately $1.7 million over the same period in 2015 due to a shipment of STA instruments to China. Sales of handpieces decreased by $274,000 over the same period in 2015 as our distributor sells though their previously purchase handpieces. In the USA, Milestone Scientific did not renew its non-exclusive distribution and marketing agreement with Aseptico Inc. after March 2016. Instead, Milestone Scientific chose to continue our distribution and marketing effort in the USA and Canada pursuant to the non-exclusive distribution agreement with Henry Schein. In June 2016, Milestone Scientific entered into an exclusive distribution agreement with Henry Schein pursuant to which Henry Schein agreed to have a dedicated independent sales force to market our dental products in the USA and Canada. We believe that this agreement with Henry Schein will lead to increased domestic sales of STA instruments and handpieces in the fourth quarter of 2016 and into 2017.

The gross margin in 2016 decreased to 59% versus 67% in 2015. This decrease in gross profit margin is due to a special price reduction given to a distributor in a key international market for instruments in an effort to stimulate growth in the 2016 sales volume. This distributor is a related party of the Company. Although the gross margin percentage decreased 8%, gross profit dollars in 2016 increased to approximately $5.3 million from approximately $4.7 million in 2015 or, by approximately $600,000 over the same prior year period.

Selling, general and administrative expenses for the nine months ended September 30, 2016 were approximately $9.2 million versus $7.0 million in 2015. This increase of approximately $2.2 million is predominantly due to the consolidation of Milestone Medical in the first half of 2016. In 2015, Milestone Medical was accounted for under the equity method, as such their line item expenses were recorded as a one line entry in the Statement of Operations as a

Loss on Earnings from Milestone Medical. The total operating expense for Milestone Medical for the nine months ending September 30, 2016 and 2015 was $2.6 million and $3.1 million, respectively. The major reduction in the total operating expense for Milestone Medical was a reduction in Salary and Research and Development Expense of approximately $485,000.

On a consolidated basis, giving effect to the consolidation of Milestone Medical, Milestone Education, LLC ("Milestone Education"), Milestone Advanced Cosmetic Systems, Inc. ("Milestone Cosmetic") and Wand Dental, Inc. ("Wand Dental"), selling, general and administrative expenses increased by approximately $2.2 million for the nine month ended September 30, 2016. This increase is related to marketing, consulting, administrative expense, and clinical studies compared to the same prior year period. However, in the remainder of 2016 Milestone Scientific expects that it will increase personnel which it believes is required to grow our business including hiring a replacement Senior Brand Manager, and an increase in our Clinical Hygienist staff to train our current and new customers.

Research and development expenses for the nine months ended September 30, 2016 and 2015 were approximately, $756,000 and $49,000, respectively. The increase is due to research and development projects within Advanced Cosmetic Systems, Inc that relates to the Botox instrument.

The loss from operations for the nine months ended September 30, 2016 and 2015 was approximately $4.7 million and $2.3 million, respectively, an increase of approximately, $2.4 million. The increase in loss from operations in 2016 is primarily the result of the consolidation Milestone Medical in 2016.

The loss on earnings from the China Joint Venture was approximately $554,000 and $187,000 for the nine months ended September 30, 2016 and 2015, respectively, an increase of approximately $367,000. The increase in loss on earning from the China Joint Venture is primarily due to the China Joint Venture being in its initial operating and expansion cycle in China. As such, we expect the China Joint Venture to continue to have losses in 2016.

For the reasons explained above, and after factoring in the positive effects of net loss attributable to non-controlling interest, the net loss for the nine months ended September 30, 2016 was $5.3 million as compared to the net loss for the nine months ended September 30, 2015 of $4.1 million.

Liquidity and Capital Resources

At September 30, 2016, Milestone Scientific had cash and cash equivalents of approximately $2.3 million, total current assets of approximately $10.7 million and working capital of approximately $6.3 million. We believe that our cash on hand and the anticipated revenues from the dental business will be sufficient to operate our ongoing business for at least the next 12 months.

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. Cash flows from operating activities for the nine months ended September 30, 2016 and 2015 were approximately a negative $4.1 million and $3.7 million, respectively.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception, except for the year ended December 31, 2013. 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. The consolidation of Milestone Medical in December 2015 and the lack of capital raising activities by Milestone Medical created a unique situation for Milestone Scientific. Milestone Scientific is not obligated to continue its financial support of Milestone Medical, but FDA clearance for Milestone Medical's 510K FDA clearance is expected in 2017. Milestone Scientific expects that clearance to commercialize the epidural and intra articular instruments in 2017 will improve the capital raising opportunities and financial condition of the Company.

Milestone Scientific believes that the new exclusive distribution agreement with Henry Schein, the world's largest supplier of medical, dental and veterinary supplies and devices, will improve our dental revenues in the upcoming 12 months. To further reduce Milestone Scientific's expenditures, Milestone Medical expenses related to FDA clearance for the epidural and intra-articular instruments can be controlled as required to meet Milestone Scientific's budget. By limiting the FDA related expenses and increasing the dental instrument revenue through the new distribution agreement and performing a detailed cash flow projection of the consolidated company and its subsidiaries, management believes that Milestone Scientific will have sufficient cash reserves to meet all of its anticipated obligations over 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, 2016 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific's internal controls over financial reporting.

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PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

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

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

In September 2016, we issued 10,709 shares of common stock as compensation to an employee. The fair market value of the shares was $22,500 The issuance was exempt from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act and a legend restricting the resale, transfer, or other disposition of such shares other than in compliance with the Act was imprinted on the stock certificate evidencing such shares.

In August 2016, we issued 101,190 shares of common stock to an accredited investor for consulting services. The fair market value of the shares was $141,666. The issuance was exempt from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act and a legend restricting the resale, transfer, or other disposition of such shares other than in compliance with the Act was imprinted on the stock certificate evidencing such shares.

In July 2016, we issued an aggregate of 20,028 shares of common stock to four accredited investors for consulting services. The fair market value of the shares was $56,078. The issuance was exempt from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act and a legend restricting the resale, transfer, or other disposition of such shares other than in compliance with the Act was imprinted on the stock certificate evidencing such shares.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which we would exchange one share of common stock for every two outstanding shares of Milestone Medical common stock. As there was no change in control, the acquisition of the non-controlling interest is reflected as an equity transaction with the carrying value of the non-controlling interest adjusted to reflect Milestone Scientific’s increased ownership interest in the subsidiary. As of September 30, 2016, 5,035,042 shares of common stock have been issued in exchange for

9,005,000 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owns approximately 91% of Milestone Medical at September 30, 2016. As a result of these exchanges, Milestone Scientific owns approximately 91% of Milestone Medical at September 30, 2016. The issuances were exempt from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act and a legend restricting the resale, transfer, or other disposition of such shares other than in compliance with the Act was imprinted on the stock certificates evidencing such shares.

ITEM 3. DEFAULT UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit No.	Description
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.**
101.INS	XBRL Instance Document.*
101.SCH	XBRL Taxonomy Extension Schema Document.*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
*	Filed herewith.
**	Furnished, not filed, in accordance with Item 601(32)(ii) of Regulation S-K.

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 9, 2016