

MILESTONE SCIENTIFIC INC.  
Form 10-Q  
November 14, 2017

**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, 2017

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      (I.R.S. Employer  
incorporation or organization)    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)

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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  
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act.

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 14, 2017, the registrant had a total of 32,989,724 shares of Common Stock, \$.001 par value, outstanding.

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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, including without limitations, Milestone Scientific’s Annual Report on Form 10-K for the year ended December 31, 2016 filed with the Securities and Exchange Commission (the “SEC”). Milestone Scientific disclaims any intent or obligation to update such forward-looking statements.*

Milestone Scientific is the owner of the following registered U.S. trademarks: *CompuDent®; CompuMed®; CompuFlo®; DPS Dynamic Pressure Sensing Technology®; Milestone Scientific ®; the Milestone logo ®; SafetyWand®; STA Single Tooth Anesthesia System®; and The Wand ®.*

**PART I—FINANCIAL INFORMATION**

## Item 1. Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016 (Audited)
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$2,307,497	\$3,602,229
Accounts receivable, net of allowance for doubtful accounts of \$10,000 as of September 30, 2017 and \$5,000 as of December 31, 2016	1,999,636	802,384
Accounts receivable from related party	712,800	2,714,600
Other receivable	-	10,000
Notes receivable from financing transaction, short term	500,000	-
Inventories	4,165,721	4,602,719
Advances on contracts	992,242	700,900
Deferred Cost	362,718	620,041
Prepaid expenses and other current assets	552,010	291,929
Total current assets	11,592,624	13,344,802
Furniture, fixtures & equipment net of accumulated depreciation of \$703,191 as of September 30, 2017 and \$659,144 as of December 31, 2016	119,729	159,026
Patents, net of accumulated amortization of \$904,295 as of September 30, 2017 and \$717,086 as of December 31, 2016	3,152,415	660,457
Notes receivable from financing transaction long term	650,000	-
Other assets	26,878	17,355
Total assets	\$15,541,646	\$14,181,640
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current Liabilities:		
Accounts payable	\$616,036	\$1,341,207
Accounts payable related party	902,341	1,235,052
Accrued expenses and other payables	2,162,786	1,436,262
Deferred profit, related party	659,931	630,990
Deferred revenue	712,800	1,001,800
Total current liabilities	5,053,894	5,645,311
Deferral from financing transaction	1,400,000	-
Total liabilities	6,453,894	5,645,311
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 of September 30, 2017 and December 31, 2016	7	7

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Common stock, par value \$.001; authorized 50,000,000 shares;33,023,057 shares issued, 1,404,405 shares to be issued and 32,989,724 shares outstanding as of September 30, 2017; 30,457,224 shares issued, 1,270,481 shares to be issued and 30,423,891 shares outstanding as of December 31, 2016	34,426	31,720
Additional paid-in capital	86,442,802	82,761,503
Accumulated deficit	(76,778,556)	(73,381,491)
Treasury stock, at cost, 33,333 shares	(911,516 )	(911,516 )
Total stockholders' equity	8,787,163	8,500,223
Noncontrolling interest	300,589	36,106
Total Equity	9,087,752	8,536,329
Total liabilities and stockholders' equity	\$15,541,646	\$14,181,640
See Notes to Condensed Consolidated Financial Statements		



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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Revenue				
Product sales, net	\$2,853,813	\$3,186,596	\$9,066,550	\$8,973,726
Cost of products sold	1,044,540	1,517,561	3,320,411	3,675,552
Gross profit	1,809,273	1,669,035	5,746,139	5,298,174
Selling, general and administrative expenses	3,205,996	2,933,950	8,996,092	9,226,062
Research and development expenses	16,884	303,268	241,964	756,045
Total operating expenses	3,222,880	3,237,218	9,238,056	9,982,107
Loss from operations	(1,413,607 )	(1,568,183 )	(3,491,917 )	(4,683,933 )
Other (expenses)	(1,046 )	(846 )	(3,278 )	(2,782 )
Interest income	3,582	-	6,495	-
Loss before provision for income tax and equity in net earnings of equity investments	(1,411,071 )	(1,569,029 )	(3,488,700 )	(4,686,715 )
Provision for income tax	(6,475 )	(16,522 )	(18,339 )	(80,147 )
Loss before equity in net earnings of equity investments	(1,417,546 )	(1,585,551 )	(3,507,039 )	(4,766,862 )
Loss on earnings from China Joint Venture	-	(253,451 )	(28,941 )	(554,766 )
Loss in equity investments	-	(253,451 )	(28,941 )	(554,766 )
Net Loss	(1,417,546 )	(1,839,002 )	(3,535,980 )	(5,321,628 )
Net loss attributable to noncontrolling interests	(6,605 )	(137,752 )	(138,915 )	(1,113,958 )
Net loss attributable to Milestone Scientific Inc.	\$(1,410,941 )	\$(1,701,250 )	\$(3,397,065 )	\$(4,207,670 )
Net loss per share applicable to common stockholders—				
Basic	\$(0.04 )	\$(0.06 )	\$(0.10 )	\$(0.16 )
Diluted	\$(0.04 )	\$(0.06 )	\$(0.10 )	\$(0.16 )
Weighted average shares outstanding and to be issued—				
Basic	33,573,676	29,155,712	32,501,221	25,965,566
Diluted	33,573,676	29,155,712	32,501,221	25,965,566
See Notes to Condensed Consolidated Financial Statements				

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY  
 (Unaudited)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock
	Shares	Amount	Shares	Amount				
Balance, January 1, 2017	7,000	\$	7 31,727,705	\$ 31,720	\$ 82,761,503	\$ (73,381,491)	\$ 36,106	\$ (911,516)
Stock based compensation	-	-			530,966	-	-	-
Common stock to be issued to employee for compensation			10,913	11	14,989	-	-	-
Common stock issued to employee for exercise of stock options			83,333	83	62,417	-	-	-
Common stock issued for payment of consulting services			245,373	260	422,249	-	-	-
Common stock to be issued to employee for bonuses			158,082	151	259,841	-	-	-
Common stock issued for assets acquired			1,646,358	1,646	2,484,354			
Common Stock exchanged for MMD			311,998	311	(403,709)	-	403,398	-
Common stock issued to directors for bonuses			120,000	120	159,480	-	-	-
Sale of Common Stock - Public			123,700	124	150,712	-	-	-

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Offering

Net loss	-	-	-	(3,397,065)	(138,915)	-								
Balance, September 30, 2017	7,000	\$	7	34,427,462	\$	34,426	\$	86,442,802	\$	(76,778,656)	\$	300,589	\$	(911,516)

See Notes to Condensed Consolidated Financial Statements

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

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$ (3,535,980)	\$ (5,321,628)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	44,046	69,345
Amortization of patents	187,209	53,017
Stock compensation	530,966	1,136,430
Loss China joint venture	28,941	545,950
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(1,197,252)	(759,385)
Decrease in accounts receivable related party	2,001,800	-
Decrease in other receivable	10,000	58,140
Decrease (increase) in inventories	436,998	(225,998)
(Increase) to advances on contracts	(291,342)	(53,566)
Increase (Decrease) to prepaid expenses and other current assets	(260,081)	27,701
(Increase) in other assets	(9,523)	-
(Decrease) increase in accounts payable	(725,170)	169,388
(Decrease) in accounts payable related party	(332,711)	-
Increase in deferred profit, related party	257,323	-
Increase in accrued expenses and other payables	1,583,624	181,324
(Decrease) in deferred revenue	(289,000)	-
Net cash used in operating activities	(1,560,152)	(4,119,282)
Cash flows from investing activities:		
Purchase of intangible assets	(39,520)	(15,616)
Purchase of property and equipment	(4,749)	(14,945)
Purchase of intangibles assets-Apad	(153,647)	-
Consolidation of variable interest entity	-	50,621
Net cash (used in) provided by investing activities	(197,916)	20,060
Cash flows from financing activities:		
Capital contribution from noncontrolling interest	-	2,543
Proceeds from Private Placement Offering	-	2,225,000
Proceed from financing transaction	250,000	-
Proceeds from exercise of stock options	62,500	-
Net proceeds on Private Placement Offering	150,836	-
Net cash provided by investing activities	463,336	2,227,543
Net decrease in cash and cash equivalents	(1,294,732)	(1,871,679)
Cash and cash equivalents at beginning of period	3,602,229	4,194,384
Cash and cash equivalents at end of period	\$ 2,307,497	\$ 2,322,705

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Supplemental disclosure of cash flow information:

Net assets acquired from variable entity		\$	14,076
Shares issued to for assets acquired	\$2,484,354	-	
Sale of Milestone China shares, financing transaction	\$ 1,400,000	-	
Shares issued to employees for bonus	\$ 259,841	\$	389,318
Shares issued to consultants in lieu of cash payments	\$ 422,249	\$	366,299
See Notes to Condensed Consolidated Financial Statements			

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**MILESTONE SCIENTIFIC INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**Note 1- ORGANIZATION and BUSINESS**

All references in this report to “Milestone Scientific,” “us,” “our,” “we,” “the Company” or “Milestone” refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Milestone Advanced Cosmetic, Milestone Medical, and Milestone Education (all described below), unless the context otherwise indicates. Milestone Scientific is the owner of the following registered U.S. trademarks: *CompuDent®*; *CompuMed®*; *CompuFlo®*; *DPS Dynamic Pressure Sensing Technology®*; *Milestone Scientific ®*; *the Milestone logo ®*; *SafetyWand®*; *STA Single Tooth Anesthesia System®*; and *The Wand ®*.

Milestone Scientific 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®*, and *STA Single Tooth Anesthesia System®* 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 47 other countries. To date there have been no medical instruments sold in the United States and limited amounts sold internationally, although certain medical instruments have obtained CE mark approval and can be marketed and sold in most European countries. In June 2017, Milestone Scientific received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) on the *CompuFlo®* Epidural Computer Controlled Anesthesia System.

During 2015, our common stock was listed on the NYSE MKT under the ticker symbol “MLSS”.

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the FDA for both intra-articular and epidural injections with the *CompuFlo®* Computer Controlled Anesthesia System. In June 2017, the FDA approved the *CompuFlo®* Epidural Computer Controlled Anesthesia System for epidural injections. Milestone Scientific is in the process of introductory meetings with medical device distributors within the United States and foreign markets. Milestone Scientific’s immediate focus is on marketing its epidural instrument throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k) application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k)

clearance. Following consultation with the FDA Office of Device Evaluation, we intend to provide additional data, which could include a new Human Factor Validation study (HFV Study) in support of a new 510(k) application for the device. An HFV Study demonstrates the ease of use of a product.

In December 2016, we completed an underwritten public offering of 2,000,000 shares of common stock and warrants to purchase up to 1,592,775 shares of common stock. The public offering price for each share and related warrant was \$1.50. The gross proceeds from this offering were approximately \$3,000,000, before deducting underwriting discounts and commissions and other offering expenses.

In January 2017, the underwriter exercised a portion of its over-allotment option and purchased an additional 123,700 shares of common stock at the public offering price of \$1.499 per share. The gross proceeds were approximately \$186,000 before deducting underwriting discounts and commissions and other offering expenses.

In June 2017, Milestone Scientific entered into an agreement for the sale of its interest in Milestone China (a forty (40%) percent interest) (the “Milestone China Shares”) to an unaffiliated United States domiciled purchaser and a 10-year option agreement to repurchase the Milestone China Shares. The purchase price for the Milestone China Shares was \$1,400,000 of which \$125,000 was paid in cash and \$1,275,000 was paid by delivery of a non-interest bearing secured promissory note. The note is payable in quarterly installments of \$125,000 and is secured by the Milestone China Shares until full repayment. In addition, the purchaser is precluded from selling all or substantially all of its assets prior to repayment of the note. The 10-year option agreement provides Milestone Scientific an option to repurchase the Milestone China Shares at \$1,400,000 within the first two years and at fair market value (as defined in such agreement) for the remainder of the 10-year term. The transaction has been accounted for as a secured financing and Milestone Scientific will continue to account for its relationship with Milestone China under the equity method of accounting. A note receivable is presented on the Company’s balance sheet, along with a deferral from financing transaction (\$1,400,000). The carrying value of the forty (40%) percent investment at the transaction date was zero (see Note 5).

On July 13, 2017, Milestone Scientific consummated a previously disclosed Asset Purchase Agreement (the “Agreement”) with APAD Octrooi B.V. and APAD B.V. (each, a “Seller” and collectively, the “Sellers”) pursuant to which Milestone Scientific acquired certain patent rights and other intellectual property rights related to the Sellers’ computer controlled injection instrument (the “Purchased Assets”) which has been accounted for as an asset acquisition. On the closing date, Milestone Scientific issued to the Sellers an aggregate of 1,646,358 shares of its common stock, valued at \$2,486,000 which shares are subject to certain post-closing upward or downward adjustments not to exceed twenty-five percent of the initial shares as of the purchase date or 250,000 Euros, as defined in the Agreement. As of September 30, 2017, Milestone Scientific has recorded a \$167,000 liability relating to the estimated additional shares that would have to be issued according this provision in the Agreement. Milestone Scientific paid approximately \$153,000 in legal fees on behalf of the Seller as stipulated based on the terms of the Agreement. The patents and other intellectual property purchased in the amount of approximately \$2,639,000 have been capitalized and will amortized over their five year estimated useful life and tested for impairment as a finite lived intangible asset.

In July 2017, Milestone Scientific's Compensation Committee approved the issuance of 400,000 stock options to Gian Domenico Trombetta, CEO of Wand Dental, a Director of Milestone Scientific and a director of Innovest S.p.A., an Italian investor (250,000 options at an exercise price of \$2.55 per share were issued on July 7, 2017 and 150,000 options having an exercise price at the higher of \$2.55 or the market price of the stock on the date of the 2018 Annual Stockholder meeting, subject to approval of a new or amended equity incentive plan at such meeting.)

Milestone Scientific has incurred operating losses and negative cash flows from operating activities in virtually each year since its inception. Milestone Scientific is actively pursuing the generation of revenue, positive operating income and net income. The capital raised in December 2016 and January 2017 provided Milestone Scientific with working capital to continue to develop its medical instruments and obtain regulatory approval for one of its medical instruments ( the June, 2017 FDA approval of the epidural instrument), as well as to aggressively market its dental instruments. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical instruments and disposables business in the United States (following June 2017 FDA approval of its *CompuFlo*® Computer Controlled Anesthesia System ) and worldwide, and a reductions in operating expenses. Management believes that Milestone Scientific will have sufficient cash reserves to meet its anticipated obligations over the next twelve month period following the date of this report. However, Milestone Scientific will likely need to raise



additional capital prior to the expected generation of sustainable positive cash flow from operating activities and may also need to raise additional capital to effectively launch its approved medical instrument and eventually generate positive cash flow from the anticipated medical business.

## **NOTE - 2 SUMMARY OF ACCOUNTING POLICIES**

### **1. Basis of Consolidation**

The accompanying condensed 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 (wholly owned), Milestone Advanced Cosmetic (majority owned) and Milestone Medical (majority owned). Milestone Education is a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

## **2. Basis of Presentation**

The unaudited condensed consolidated financial statements of Milestone Scientific have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information with the instructions for Form 10Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present such interim results. Interim results are not necessarily indicative of the results of operations which may be expected for a full year or any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2016, included in Milestone Scientific's Annual Report on Form 10-K.

## **3. Reclassifications**

Certain reclassifications have been made to the 2016 financial statements to conform to the consolidated 2017 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

## **4. 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 Education as of January 2016. Accordingly, the assets and liabilities of Milestone Education are included in the accompanying condensed consolidated financial statements.

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; and

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 Milestone 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 Milestone 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 Milestone China. Management has concluded 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.

## **5. Cash and Cash Equivalents**

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

## **6. 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 to date.

## **7. Product Return and Warranty**

Milestone Scientific generally 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.

## **8. 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 requirements.

## **9. Equity Method Investments**

Investments in which Milestone Scientific has 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, Milestone Scientific's share of the net earnings or losses of the investee is presented below the income tax line on the condensed consolidated statements of operations.

Milestone Scientific evaluates its 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.

## **10. 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.

#### **11. Intangible Assets - Patents**

Patents are recorded at cost to prepare and file the applicable documents with the US Patent Office, or internationally with the applicable governmental office in the respective country. The costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. Patents acquired from another business entity will be amortized at the estimated average useful life of the patent. These patents are recorded at the acquisition cost and included legal fees.

#### **12. 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, 2017.

### **13. Revenue Recognition**

Revenue from product sales is recognized, net of discounts and allowances to domestic distributors, on the date of shipment for substantially all shipments, since the shipment terms are FOB warehouse. Milestone Scientific recognizes revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. 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. Instrument and hand pieces are not bundled but rather sold separately and, as such, there are no multiple element determinations in connection with the revenue recognition.

### **14. Shipping and Handling Costs**

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

### **15. 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.

### **16. 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.

### **17. Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the allowance for doubtful accounts, inventory valuation, and cash flow assumptions regarding evaluations for impairment of long-lived assets and going concern considerations, and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

## **18. Fair Value of Financial Instruments**

**Fair Value Measurements:** Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market at the measurement date (exit price). We are required to classify fair value measurements in one of the following categories:

Level 1 inputs which are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 inputs which are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.

Level 3 inputs are defined as unobservable inputs for the assets or liabilities.

Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement requires judgment, and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels.

## 19. 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. 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 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. The Company has adopted this pronouncement as of January 1, 2017, and applied retrospectively, for its provision for income taxes disclosure. The adoption did not have an impact on the presentation of the balance sheet, as the Company assigns a full valuation allowance to its net deferred tax asset.

In February 2016, the FASB issued a new standard Accounting Standards Update ("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, 2018. Milestone Scientific is in the process of determining what impact, 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 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. The adoption of this standard did not have a material impact on our financial statements.

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 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. The adoption of this standard did not have a material impact on our financial statements.



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, 2018. 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 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.

In October 2016, the FASB issued a new standard ASU No.2016-17, "Consolidation Interests Held through Related Parties That Are under Common Control"(Topic 810). The new standard provides guidance as to consideration of consolidation requirements of a primary beneficiary and variable interest entity that are part of related party group under common control. It will be effective for fiscal years and interim periods, beginning after December 15, 2016. Milestone Scientific has adopted the standard, effective January 1, 2017, which did not have an impact on its financial reporting.

In November 2016, the FASB issued a new standard ASU No.2016-18, "Statement of Cash Flows – Restricted Cash" (Topic 230). The new standard provides guidance as to address the diversity of treatment of restricted cash on the statement of cash flows. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017 and

interim periods therein. Milestone Scientific does not expect the adoption of this ASU to have a material effect on its presentation within the statement of cash flows.

In January 2017, the FASB issued a new standard ASU No.2017-01, "Business Combinations" (Topic 805). The new standard provides guidance to clarify the definition of a 'business', and assist entities in evaluation whether a transaction should be accounted for as an acquisition/disposal of assets or a business. It will be effective for public entities for fiscal years and interim periods, beginning after December 15, 2017, with limited early application. 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.

In May 2017, the FASB issued a new standard ASU No.2017-09, "Compensation – Stock Compensation" (Topic 718). The new standard provides guidance and clarity for modification to equity based compensation programs. 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.

#### **NOTE - 3 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 three months and nine months ended September 30, 2017 and 2016, the assumed effects of the exercise of potentially dilutive outstanding stock options and warrants were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 4,629,557 and 1,885,010 at September 30, 2017 and 2016, respectively.

#### **NOTE - 4 CONSOLIDATION OF VARIABLE INTEREST ENTITY**

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 81% of the revenue earned by Milestone Education is from services performed for Milestone Scientific as of September 30, 2017. As a result of this dependency and relationship, we determined that we had the power to direct the activities that most significantly impact Milestone Education's economic performance, and therefore is consolidated in our financial statements.

## **NOTE - 5 INVESTMENTS IN UNCONSOLIDATED SUBSIDIARIES**

### **Advance Ocular Science SA**

Advanced Ocular Sciences SA ("Advanced Ocular") is a shell company attempting to develop an instrument to deliver injections into the eyes. As of September 30, 2017, Milestone Scientific owns 25% of this entity. During 2015, Milestone Scientific advanced \$78,798 for marketing and strategy planning to Advanced Ocular and it, or its organizers, were obligated to repay this advance if a public offering of Advanced Ocular equity was approved and funded in Poland during 2016. However, a public offering has yet to be completed in Poland. As a result, Milestone Scientific wrote-off the \$78,798 advanced to Advanced Ocular as of December 31, 2016. Advance Ocular was not included in the condensed consolidated financial statements at September 30, 2017 as no further investment has been made by Milestone Scientific.

### **Milestone China Ltd.**

In June 2014, Milestone Scientific invested \$1 million in Milestone China Ltd. ("Milestone China") by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting. Milestone Scientific recorded a loss on its investment in Milestone China of \$0 and \$164,837, as of September 30, 2017 and 2016, respectively. Milestone Scientific's investment in Milestone China was \$0 as of September 30, 2017 and December 31, 2016, respectively. Milestone Scientific incurred cumulative losses on its investment in Milestone China of \$2,078,484 and \$1,124,350 as of September 30, 2017 and December 31, 2016, respectively, which have been suspended.

In June 2017, Milestone Scientific entered into an agreement for the sale of the Milestone China Shares to an unaffiliated United States domiciled purchaser and a 10-year option agreement to repurchase the Milestone China Shares. The purchase price for the Milestone China Shares was \$1,400,000 of which \$125,000 was paid in cash and \$1,275,000 was paid by delivery of a non-interest bearing secured promissory note. The note is payable in quarterly installments of \$125,000 until paid in full and is secured by the Milestone China Shares until full repayment. In addition, pursuant to such note, the purchaser is precluded from selling all or substantially all of its assets prior to repayment of the note. The 10-year option agreement provides Milestone Scientific an option to repurchase the 40% equity interest at \$1,400,000 within the first two years and at fair value (as defined in such agreement) for the remainder of the 10-year term. The transaction has been accounted for as a secured financing and Milestone Scientific will continue to account for its relationship with Milestone China under the equity method of accounting. A note receivable is presented on the Balance Sheet, along with a deferral from financing transaction (\$1,400,000). The carrying value of the forty (40%) percent investment at the transaction date was zero.

Milestone Scientific had \$356,400 and \$1,714,600 of related party sales of handpieces and instruments to Milestone China and Milestone China's agent during the three and nine months ended September 30, 2017 respectively. Milestone Scientific had \$1,977,862 and \$3,203,466 of related party sales of handpieces and instruments to Milestone China during the three and nine months ended September 30, 2016, respectively. As of September 30, 2017 and December 31, 2016, Milestone Scientific recorded deferred revenues and deferred costs associated with sales to Milestone China of \$712,800 and \$362,718, and \$1,001,800 and \$620,041, respectively. As of September 30, 2017 and December 31, 2016, Milestone China's agent owed \$712,800 and \$2,714,600, respectively, to Milestone Scientific which is included in related party accounts receivable on the condensed consolidated balance sheets.

Milestone Scientific defers the total revenue and costs of goods sold when instruments and handpieces are shipped to Milestone China and Milestone China's agent due to market conditions and Milestone China liquidity concerns. Due to timing differences of when the inventory sold to Milestone China is actually recognized and when Milestone China sells the acquired inventory to third parties, an 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 40% of the gross profit associated with recognized revenue from Milestone China that has not been sold to third parties. At September 30, 2017 and December 31, 2016, the deferred profit was \$659,931 and \$630,990, respectively, which is included in the condensed consolidated balance sheets. For the nine months ended September 30, 2017 and 2016, the loss on equity investment was \$28,941 and \$554,766, respectively, which is included in the condensed consolidated statements of operation. For the three months ended September 30, 2017 and 2016, the loss on equity investment was \$0 and \$253,451, respectively, which is included in the condensed consolidated statements of operation.

The following table includes summarized financial information (unaudited) of Milestone China:

	September 30, 2017	December 31, 2016
Assets:		
Current Assets	\$7,127,064	\$9,362,198

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Non-Current Assets	2,981,574	2,467,547
Total Assets:	10,108,638	11,829,745

Liabilities:

Current Liabilities	10,449,791	9,900,611
Stockholders' equity	(341,153)	1,929,134
Total liabilities and stockholders' equity	\$ 10,108,638	\$ 11,829,745

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Net Sales	\$1,382,588	\$329,617	\$2,548,140	\$658,939
Cost of Goods Sold	556,430	262,576	1,445,634	546,440
Gross Profit	826,158	(67,041 )	1,102,506	112,499
Other Expenses	(1,886,180)	(1,160,834)	(3,487,845)	(1,673,731)
Net Losses	\$(1,060,022)	\$(1,093,793)	\$(2,385,339)	\$(1,561,232)

**NOTE – 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 and nine months ended September 30, 2017 Milestone Scientific recognized \$299,175 and \$543,290 of total employee stock based compensation cost, respectively. For the three and nine months ended September 30, 2016, Milestone Scientific recognized \$81,678 and \$107,205 of total employee stock based compensation cost, respectively. As of September 30, 2017 and 2016, there was \$1,389,525 and \$580,331 of total unrecognized compensation cost related to nonvested options, respectively, which Milestone Scientific expects to recognize these cost over a weighted average period of 2.5 years and 2.49 years as of September 30, 2017 and 2016, respectively.

A summary of option activity for employees under the plans and changes during the nine month ended September 30, 2017, is presented below:

	<b>Number of Options</b>	<b>Weighted Averaged Exercise Price \$</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Aggregate Intrinsic Options Value \$</b>
Options outstanding January 1, 2017	1,511,995	1.74	2.97	-
Granted	1,383,121	2.04	4.26	
Exercised during 2017	(83,333)	0.75		
Forfeited or expired				
Options outstanding September 30, 2017	2,811,783	1.98	3.31	
Exercisable, September 30, 2017	1,380,958	1.98	2.22	

A summary of option activity for non-employees under the plans As of September 30, 2017 and changes during the six month ended is

	<b>Number of Options</b>	<b>Weighted Averaged Exercise Price \$</b>	<b>Weighted Average Remaining Contractual Life (Years)</b>	<b>Aggregate Intrinsic Options Value \$</b>
Options outstanding January 1, 2017	224,999	2.52	5.32	-

Granted	-			
Exercised during 2017	-			
Forfeited or expired	-			
Options outstanding September 30, 2017	224,999	2.52	4.57	-
Exercisable, September 30, 2017	12,960	2.33	3.68	-

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 re-measures the value of the grant at each presentation date unless there is a significant disincentive for non-performance or until performance has been. For the three and nine months ended September 30, 2017, Milestone Scientific recognized income of \$6,067 and \$12,324, respectively related to non-employee options. For the three and nine months ended September 30, 2016, Milestone Scientific recognized expense of \$2,807 and \$8,421 respectively related to non-employee options.

#### **NOTE – 7 CONCENTRATION OF CREDIT RISK**

Milestone Scientific's consolidated financial instruments that are exposed to concentrations of credit risk consist primarily of cash, trade accounts receivable, and advances on contracts. Milestone Scientific places its cash and cash equivalents with large financial institutions. At times, such investments may be in excess of the Federal Deposit Insurance Corporation insurance limit. Milestone Scientific has not experienced any losses in such accounts and believes it is not exposed to any significant credit risks. Financial instruments which potentially subject Milestone Scientific to credit risk consist principally of trade accounts receivable, as Milestone Scientific does not require collateral or other security to support customer receivables, and advances on contracts. Milestone Scientific closely monitors the extension of credit to its customers while maintaining allowances, if necessary, for potential credit losses. On a periodic basis, Milestone Scientific evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit conditions.

**NOTE – 8 ADVANCES ON CONTRACTS**

The advances on contracts represent funding of future STA inventory purchases and Epidural replacements parts. The balance of the advances As of September 30, 2017 and December 31, 2016 is \$992,242 and \$700,900, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

**NOTE – 9 INCOME TAXES**

Due to Milestone Scientific's history of operating losses, a full valuation allowances has been provided for all of Milestone Scientific's deferred tax assets At September 30, 2017 and December 31, 2016, no recognition was given to the utilization of the remaining net operating loss carryforwards in each of these periods.

The utilization of Milestone Scientific's net operating losses may be subject to a substantial limitation due to the "change of ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation may result in the expiration of the net operating loss carry forwards before their utilization. Milestone Scientific has established a 100% valuation allowance for all of its deferred tax assets due to uncertainty as to their future realization.

As of September 30, 2017 and December 31, 2016, state tax liability was approximately \$18,339 and \$63,000, respectively. Such expense was recognized in the accompanying condensed consolidated financial statements.

**NOTE – 10 SIGNIFICANT CONCENTRATIONS & GEOGRAPHICAL INFORMATION**

Milestone Scientific's consolidated dental sales by product and by geographical region are as follows: Revenue from the medical segment is not material as of September 2017.

	Three months Ended		Nine months Ended	
	September 30, 2017	2016	September 30, 2017	2016
<b>DOMESTIC</b>				
Instruments	\$452,232	\$-	\$857,525	\$852,149
Handpieces	893,496	106,908	3,230,567	1,860,593
Other	12,338	12,508	53,037	46,634
Total Domestic	\$1,358,066	\$119,416	\$4,141,129	\$2,759,376



**INTERNATIONAL-Europe**

Instruments	\$ 340,575	\$ 1,416,030	\$ 1,053,050	\$ 1,974,280
Handpieces	765,821	713,766	2,068,007	1,845,424
Other	32,951	87,984	89,764	188,046
Total International -Europe	\$ 1,139,347	\$ 2,217,780	\$ 3,210,821	\$ 4,007,750

**INTERNATIONAL-China**

Instruments	\$-	\$ 493,000	\$ 1,000,000	\$ 1,493,800
Handpieces	356,400	356,400	712,800	712,800
Other	-	-	1,800	-
Total International-China	\$ 356,400	\$ 849,400	\$ 1,714,600	\$ 2,206,600

Domestic	\$ 1,358,066	\$ 119,416	\$ 4,141,129	\$ 2,759,376
International -Europe	1,139,347	2,217,780	3,210,821	4,007,750
International -China	356,400	849,400	1,714,600	2,206,600
	\$ 2,853,813	\$ 3,186,596	\$ 9,066,550	\$ 8,973,726

Milestone Scientific has informal arrangements with a third party 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. In March 2016, Milestone Scientific entered into a purchase commitment for delivery of 3,000 instruments, as of September 30, 2017 all instruments have been received. In January 2017, Milestone Scientific entered into a purchase commitment for the delivery of 2,000 instruments beginning in the 4<sup>th</sup> quarter

of 2017. An advance of \$948,094 was recorded at September 30, 2017. At September 30, 2017, Milestone Scientific's purchase commitment for this purchase order was \$431,619. Consequently, advances on contracts have been classified as current at September 30, 2017 and December 31, 2016.

For the three months ended September 30, 2017, an aggregate of approximately 67% of Milestone Scientific's net product sales were to two customers/ distributors (one of which, Milestone China, is a related party), 54%, and 13%, respectively. For the nine months ended September 30, 2017, an aggregate of approximately 72% of Milestone Scientific's net product sales were to two customers/distributors (one of which, Milestone China, is a related party), 53%, and 19%, respectively. Accounts receivable for the major customer/distributors amounted to an aggregate of approximately \$1,403,148, or 70% of Milestone Scientific's accounts receivable for nine months ended September 30, 2017. For the three months ended September 30, 2016, an aggregate of 61% of Milestone Scientific's net product sales were to two customers/distributors (one of which, Milestone China, is a related party), 44%, and 17%, respectively. For the nine months ended September 30, 2016, an aggregate of approximately 70% of Milestone Scientific's net product sales were to two customers/distributors (one of which, Milestone China, is a related party), 62%, and 8%, respectively.

#### **NOTE – 11 Employment and Consulting Agreements**

In July 2017, Milestone Scientific entered into a three-year employment agreement with Daniel Goldberger to serve as President and Chief Executive Officer of Milestone Scientific. Under the agreement, Mr. Goldberger would receive base compensation of \$300,000 per annum and may additionally earn annual bonuses of up to an aggregate of \$400,000, payable one half in cash and one half in Milestone Scientific common stock ("Bonus Shares") contingent upon achieving performance benchmarks periodically set for each year by the compensation committee of the Board. In addition to any such shares of common stock, Mr. Goldberger was entitled to receive stock options ("Bonus Options") to acquire twice the number of any Bonus Shares earned, pursuant to a non-qualified stock option grant agreement under Milestone Scientific's then existing equity compensation plan. The Bonus Options had a five-year term and were to vest in equal annual installments on each of the first, second and third anniversary of the grant date, subject to continued employment on such vesting date and accelerated vesting upon the occurrence of certain events. The exercise price of the Bonus Options was based on the fair market value of per share of common stock on the date of grant.

In July 2017, Milestone Scientific granted to Mr. Goldberger non-qualified stock options to purchase 921,942 shares of common stock at an exercise price of \$2.00 per share. Those options had a five-year term and were to vest in equal annual installments on each of the first, second and third anniversaries of the grant date, subject to his continued employment on the vesting date and accelerated vesting upon the occurrence of certain events.

On October 5, 2017, Milestone Scientific Inc. announced that Daniel Goldberger had resigned as President and Chief Executive Officer effective October 2, 2017, upon which the previously described stock options granted to him in July

2017 terminated prior to vesting (see Note 14).

In July 2017, Milestone Scientific entered into a ten-year new employment agreement with Leonard Osser, who previously served as the Company's President and Chief Executive Officer, to serve as Managing Director – China Operations. This new agreement provides for annual compensation of \$300,000 consisting of \$100,000 in cash and \$200,000 in the Company's common stock valued at the average closing price of the Company's common stock on the NYSE or such other market or exchange on which its shares are then traded during the first fifteen (15) trading days of the last full calendar month of each year during the term of this agreement. This agreement supersedes all prior employment agreements between Mr. Osser and Milestone Scientific. If the Company terminates Mr. Osser's employment "Without Cause," other than due to his death or disability, or if Mr. Osser terminates his employment for "Good Reason" (both as defined in the agreement), Mr. Osser is entitled to be paid in one lump sum payment as soon as practicable following such termination: an amount equal to the aggregate present value (as determined in accordance with Section 280G(d)(4) of the Code) of all compensation pursuant to this agreement from the effective date of termination hereunder through the remainder of the Employment Term.

In July 2017, Mr. Osser also resigned from his positions of Chairman of the Board, Chief Executive Office and President of Milestone Medical. Upon his resignation, Milestone Medical entered in a consulting agreement with U.S. Asian Consulting Group LLC, an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten- year term. Pursuant to the consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive \$100,000 per year for Mr. Osser's services.

## **NOTE – 12 RELATED PARTIES**

Milestone Scientific has a manufacturing agreement with United Systems (a significant stockholder of Milestone), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were \$721,225 and \$1,690,582 for the three and nine months ended September 30, 2017, respectively. Purchases of handpieces from this manufacturer were \$967,003 and \$2,088,229 for the three and nine months ended September 30, 2016, respectively. Milestone Scientific owed \$902,341 and \$984,286 to this manufacturer as of September 30, 2017 and December 31, 2016, respectively.

Milestone Scientific had \$356,400 and \$1,714,600 of related party sales of handpieces and instruments to Milestone China and Milestone China's agent during the three and nine months ended September 30, 2017 respectively. Milestone Scientific had \$1,977,862 and \$3,203,466 of related party sales of handpieces and instruments to Milestone China during the three and nine months ended September 30, 2016, respectively. As of September 30, 2017 and December 31, 2016, Milestone Scientific recorded deferred revenues and deferred costs associated with sales to Milestone China of \$712,800 and \$362,718, and \$1,001,800 and \$620,041, respectively. As of September 30, 2017 and December 31, 2016, Milestone China's agent owed \$712,800 and \$2,714,600, respectively, to Milestone Scientific which is included in related party accounts receivable on the condensed consolidated balance sheets.

In August 2016, a stockholder of Milestone Scientific entered a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$25,000 and \$75,000 for the three and nine months ended September 30, 2017, respectively. Expenses recognized on this agreement were \$25,000 and \$75,000 for the three and nine months ended September 30, 2016, respectively.

In January 2017, Milestone Scientific entered into a 12 month agreement with Innovest S.p.A. to provide consulting services (see Note 13).

## **NOTE – 13 COMMITMENTS AND CONTINGENCIES**

### **(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 and provides for a monthly lease payment of \$12,522. Additionally, Milestone Scientific has other smaller insignificant leases ending through 2017. Further, 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, 2017, rent

expense amounted to \$36,658 and \$106,828 respectively. For the three and nine months ended September 30, 2016 rent expense amounted to \$25,031 and \$95,019, respectively.

## (2) Other Commitments

Milestone Scientific's employment agreement (the "2009 Agreement") with Leonard Osser, its former Chief Executive Officer, provided 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. Milestone Scientific expensed approximately \$51,000 and \$152,000 for the three and nine months ended September 30, 2017, and 2016 respectively to fund this obligation. In July 2017, Milestone Scientific entered into a new employment agreement with Mr. Osser, which superseded the 2009 Agreement pursuant to which he stepped down from his position as Chief Executive Officer and became Managing Director – China Operations (see Note 11). Pursuant to the new agreement, Milestone Scientific agreed to fund the last installment of \$203,111 in January 2018 as provided for in the 2009 Agreement.

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 Milestone Scientific. Milestone Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs 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 until the expiration of the last patent. 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 \$122,606 and \$446,098 for the three and nine months ended September 30, 2017, respectively. The Director of Clinical Affairs' royalty fee was \$148,185 and \$449,875 for the three and nine months ended September 30, 2016, 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, 2017, and 2016 respectively.

In January 2017, Milestone Scientific entered into a 12 month agreement with Innovest S.p.A. to provide consulting services. This agreement will renew for successive 12 month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were \$20,000 and \$60,000 for the three and nine months ended September 30, 2017, respectively.

On October 2, 2017, Milestone Scientific accepted the resignation of the then CEO, Daniel Goldberger. Subsequent to that date, Mr. Goldberger through his attorney advised Milestone Scientific's attorneys, that Mr. Goldberger was entitled, based on the circumstances he asserted with respect to his resignation after acceptance of such resignation, to his basic salary (\$300,000) for one year and certain other benefits (health and disability insurance for one year (\$30,000 estimated) and a car allowance of \$1,200 per month), in accordance with his employment contract dated July 10, 2017. Under the circumstances asserted by Mr. Goldberger, he would also be entitled to the immediate vesting of options under the Milestone Scientific's Stock Option Plan agreed to be granted to him pursuant to his employment agreement, exercisable for ninety days after his resignation, for 921,942 shares of Milestone Scientific at a price of \$2.00 per share, which exercise price is in excess of the market price of Milestone Scientific's shares on the date hereof. Milestone Scientific believes that the assertion of Mr. Goldberger is not in accordance with the facts or the requirements of his employment contract, and Milestone Scientific intends to vigorously contest his assertion.

#### **NOTE 14- Subsequent Events**

On October 5, 2017, Milestone Scientific announced that Daniel Goldberger had resigned as President and Chief Executive Officer effective October 2, 2017.

On October 5, 2017, Milestone Scientific also announced the appointment of Leslie Bernhard, the Company's current Chairman of the Board, as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer.

In connection with her appointment to serve as the Company's Interim Chief Executive Officer, Ms. Bernhard will be paid an annual salary of \$200,000 and receive a one-time bonus of 100,000 shares of the Company's Common Stock. In addition, at the completion of her service as Interim Chief Executive Officer, Ms. Bernhard shall be entitled to receive a cash bonus in an amount to be determined by the Board of Directors at that time.



## 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

Our common stock was listed on the NYSE MKT on June 1, 2015 and trades under the symbol "MLSS". We have 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*®, and *STA Single Tooth Anesthesia System*® 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. Certain of our medical instruments have obtained European CE mark approval and can be marketed and sold in most European countries. In June 2017, the FDA approved our 510(k) application for marketing clearance in the United States of our *CompuFlo*® Epidural Computer Controlled Anesthesia System. We are in the process of introductory meetings with medical device distributors within the United States and foreign markets.

In 2017, we remained focused on advancing efforts to achieve our four primary objectives; those being:

Obtaining the 510(k) marketing clearance with the FDA for the intra articular instruments

Identify distributors in the United States for the Epidural instruments, now that FDA clearance has been received;

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 System*® Instrument (STA Instrument).



## **STA Instrument Growth**

Since its market introduction in early 2007, the STA Instrument and prior C-CLAD products have been used to deliver over 66 million safe, effective and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

## **Global Distribution Network**

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

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein, Inc. (“Henry Schein”). In June 2016, that agreement was replaced with an exclusive distribution arrangement for our dental products for the United States and Canada with Henry Schein. Under this arrangement we have a semi-dedicated independent sales force visiting dentists. We believe that this arrangement will be more effective than previous arrangements which primarily relied upon appearances at dental shows and catalog sales.

To date, Henry Schein has endeavored to accomplish the goals set forth in the exclusive distribution agreement for *The Wand*® STA instrument and handpieces, including training of its exclusive products sales specialists. Specifically, 25 exclusive product sales specialists have now been fully trained as experts in the features, advantages and benefits of *The Wand*® STA instrument and handpieces and all 25 are currently in the field selling the instrument.

Henry Schein also plans to train an additional two to three dedicated customer service representatives to support dentists across North America through its exclusive product sales customer call center, as business volume increases.

Henry Schein's exclusive products sales specialist team, which is comprised of 25 products sales specialists and supported by over 1,000 field service representatives, will exclusively market and distribute *The Wand*® STA instrument and handpieces, together with a select group of other devices in the United States and Canada. Our agreement with Henry Schein has minimum purchase order requirements to maintain exclusivity in the third through tenth year of the term of the agreement.

### **International Market**

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

In October 2012, the State Food and Drug Administration (CFDA) of the People's Republic of China approved our *STA Single Tooth Anesthesia System*® (STA System). In May 2014, the CFDA also approved the STA handpieces for sale in China.

In September 2014, Milestone Medical received CE clearance to distribute their epidural and intra-articular instruments in the European Community (EU). Milestone Medical signed a distribution agreement in March 2015 with a medical distributor in Poland for the distribution of the epidural instrument. This distribution agreement was terminated in late 2016 due to the distributor's inadequate performance under the distribution agreement. Milestone Medical is continuing to pursue distributors for the instrument in the EU community.

In June 2014, Milestone Scientific invested \$1 million in Milestone China Ltd. ("Milestone China") by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting. Milestone Scientific recorded a loss on its investment in Milestone China of \$0 and \$164,837, as of September 30, 2017 and 2016, respectively. Milestone Scientific's investment in Milestone China was \$0 as of September 30, 2017 and December 31, 2016, respectively. Milestone Scientific incurred cumulative losses beyond its investment in Milestone China of \$1,606,913 and \$1,124,350 as of September 30, 2017 and December 31, 2016, respectively, which have been suspended.

In June 2017, Milestone Scientific entered into an agreement for the sale of its interest in Milestone China (a forty (40%) percent interest) (the "Milestone China Shares") to an unaffiliated United States domiciled purchaser and a 10-year option agreement to repurchase the Milestone China Shares. The purchase price for the Milestone China Shares was \$1,400,000 of which \$125,000 was paid in cash and \$1,275,000 was paid by delivery of a non-interest bearing secured promissory note. The note is payable in quarterly installments of \$125,000 until paid in full and is secured by the Milestone China Shares until full repayment. In addition, pursuant to such note, the purchaser is precluded from selling all or substantially all of its assets prior to repayment of the note. The 10-year option agreement provides Milestone Scientific an option to repurchase the Milestone China Shares at \$1,400,000 within the

first two years and at fair market value (as defined in such agreement) for the remainder of the 10-year term. The transaction has been accounted for as a secured financing and Milestone Scientific will continue to account for its relationship with Milestone China under the equity method of accounting. A note receivable is presented on the Company's balance sheet, along with a deferral from financing transaction (\$1,400,000). The carrying value of the forty (40%) percent investment at the transaction date was zero.

The sale of the Milestone China Shares allows Milestone Scientific to continue to expand in the China market by supplying Milestone China with the *STA Single Tooth Anesthesia System*® and related hand pieces, while eliminating the burden on Milestone Scientific's management as a 40% minority owner. Milestone Scientific believes that the sale will provide Milestone China with a new partner that may accelerate its penetration of the China market.

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,			
	2017		2016		2017		2016	
<b>DOMESTIC</b>								
Instruments	\$452,232	33.3 %	\$-	—	\$857,525	20.7 %	\$852,149	30.9 %
Handpieces	893,496	65.8 %	106,908	89.5 %	3,230,567	78 %	1,860,593	67.4 %
Other	12,338	0.9 %	12,508	10.5 %	53,037	1.3 %	46,634	1.7 %
Total Domestic	\$1,358,066	100.0%	\$119,416	100.0%	\$4,141,129	100.0%	\$2,759,376	100.0%
<b>INTERNATIONAL-Europe</b>								
Instruments	\$340,575	29.9 %	\$1,416,030	63.8 %	\$1,053,050	32.8 %	\$1,974,280	49.3 %
Handpieces	765,821	67.2 %	713,766	32.2 %	2,068,007	64.4 %	1,845,424	46.0 %
Other	32,951	2.9 %	87,984	4.0 %	89,764	2.8 %	188,046	4.7 %
Total International -Europe	\$1,139,347	100.0%	\$2,217,780	100.0%	\$3,210,821	100.0%	\$4,007,750	100.0%
<b>INTERNATIONAL-China</b>								
Instruments	\$-	—	\$493,000	58.0 %	\$1,000,000	58.3 %	\$1,493,800	67.7 %
Handpieces	356,400	100.0%	356,400	42.0 %	712,800	41.6 %	712,800	32.3 %
Other	-	—	-	—	1,800	0.1 %	-	—
Total International-China	\$356,400	100.0%	\$849,400	100.0%	\$1,714,600	100.0%	\$2,206,600	100.0%
Domestic	\$1,358,066	47.6 %	\$119,416	3.7 %	\$4,141,129	45.7 %	\$2,759,376	30.7 %
International-Europe	1,139,347	39.9 %	2,217,780	69.6 %	3,210,821	35.4 %	4,007,750	44.7 %
International-China	356,400	12.5 %	849,400	26.7 %	1,714,600	18.9 %	2,206,600	24.6 %
Total Product Sales	\$2,853,813	100.0%	\$3,186,596	100.0%	\$9,066,550	100.0%	\$8,973,726	100.0%

Milestone Scientific plans to support increased sales and marketing activity through our current distributors and through newly appointed distributors of the STA instruments and handpieces in the international market. In the United States and Canada, Milestone Scientific will continue the utilization of independent hygienists for training individual practitioners and group practices domestically, refined and directed advertising to dental professionals, continue to develop Key Opinion Leaders (KOL) and support and broaden our global distribution network. Additionally with the recent FDA marketing clearance for the epidural instrument, Milestone Scientific is initiating marketing and sales efforts in the US to establish medical sector distributors for the sale of this instrument

**Results of Operations**

The following table sets forth for the consolidated results of operations for the three and nine months ended September 30, 2017, respectively, as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

	Three months Ended September 30, 2017		2016		Nine months Ended September 30, 2017		2016	
Revenue								
Product sales, net	\$ 2,853,813	100%	\$ 3,186,596	100%	\$ 9,066,550	100%	\$ 8,973,726	100%
Cost of products sold	1,044,540	37%	1,517,561	48%	\$ 3,320,411	37%	3,675,552	41%
Gross profit	1,809,273	63%	1,669,035	52%	5,746,139	63%	5,298,174	59%
Selling, general and administrative expenses	3,205,996	112%	2,933,950	92%	8,996,092	99%	9,226,062	103%
Research and development expenses	16,884	1%	303,268	10%	241,964	3%	756,045	8%
Total operating expenses	3,222,880	113%	3,237,218	102%	9,238,056	102%	9,982,107	111%
Loss from operations	(1,413,607)	(50)%	(1,568,183)	(49)%	(3,491,917)	(39)%	(4,683,933)	(52)%
Other (expenses)	(1,046)	(0)%	(846)	(0)%	(3,278)	(0)%	(2,782)	(0)%
Interest expense	3,582	0%	-	0%	6,495	0%	-	0%
Loss before provision for income tax and equity in net earnings of equity investments	(1,411,071)	(49)%	(1,569,029)	(49)%	(3,488,700)	(38)%	(4,686,715)	(52)%
Provision for income tax	(6,475)	(0)%	(16,522)	(1)%	(18,339)	(0)%	(80,147)	(1)%
Loss before equity in net earnings of equity investments	(1,417,546)	(50)%	(1,585,551)	(50)%	(3,507,039)	(39)%	(4,766,862)	(53)%
Loss on earnings from China Joint Venture	-	0%	(253,451)	(8)%	(28,941)	(0)%	(554,766)	(6)%
Loss in equity investments	-	0%	(253,451)	(8)%	(28,941)	(0)%	(554,766)	(6)%
Net Loss	(1,417,546)	(50)%	(1,839,002)	(58)%	(3,535,980)	(39)%	(5,321,628)	(59)%
Net loss attributable to noncontrolling interests	(6,605)	(0)%	(137,752)	(4)%	(138,915)	(2)%	(1,113,958)	(12)%
Net loss attributable to Milestone Scientific Inc.	\$ (1,410,941)	(49)%	\$ (1,701,250)	(53)%	\$ (3,397,065)	(37)%	\$ (4,207,670)	(47)%

Milestone Scientific earned gross profit of approximately \$1.8 million and \$5.7 million in the three and nine months ended September 30, 2017. Milestone Scientific earned gross profit of approximately \$1.7 million and \$5.3 million in the three and nine months ended September 30, 2016. However, the revenues and related gross profits have not been sufficient to support overhead, new product introduction and research and development expenses.

**The Three Months Ended September 30, 2017 compared to the Three Months Ended September 30, 2016**

Total revenues for the three months ended September 30, 2017 and 2016 were approximately \$2.9 million and \$3.2 million, respectively. Total revenues decreased by approximately 10% which was principally related to the decrease in international sales of approximately \$1.6 million, offset by the increase in domestic sales of approximately \$1.2 million in 2017. International sales in 2017 decreased due to a reduction in shipments of handpieces and instruments to Milestone China. The decrease in Milestone China revenue is due to Milestone China working through its current inventories and adjusting its business model. This trend of reduced revenue for shipments of Milestone China is not expected to continue in 2018. However, we believe that the June 2016 exclusive distribution agreement with Henry Schein will continue to lead to increased domestic sales in 2017 as the product and sales force training has been substantially completed as of September 30, 2017. Additionally, the Company has increased its exposure to the general dentist population in the USA by expanding our “KOL” (Key Opinion Leaders) coverage and specific hands on continuing education course throughout the USA.

Gross margin for the three months ended September 30, 2017 was 63%, which increased from 52% for the three months ended September 30, 2016. The increase in gross profit relates to the increase in US sales in 2017 which is was offset by special pricing in China to facilitate an increase in market share.

Selling, general and administrative expenses for the three months ended September 30, 2017 and 2016 were approximately \$3.2 million versus \$2.9 million, respectively. The increase of approximately \$272,000 predominantly due to the additional selling, general and administrative expenses is resulting from the completion of the clinical studies relating to Milestone Medical's epidural instruments in 2016 and Milestone Scientific initiating marketing and sales efforts in the U.S. to establish the medical sector.

Research and development for the three months ended September 30, 2017 and 2016 were approximately \$17,000 verse \$303,000, respectively. The decrease of approximately \$286,000 is predominantly due to the completion of the clinical studies relating to Milestone Medical's epidural instruments in 2016.

The loss from operations for the three months ended September 30, 2017 and 2016 was approximately \$1.4 million, verse \$1.6 million respectively, a decrease of approximately \$155,000. This decrease is primarily attributable to the completion of the clinical studies relating to Milestone Medical's epidural and intra articular instruments in 2016.

#### **Nine months ended September 30, 2017 compared to Nine Months Ended September 30, 2016**

Total revenues for the nine months ended September 30, 2017 and 2016, was from dental revenues, were approximately \$9.1 million and \$9.0 million, respectively. Total revenues increased by approximately 1% which was principally related to increased handpiece sales in the United States domestic sales by approximately \$1.7 million in 2017 to 2016. International sales in 2017 decreased by approximately \$1.6 million over the same period in 2016 due to a reduction in shipments to Milestone China. The reductions in shipments to Milestone China is due to Milestone China working through inventory purchases from late 2016. However, we believe that the June 2016 exclusive distribution agreement with Henry Schein will continue to increase domestic sales in 2017 as the product and sales force training has been substantially completed as of September 30, 2017.

Gross margin for the nine months ended September 30, 2017 was 63%, which increased from 59% for the nine months ended September 30, 2016. The increase in gross profit relates to the increase in US sales in which was offset by special pricing in China to facilitate an increase in market share.

Selling, general and administrative expenses for the nine months ended September 30, 2017 and 2016 were approximately \$9 million versus \$9.2 million, respectively. The decrease of approximately \$230,000 is predominantly due to the reduction in expenses resulting from the completion of the clinical studies relating to Milestone Medical's

epidural and intra articular instruments in 2016.

Research and development expenses for the nine months ended September 30, 2017 and 2016 were approximately \$242,000 and \$756,000, respectively. The decrease is due to reduction in development cost associated with epidural and intra articular instruments.

The loss from operations for the nine months ended September 30, 2017 and 2016 was approximately \$3.5million and \$4.7 million, respectively, a decrease of approximately \$1.2 million. This decrease is primarily attributable to the completion of the clinical studies and reduced research and development expenses relating to our epidural and intra articular instruments in 2017 and gross profit.

### **Liquidity and Capital Resources**

At September 30, 2017, Milestone Scientific had cash and cash equivalents of approximately \$2.3 million, total current assets of approximately \$11.6 million and working capital of approximately \$6.5 million. We believe that our cash on hand, accounts receivable and the anticipated revenues from the dental business will be sufficient to fund our business operations for at least the next 12 months from the filing date of this Form 10-Q.

Milestone Scientific continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements. For the nine months ended September 30, 2017 and 2016, our net cash used in operating activities was approximately \$1.6 million and \$4.1 million, respectively, which represents a decrease of approximately \$2.5 million year over year.



Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception. The capital raised in December 2016 and January 2017 provided Milestone Scientific with working capital to continue to develop its medical instruments and obtain regulatory approval for one of its medical instruments (the June 2017 FDA approval of the epidural instrument), as well as to aggressively market its dental instruments. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, and a reductions in operating expenses. Management believes that the Company will have sufficient cash and liquidity to meet its anticipated obligations over the next twelve-month period following the date of this report.

Milestone Scientific believes that the FDA clearance of its 510(k) application with respect to the *CompuFlo*® Epidural Computer Controlled Anesthesia will provide Milestone Scientific with the opportunity to enter the US medical device market and generate revenues in the future. Milestone Scientific believes that it has sufficient inventory of the epidural instruments to satisfy the near term marketing opportunities.

Our condensed consolidated balance sheets included in this Report reflects a decrease of approximately \$1.8 million in current assets from December 31, 2016 to September 30, 2017. This decrease in current assets was primarily due to a reduction in cash, accounts receivable from related parties, deferred cost, other receivables and inventory of approximately \$4 million. This was offset by an increase in accounts receivable, advances on contracts, note receivable and prepaid expenses and other current assets of an aggregate of approximately \$2.2 million.

Current liabilities decrease by approximately \$591,000 from approximately \$5.6 million to approximately \$5.1 million. The decrease is primarily due to a decrease in accounts payable of approximately \$725,000, accounts payable related party of approximately \$333,000, deferred revenue of approximately \$289,000 offset by an increase in deferred profit China of approximately \$29,000, and an increase in accrued expenses of approximately \$727,000.

### **Subsequent Events**

On October 5, 2017, Milestone Scientific announced that Daniel Goldberger had resigned as President and Chief Executive Officer effective October 2, 2017.

On October 5, 2017, Milestone Scientific also announced the appointment of Leslie Bernhard, the Company's current Chairman of the Board, as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer.

In connection with her appointment to serve as the Company's Interim Chief Executive Officer, Ms. Bernhard will be paid an annual salary of \$200,000 and receive a one-time bonus of 100,000 shares of the Company's Common Stock.

In addition, at the completion of her service as Interim Chief Executive Officer, Ms. Bernhard shall be entitled to receive a cash bonus in an amount to be determined by the Board of Directors at that time.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Milestone Scientific is a “smaller reporting company” as defined by Regulation S-K and, as such, is not required to provide the information required by this item.

**Item 4. Controls and Procedures**

Milestone Scientific’s Interim 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. Based upon that evaluation, Milestone Scientific’s Interim Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of September 30, 2017 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 Interim Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required 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, 2017 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific’s internal controls over financial reporting.

## **PART II – OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

None.

### **ITEM 1A. RISK FACTORS**

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

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

#### Recent Sales of Unregistered Securities

In the quarter ended September 30, 2017, Milestone Scientific issued a total of 352,015 shares of its common stock as follows:

120,000 shares to the Board of Directors with a total value of \$159,480;

10,913 shares to an employee for compensation with a total value of \$15,000; and

an aggregate of 221,102 shares to consultants for services rendered with a total value of \$378,530.

In addition, as of July 13, 2017, pursuant to the Asset Purchase Agreement with APAD Octrooi B.V. and APAD B.V. (collectively, the “Sellers”), Milestone Scientific issued an aggregate of 1,646,358 shares of its common stock to the Sellers in consideration for certain patent rights and other intellectual property rights related to the Sellers’ computer controlled injection instrument.

The foregoing shares were issued in reliance upon the exemptions from the registration requirements of the Securities Act of 1933, as amended (the "Act"), pursuant to Sections 4(a)(2), Section 4(a)(5) and/or Regulation D promulgated thereunder. A legend restricting resale, transfer, or other disposition of these 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**

- 10.5 New Employment Agreement between Milestone Scientific Inc. and Leonard Osser dated as of July 10, 2017. (1)
- 10.6 Employment Agreement between Milestone Scientific Inc. and Daniel Goldberger dated as of July 10, 2017. (1)
- 10.7 Covenant Agreement between Milestone Scientific Inc. and Daniel Goldberger dated and effective as of July 10, 2017. (1)
- 10.8 Consultant Agreement between Milestone Medical Inc. and U.S. Asian Consulting Group, LLC dated as of July 10, 2017\*
  
- 31.1 Chief Executive Officer Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002.\*
- 31.2 Chief Operating Officer Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002.\*
- 32.1 Chief Executive Officer Certification pursuant to section 906 of the Sarbanes-Oxley Act of 2002.\*\*
- 32.2 Chief Operating Officer Certification pursuant to section 906 of the Sarbanes-Oxley Act of 2002.\*\*

101.INS XBRL Instance Document.\*

- 101.SCH XBRL Taxonomy Extension Schema Document.\*
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document.\*
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document.\*
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document.\*
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document.\*

\* Filed herewith.

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

\*\*

- (1) Incorporated herein by reference to the Current Report on Form 8-K filed with the Securities and Commission on July 11, 2017.

SIGNATURES

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

**MILESTONE SCIENTIFIC INC.**

/s/ Leslie Bernhard  
Leslie Bernhard  
Interim Chief Executive Officer  
(Principal Executive Officer)

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

Date: November 14, 2017