

MILESTONE SCIENTIFIC INC.
Form 10-Q
August 11, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

Or

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

For the transition period from _____ to _____

Commission File Number: 001-14053

MILESTONE SCIENTIFIC INC.

(Exact name of registrant as specified in its charter)

Delaware

13-3545623

**(State or other jurisdiction of
incorporation or organization)**

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

220 South Orange Avenue, Livingston, New Jersey 07039

(Address of principal executive offices)

(973) 535-2717

(Registrant's telephone number, including area code)

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

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

Title of each class

Name of each exchange on which registered

Common Stock, par value \$.001 per share

NYSE MKT LLC

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

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

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

Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

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

Yes No

As August 11, 2016, the Issuer had a total of 27,293,039 shares of Common Stock, \$.001 par value, outstanding.

MILESTONE SCIENTIFIC INC

TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

Condensed Consolidated Balance Sheets June 30, 2016 (Unaudited) and December 31, 2015 (Audited)

4

Condensed Consolidated Statements of Operations three and six months ended June 30, 2016 and 2015 (Unaudited)

5

Condensed Consolidated Statement of Changes in Stockholders' Equity for the six months ended June 30, 2016 (Unaudited)

6

**Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015
(Unaudited)**

7

Notes to Condensed Consolidated Financial Statements (Unaudited)

8

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

18

Item 3. Quantitative and Qualitative Disclosures About Market Risk

22

Item 4. Controls and Procedures

22

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

23

Item 1A. Risk Factors

23

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

23

Item 3. Defaults Upon Senior Securities

23

Item 4. Mine Safety Disclosures

23

Item 5. Other Information

23

Item 6. Exhibits

23

Signatures

24

2

FORWARD-LOOKING STATEMENTS

When used in this Quarterly Report on Form 10-Q, the words “may”, “will”, “should”, “expect”, “believe”, “anticipate”, “continue”, “estimate”, “project”, “intend” and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) regarding events, conditions and financial trends that may affect Milestone Scientific’s future plans of operations, business strategy, results of operations and financial condition. Milestone Scientific wishes to ensure that such statements are accompanied by meaningful cautionary statements pursuant to the safe harbor established in the Private Securities Litigation Reform Act of 1995. Prospective investors are cautioned that any forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties and the actual results may differ materially from those included within the forward-looking statements as a result of various factors. Such forward-looking statements should, therefore, be considered in light of various important factors, including those set forth herein and others set forth from time to time in Milestone Scientific’s reports and registration statements filed with the Securities and Exchange Commission (the “SEC”). Milestone Scientific disclaims any intent or obligation to update such forward-looking statements.

Milestone Scientific has rights to the following trademarks: *CompuDent®*, *CompuMed®*, *CompuFlo®*, *The Wand®*, *The Wand Plus®*, *The SafetyWand®*, *Dynamic Pressure Sensing Technology®*, and *STA Single Tooth Anesthesia™* (STA Instrument, instruments and handpieces).

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

June 30, 2016

December 31, 2015

(unaudited)

(audited)

ASSETS

Current Assets:

Cash and cash equivalents

\$ 3,183,727 \$ 4,194,384

Accounts receivable, net of allowance for doubtful accounts of \$10,000 as of June 30, 2016 and \$5,000 as of December 31, 2015

2,583,219 1,793,801

Other receivable

67,115 58,140

Inventories

4,268,768 4,258,094

Advances on contracts

1,215,011 1,215,128

Prepaid expenses and other current assets

375,844 304,604

Total current assets

11,693,684 11,824,151

Investment in Milestone Education LLC

- 16,346

Furniture, fixtures & equipment net of accumulated depreciation of \$635,880 as of June 30, 2016 and \$566,477 as of December 31, 2015

201,708 235,935

Patents, net of accumulated amortization of \$699,633 as of June 30, 2016 and \$646,388 as of December 31, 2015

695,449 715,540

Other assets

11,380 17,355

Total assets

\$ 12,602,221 \$ 12,809,327

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:

Accounts payable

\$ 2,497,719 \$ 2,088,268

Accrued expenses and other payables

1,492,920 1,555,567

Total current liabilities

3,990,639 3,643,835

Commitments and Contingencies

Stockholders' Equity

Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, 7,000 shares issued and outstanding, respectively

7 7

Common stock, par value \$.001; authorized 50,000,000 shares; 26,293,039 shares issued, 1,115,405 shares to be issued and 27,259,706 shares outstanding as of June 30, 2016; 21,720,497 shares issued, 963,451 shares to be issued and 21,687,164 shares outstanding as of December 31, 2015.

28,408 22,685

Additional paid-in capital

79,126,690 78,632,383

Accumulated deficit

(69,813,638) (67,434,984)

Treasury stock, at cost, 33,333 shares

(911,516) (911,516)

Total Milestone Scientific Inc. stockholders' equity

8,429,951 10,308,575

Noncontrolling interest

181,631 (1,143,083)

Total Equity

8,611,582 9,165,492

Total liabilities and stockholders' equity

\$ 12,602,221 \$ 12,809,327

See Notes to Unaudited Condensed Consolidated Financial Statements

4

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

Three Months Ended June 30,

Six Months Ended June 30,

2016

2015

2016

2015

Product sales, net

\$ 2,371,710	\$ 1,766,759	\$ 5,836,196	\$ 4,536,963
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Cost of products sold

789,801	570,729	2,157,990	1,503,877
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Gross profit

1,581,909	1,196,030	3,678,206	3,033,086
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Selling, general and administrative expenses

3,290,998	2,590,897	6,292,109	4,488,978
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Research and development expenses

309,335	18,820	452,780	28,938
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Total operating expenses

3,600,333	2,609,717	6,744,889	4,517,916
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Loss from operations

(2,018,424)	(1,413,687)	(3,066,683)	(1,484,830)
-------------	-------------	-------------	-------------

Interest income

(1,004)	(1,130)	(1,936)	80
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Total other expenses, net

(1,004)	(1,130)	(1,936)	80
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Loss before provision for income tax and equity in net earnings of equity investments

(2,019,428)	(1,414,817)	(3,068,619)	(1,484,750)
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Provision for income tax

(16,791)	(13,646)	(63,624)	(13,646)
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Loss before equity in net earnings of equity investments

(2,036,219)	(1,428,463)	(3,132,243)	(1,498,396)
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Loss on earnings from Milestone Medical

-	(525,938)	-	(976,099)
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Loss on earnings from Education Joint Venture

-	(3,621)	-	(7,836)
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(Loss) Gain on earnings from China Joint Venture

(57,882)	(160,654)	(222,719)	(63,979)
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Loss in equity investments

(57,882)	(690,213)	(222,719)	(1,047,914)
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Net Loss

(2,094,101) (2,118,676) (3,354,962) (2,546,310)

Net loss attributable to noncontrolling interests

(507,262) (45,727) (976,308) (53,987)

Net loss attributable to Milestone Scientific Inc.

\$ (1,586,839) \$ (2,072,949) \$ (2,378,654) \$ (2,492,323)

Net loss per share applicable to common stockholders—

Basic

\$ (0.06) \$ (0.09) \$ (0.10) \$ (0.11)

Diluted

\$ (0.06) \$ (0.09) \$ (0.10) \$ (0.11)

Weighted average shares outstanding and to be issued—

Basic

25,989,857 22,405,897 24,362,441 22,390,332

Diluted

25,989,857 25,114,399 24,362,441 25,132,192

See Notes to Unaudited Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

SIX MONTHS ENDED JUNE 30, 2016

(Unaudited)

Preferred Stock

Common Stock

Shares

Amount

Shares

Amount

Additional
Paid-in
Capital

Accumulated
Deficit

Noncontrolling
interest

Treasury
Stock

Total

Balance, January 1, 2016

7,000 \$ 7 22,683,948 \$ 22,685 \$ 78,632,383 \$ (67,434,984) \$ (1,143,083) \$ (911,516) \$ 9,165,492

Consolidation of Milestone Education

- - - - - 16,346 - 16,348

Stock based compensation

- - - - 276,256 - - - 276,256

Common stock to be issued to employee for bonuses

- - 151,954 151 339,549 - - - 339,700

Common stock issued for payment of consulting services

75,000 75 168,675 168,750

Common Stock exchanged for MMD

4,497,542 4,497 (2,289,173) 2,284,676 -

Sale of Common Stock - Innovest

1,000,000 1,000 1,999,000 2,000,000

Net loss

- - - - - (2,378,654) (976,308) - (3,354,962)

Balance, June 30, 2016

7,000 \$ 7 28,408,444 \$ 28,408 \$ 79,126,690 \$ (69,813,638) \$ 181,631 \$ (911,516) \$ 8,611,582

See Notes to Unaudited Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

Six Months Ended June 30,

2016

2015

Cash flows from operating activities:

Net loss

\$ (3,354,962) \$ (2,546,310)

Adjustments to reconcile net cash used in operating activities:

Depreciation expense

46,177 13,930

Amortization of patents

35,707 34,647

Common stock and options for compensation, consulting and vendor services

784,480 391,844

Equity loss on Milestone Medical

- 976,099

Equity loss on Education joint venture

- 7,836

Equity loss (gain) on China joint venture

222,719 63,979

Changes in operating assets and liabilities:

Increase in accounts receivable

(789,418) (93,620)

Increase in other receivable

(8,975) -

Increase in inventories

(233,393) (743,299)

(Increase) decrease to advances on contracts

117 (1,870)

(Increase) decrease to prepaid expenses and other current assets

(71,240) (15,215)

Decrease (Increase)in other assets

5,975 (2,670)

Increase (decrease) in accounts payable

407,536 (657,989)

Increase in accrued expenses and other payables

(67,367) 162,551

Net cash used in operating activities

(3,022,644) (2,410,087)

Cash flows from investing activities:

Notes receivable from Milestone Medical

- (1,000,000)

Due from related party

- (430,629)

Investment in Treasury Bills

- (5,550,283)

Purchases of intangible assets

(15,616) -

Purchases of property and equipment

(15,668) (42,418)

Cash acquired from variable interest entity

26,925

Net cash used in investing activities

(4,359) (7,023,330)

Cash flows from financing activities:

Proceeds from exercise of stock options

- 12,750

Net Proceeds on Private Placement Offering

2,000,000 -

Capital contribution from noncontrolling interest

16,346 500,000

Net cash provided by financing activities

2,016,346 512,750

Net decrease in cash and cash equivalents

(1,010,657) (8,920,667)

Cash and cash equivalents at beginning of period

4,194,384 10,367,993

Cash and cash equivalents at end of period

\$ 3,183,727 \$ 1,447,326

Supplemental disclosure of cash flow information:

Net assets acquired from variable interest entity

\$ 6,307 \$ -

Shares issued to employees in lieu of cash compensations

\$ - \$ 35,000

Shares issued to employees for bonus

\$ 339,549 \$ 100,000

Shares issued to consultants in lieu of cash payment

\$ 75,000 \$ 30,000

See Notes to Unaudited Condensed Consolidated Financial Statements

7

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Milestone Scientific Inc. and Subsidiaries, (collectively “Milestone Scientific”, “our”, “us” or “we”) was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery instrument, through the use of *The Wand*®, a single use disposable handpiece. The instrument is marketed in dentistry under the trademark *CompuDent*®, *Wand Plus*® and *STA (Single Tooth Anesthesia) TM* and in medicine under the trademark *CompuMed*®. *CompuDent*® is suitable for all dental procedures that require local anesthetic. *CompuMed*® and *Wand Plus* are 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 instruments are sold in the United States and in over 47 countries abroad. Milestone Scientific’s products are manufactured by a third-party contract manufacturer.

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

The unaudited consolidated financial statements of Milestone Scientific have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. These unaudited consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2015 included in Milestone Scientific Annual Report on Form 10-K.

Milestone Scientific Inc. and Subsidiaries, (collectively “Milestone Scientific”, “our”, “us” or “we”) was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery instrument, through the use of *The Wand*®, a single use disposable handpiece. The instrument is marketed in dentistry under the trademark *CompuDent*®, *Wand Plus*® and *STA (Single Tooth Anesthesia) TM* and in medicine under the trademark *CompuMed*®. *CompuDent*® is suitable for all dental procedures that require local anesthetic. *CompuMed*® and *Wand Plus* are 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 instruments are sold in the United States and in over 47 countries abroad. Milestone Scientific’s products are

manufactured by a third-party contract manufacturer.

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

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

In June 2016, a group of investors that participated in our May 2014 financing invested an additional \$2 million in Milestone Scientific through a private placement of one million shares of our restricted common stock, \$.001 par value per share (“common stock”), at a price of \$2.00 per share.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which we would exchange one share of common stock for every two outstanding shares of Milestone Medical (defined below) common stock, a consolidated variable interest entity. As of June 30, 2016, 4,497,542 shares of common stock has been exchanged for 8,995,084 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owns approximately 86% of Milestone Medical at June 30, 2016.

Milestone Scientific has incurred operating losses and negative cash flows from operating activities since its inception, except for 2013. Milestone Scientific is actively pursuing the generation of revenue, positive operating income and net income. The capital raised in May 2014, and June 2016 provided Milestone Scientific with the opportunity to continue to develop and commercialize additional medical instruments and aggressively market the

dental instruments throughout the world. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue based upon management's assessment of present contracts.

NOTE – 1 SUMMARY OF ACCOUNTING POLICIES

1.

Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of Milestone Scientific and its wholly owned and majority owned subsidiaries, including Wand Dental, as well as Milestone Medical Inc. ("Milestone Medical"), Milestone Advanced Cosmetic Systems, and Milestone Education LLC ("Milestone Education"), both variable interest entities for which Milestone Scientific is the primary beneficiary. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

8

2.

Variable Interest Entities

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

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

Milestone Scientific is the primary beneficiary of Milestone Medical and Milestone Education, as VIEs. Accordingly, the assets and liabilities of Milestone Medical and Milestone Education are included in the accompanying consolidated financial statements. Please refer to Note 3 for further details regarding the treatment of the VIE.

3.

Cash

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

4.

Accounts Receivable

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

5.

Product Return and Warranty

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

6.

Inventories

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

7.

Equity Method Investments

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

8.

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.

9

9.

Intangible Assets - Patents

Patents are recorded at cost to prepare and file the applicable documents with the United States Patent Office, or internationally with the applicable governmental office in the respective country. Although certain patents have not yet been approved, the costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. If the applicable patent application is ultimately rejected, the remaining unamortized balance will be expensed in the period in which Milestone Scientific receives a notice of such rejection.

Patent defense costs, to the extent applicable are expensed as incurred. Patent applications filed and patents obtained in foreign countries are subject to the laws and procedures that differ from those in the United States. Patent protection in foreign countries may be different from patent protection under United States laws and may not be favorable to Milestone Scientific. Milestone Scientific also attempts to protect the proprietary information through the use of confidentiality agreements and by limiting access to the facilities. There can be no assurance that the program of patents, confidentiality agreements and restricted access to the facilities will be sufficient to protect the proprietary technology.

10.

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 June 30, 2016.

11.

Revenue Recognition

Revenue from product sales is recognized net of discounts and allowances to domestic distributors on the date of shipment for essentially all shipments, since the shipment terms are FOB warehouse. Milestone Scientific will

recognize revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. Shipments to international distributors are FOB warehouse, therefore revenue is recognized on shipment of the goods. In all cases the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone Scientific has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

12.

Shipping and Handling Costs

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

13.

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.

14.

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. The income tax provision or credit is the tax payable or refundable for the period plus or minus the change during the

period in deferred tax assets and liabilities.

15.

Recent Accounting Pronouncements

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

10

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

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

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

In March 2016, the Financial Accounting Standards Board 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. Milestone Scientific is in the process of determining what impact, if any the adoption of this ASU will have on its financial position, results of operations and cash flows.

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

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

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

Milestone Scientific presents “basic” earnings (loss) per common share applicable to common stockholders and, if applicable, “diluted” earnings (loss) per common share applicable to common stockholders pursuant to the provisions of Statement of Financial Accounting Standards ASC Topic 260. Basic earnings (loss) per common share is calculated by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding and to be issued during each period. The calculation of diluted earnings per common share is similar to that of basic earnings per common share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if all potentially dilutive common shares, such as those issuable upon the exercise of stock options, warrants, and the conversion of debt were issued during the period.

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

For the three and six months ended June 30, 2016 and 2015, Milestone Scientific calculated basic and fully diluted earnings per common share as described in the previous paragraph.

NOTE – CONSOLIDATION OF VARIABLE INTEREST ENTITY

Milestone Medical

Milestone Medical is approximately 86% owned by Milestone Scientific as of June 30, 2016. Milestone Scientific has been established to develop and commercialize intra-articular and epidural drug delivery instruments, utilizing an exclusive royalty-free license to Milestone Scientific’s CompuFlo technology. The license was contributed by Milestone Scientific for our initial ownership in Milestone Medical.

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

As a result of the change in circumstances around the proposed offering in December 2015 by Milestone Medical, we reevaluated the relationship between the two entities and the status of Milestone Medical as a VIE. We have concluded that Milestone Medical does not have sufficient capital at risk to support its activities without additional financial support from Milestone Scientific

Since the factors giving rise to concluding that Milestone Medical is a VIE happened so close to the end of fiscal year 2015, the acquisition date for measuring the consolidation of Milestone Medical has been deemed to be December 31, 2015.

In the second quarter of 2016, Milestone Scientific initiated a share exchange program pursuant to which we would exchange one share of common stock for every two outstanding shares of Milestone Medical common stock. As there was no change in control, the acquisition of the non-controlling interest is reflected as an equity transaction with the carrying value of the non-controlling interest adjusted to reflect Milestone Scientific's increased ownership interest in the subsidiary. As of June 30, 2016, 3,965,000 shares of common stock have been issued in exchange for 7,930,000 shares of Milestone Medical common stock. An additional 532,542 shares were issued but not outstanding as of June 30, 2016. As a result of these exchanges, Milestone Scientific owns approximately 86% of Milestone Medical at June 30, 2016.

As a result of our increased ownership in Milestone Medical, approximately 86% as of June 30, 2016, we have determined that we have control of Milestone Medical and have consolidated Milestone Medical in the accompanying condensed consolidated financial statements.

Milestone Education LLC

Milestone Education is a 50% owned subsidiary of Milestone Scientific which began operations in 2013 to provide training and education to our dentists throughout the world. Milestone Scientific accounted for its investment in Milestone Education using the equity method of accounting through December 31, 2015. Approximately 83% of the revenue earned by Milestone Education is from services performed for Milestone Scientific. As a result of this relationship, we concluded that we have the power to direct the activities that most significantly impact Milestone Education's economic performance, and that it is a VIE and should be consolidated in the financials of Milestone Scientific in the first quarter of 2016.

The financial statements of Milestone Medical and Milestone Education are included in the accompanying condensed consolidated financial statements.

The financial information in the table below summarizes the combined results of operations of Milestone Scientific, and its subsidiaries including Milestone Medical and Milestone Education (a VIE) on a pro forma basis as though the companies had been combined as of the beginning of the earliest period presented. The pro forma financial

information is presented for informational purposes only and is not indicative of the result of operations that would have been achieved if the consolidation had taken place at the beginning of the period presented.

June 30, 2015

Pro Forma

Total revenue

\$ 4,590,067

Cost of products sold

1,507,552

Gross Profit

3,082,515

Selling, general and administrative expenses

6,148,121

Research and development expenses

384,752

Operating expenses

6,532,873

Loss from operations

(3,450,358)

Other expenses

-

Interest income

(3,412)

Total other expenses, net

(3,412)

Loss before provision for income tax and equity in net earnings of equity investments

(3,453,770)

Provision for Income Tax

(13,646)

Loss before equity in net earnings of equity investments

(3,467,416)

Loss on earnings from Milestone Medical

-

Loss on earnings from Education Joint Venture

-

(Loss) Gain on earnings from China Joint Venture

(63,979)

Loss in equity investments

(63,979)

Net loss

(3,531,395)

Less: Net loss attributable to the noncontrolling interests

1,038,888

Net loss attributable to Milestone Scientific Inc.

\$ (2,492,507)

NOTE – INVESTMENT IN UNCONSOLIDATED SUBSIDIARIES

Advance Ocular Science SA

Advanced Ocular Sciences SA is an entity organized to develop an instrument that delivers injections into the eyes. The company is a shell company as of June 30, 2016. Milestone Scientific owns 25% of this entity. As of the balance sheet date, no equity has been contributed to the company by Milestone Scientific. During 2015, Milestone Scientific

advanced \$78,798 for marketing and strategy planning to Advanced Ocular Sciences SA. Advanced Ocular Sciences SA., or their organizers are obligated to repay this advance once the public offering is approved and funded in Poland during 2016. Advanced Ocular Sciences SA was not included in the consolidated financial statements at June 30, 2016 as no investment has been made by Milestone Scientific. The suspended losses approximated \$19,700 at June 30, 2016.

Milestone China Ltd.

In June 2014, Milestone Scientific agreed to invest \$1 million through the contribution of 772 STA instruments (at a distributor price of approximately \$1,296 per instrument) for a forty percent (40%) ownership in Milestone China Ltd. ("Milestone China"). In 2014, the instruments were shipped and were recorded as an investment in Milestone China at the cost of the inventory contributed. In January 2016, Milestone Scientific contributed 308 STA instruments with a retail value of approximately \$400,000 (\$1,296 per instrument) to Milestone China which increased the Milestone Scientific's investment by approximately \$165,000 which represents the cost of the instruments. This did not increase the company's percentage of ownership since the contribution is proportionate to the other shareholder contribution. Milestone Scientific recorded a loss on its investment in Milestone China of \$57,882 and \$222,719 for the three and six months ended June 30, 2016. Milestone Scientific recorded a loss on its investment in Milestone China of \$160,654 and \$63,979 for the three and six months ended June 30, 2015. Milestone's investment in Milestone China was \$0 and \$284,672 at June 30, 2016 and 2015, respectively. Milestone Scientific had suspended losses on its investment in Milestone China of \$363,833, as of June 30, 2016.

Wand Dental sold \$1,356,000 in instruments and handpieces during the six months ended June 30, 2016 to Milestone China. Milestone China owes \$1,156,000 Wand Dental for STA instruments and handpieces shipped in 2016, which is included in accounts receivable at June 30, 2016.

Milestone Scientific recognizes the total revenue and costs of goods sold at the time the shipment of instruments and handpieces. However, due to timing differences of when the inventory is sold to Milestone China and when Milestone China sells the acquired inventory to third parties, elimination of the intra-entity profit is required as of the balance sheet date. In accordance with Accounting Standard Codification ("ASC") 323 – *Equity Method and Joint Ventures*, Milestone Scientific has deferred the gross profit associated with inventory shipped to Milestone China that has not been sold to third parties. The deferred profit of \$127,663 is included in the loss from Milestone China within the Condensed Consolidated Statements of Operations and presented as a reduction of the accounts receivable in the Condensed Consolidated Balance Sheets.

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

June 30, 2016

December 31, 2015

(unaudited)

(audited)

Assets:

Current Assets

\$ 5,114,791 \$ 772,999

Non-Current Assets

1,373,209 903,766

Total Assets:

\$ 6,488,000 \$ 1,676,765

Liabilities

Current Liabilities

4,427,526 580,613

Stockholders' equity

2,060,474 1,096,152

Total liabilities and stockholders' equity

\$ 6,488,000 \$ 1,676,765

Three Months Ended June 30,

Six Months Ended June 30,

2016

2015

2016

2015

(unaudited)

(audited)

(unaudited)

(audited)

Net Sales

\$ 2,043,282 \$ - \$ 2,315,502 \$ 1,033,200

Cost of Good Sold

1,729,489 - 2,085,119 668,289

Gross Profit

313,793 - 230,383 364,911

Other Expenses

463,199 (401,632) 696,742 524,897

Net Loss

\$ (149,406) \$ (401,632) \$ (466,359) \$ (159,986)

13

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 six months ended June 30, 2016 and 2015, Milestone Scientific recognized \$266,601 and \$226,844 of total employee compensation cost related to options that vested each year, respectively. As of June 30, 2016 and 2015, there was \$884,183 and \$995,813, respectively, of total unrecognized compensation cost related to non-vested options. Milestone Scientific expects to recognize these cost over a weighted average period of 2.74 years and 2.10 years as of June 30, 2016 and 2015, respectively.

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

Number of Options

Weighted Averaged
Exercise Price \$

Weighted Average
Remaining
Contractual Life
(Years)

Aggregate Intrinsic
Options Value \$

Outstanding, January 1, 2016

1,419,436	1.56	2.78	1,220,338
-----------	------	------	-----------

Granted

348,908	1.72	4.85	-
---------	------	------	---

Exercised

- - - -

Forfeited or expired

- - - -

Outstanding, June 30, 2016

1,768,344 1.59 2.74 2,099,051

Exercisable, June 30, 2016

1,170,718 1.36 2.43 1,721,587

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

Number of Options

Weighted Averaged
Exercise Price \$

Weighted Average
Remaining
Contractual Life
(Years)

Aggregate Intrinsic
Options Value \$

Outstanding, January 1, 2016

8,333 2.70 4.83 -

Granted

200,000	2.55	1.59	-
Expired			
-	-	-	-
Exercised			
-	-	-	-
Outstanding, June 30, 2016			
208,333	2.56	4.58	50,833
Exercisable, June 30, 2016			
2,777	2.70	4.33	-

The fair value of the options was estimated on the date of grant using the Black Scholes option-pricing model at the date of grant. In accordance with the provisions of FASB ASC 505 Milestone Scientific will re-measure the value of the grant at each presentation date unless there is significant disincentive for non-performance until performance is completed. As of June 30, 2016, Milestone Scientific recognized \$8,421 expense related to non-employee options. As of June 30, 2016 there was a total of \$514,792 unrecognized compensation cost related to non-vested options which the company expects to recognize over a weighted average period of 5.7 years. There was no compensation cost for the six month ended June 30, 2015.

In accordance with the provisions of FASB ASC 505-50-15, all other issuances of common stock, stock options or other equity instruments to non-employees as consideration for goods or services received by Milestone Scientific are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of any options or similar equity instruments issued is estimated based on the Black-Scholes option-pricing model and the assumption that all of the options or other equity instruments will ultimately vest. Such fair value is measured as of an appropriate date pursuant to the guidance, (generally, the earlier of the date the other party becomes committed to provide goods or services or the date of performance by the other party is complete) and re-measured at each reporting period whether capitalized or expensed as if Milestone Scientific had paid cash for the goods or services.

NOTE – 6 CONCENTRATION OF CREDIT RISK

Milestone Scientific's consolidated financial instruments that are exposed to concentrations of credit risk consist primarily of cash, trade accounts receivable, and advances on contracts. Milestone Scientific places its cash and cash equivalents with large financial institutions. At times, such investments may be in excess of the Federal Deposit Insurance Corporation insurance limit. Milestone Scientific has not experienced any losses in such accounts and believes it is not exposed to any significant credit risks. 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. Milestone Scientific evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit conditions. Management has provided a reserve that it believes is sufficient to record accounts receivable at net realizable value as of June 30, 2016, and 2015, respectively.

NOTE – 7 ADVANCES ON CONTRACTS

The advances on contracts represent funding of future STA inventory purchases. The balance of the advances as of June 30, 2016 and December 31, 2015, is \$1,215,011 and \$1,215,128, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE – 8 INCOME TAXES

For the six months ended June 30, 2016, and 2015 state tax liability was approximately \$63,000 and \$13,000, respectively. Due to Milestone Scientific's history of past operating losses, which required a full valuation allowances for all of Milestone Scientific's deferred tax assets at June 30, 2016 and 2015, no recognition was given to the utilization of the remaining Federal net operating loss carryforwards.

NOTE – 9 SIGNIFICANT CUSTOMERS & GEOGRAPHICAL INFORMATION

Milestone Scientific has informal arrangements with the manufacturer of the STA, CompuDent® and CompuMed® instruments, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. The Company has open purchase orders with a contract

manufacturer to manufacture STA instruments. The contract manufacturer bills Wand Dental as the work progresses and it is Wand Dental's policy to record these billings as advances on contracts. These advances are reclassified into inventory when the contract manufacturer ships the product and title passes to Wand Dental. The advances on contracts represent funding of future STA inventory purchases. The balance of the advances as of June 30, 2016 and December 31, 2015 is \$1,170,863 and \$1,171,604, respectively. The advance is classified as current, based on the estimated annual usage of the underlying inventory

Milestone Scientific has a manufacturing agreement with one of the principal manufacturers, which is a related party, of its handpieces pursuant to which they manufacture products under specific purchase orders but without minimum purchase commitments. A five percent shareholder of Milestone Scientific is also a shareholder of this vendor. Purchases from this supplier were \$1,121,226 and \$1,353,632 for the six months ended June 30, 2016 and 2015, respectively. Milestone Scientific owed \$687,522 and \$455,573 to this supplier as of June 30, 2016 and 2015, respectively .

For the six months ended June 30, 2016, and 2015 Milestone Scientific had three customers (distributors) that had approximately 38%, 22% and 12%, and 26%, 11% and 11%, respectively, of its net product sales. Accounts receivable for two of the major customers amounted to approximately \$972,000 and \$1,156,000 of gross accounts receivable for the six month ended June 30, 2016. Milestone Scientific had gross accounts receivable for three major customers that amounted to \$1,150,101, (\$263,861, \$346,839 and \$539,400) as of June 30, 2015.

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

Three Months Ended June 30,

Six Months Ended June 30,

2016

2015

2016

2015

DOMESTIC

Instruments

\$ 190,504	\$ 153,325	\$ 852,149	\$ 602,290
------------	------------	------------	------------

Handpieces

695,761	673,062	1,753,685	1,105,124
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Other

20,652	15,229	34,126	1,762
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Total Domestic

\$ 906,917	\$ 841,616	\$ 2,639,960	\$ 1,709,176
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INTERNATIONAL

Instruments

\$ 535,335	\$ 136,430	\$ 1,559,050	\$ 814,044
------------	------------	--------------	------------

Handpieces

882,135	757,079	1,537,124	1,971,531
---------	---------	-----------	-----------

Other

47,323	31,635	100,062	42,212
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Total International

\$ 1,464,793	\$ 925,144	\$ 3,196,236	\$ 2,827,787
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Total Product Sales

\$ 2,371,710	\$ 1,766,760	\$ 5,836,196	\$ 4,536,963
--------------	--------------	--------------	--------------

NOTE – 10 PENSION PLANS

Milestone Scientific has a Defined Contribution Plan that allows eligible employees to contribute part of their salary through payroll deductions. Milestone Scientific does not contribute to this plan, but does pay the administrative costs of the plan, which were not significant.

NOTE – 11 COMMITMENTS AND OTHER**(1) Lease Commitments**

The headquarters for Milestone Scientific is located at 220 South Orange Ave, Livingston, New Jersey. Milestone Scientific leases approximately 7,625 square feet of office space. The lease term expires January 31, 2020 at a monthly cost of \$12,522. Additionally, Milestone Scientific has other smaller insignificant leases ending through 2017. A third party distribution and logistics center in Pennsylvania handles shipping and order fulfillment on a month-to-month basis. For the three and six months ended June 30, 2016 rent expense amounted to \$34,749, and \$69,987, respectively. For the three and six months ended June 30, 2015, rent expense amounted to \$23,927 and \$37,752, respectively.

(2) Contract Manufacturing Arrangement

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

The termination of the manufacturing relationship with any of the above manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, whether or not as a result of termination of such a relationship, would adversely affect Milestone Scientific.

(3) Other Commitments and Subsequent Events

Other Commitments

In March 2014, the Board of Directors approved the Compensation Committee's request to amend the Chief Executive Officer of Milestone Scientific's employment agreement to provide benefits to make payments of \$203,111 per year for five years to the Executive, or as he directs such payments to a third party, to fund his acquisition of, or contribution to an annuity, pension, or deferred distribution plan or for an investment for the Executive and his family. For the three and six months ended June 30, 2016, approximately \$51,000 and \$100,000 was charged to expense, respectively. For the three and six months ended June 30, 2015, approximately \$51,000 and \$102,000 was charged to expense, respectively.

The technology underlying the SafetyWand and CompuFlo®, and an improvement to the controls for CompuDent® were developed by the Director of Clinical Affairs and assigned to us. Milestone Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director will receive additional payments of 2.5% of the total sales of products using certain of these technologies, and 5% of the total sales of products using certain other of the technologies. The Director of Clinical Affairs was granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant, 8,333 shares of the common stock upon the issuance of each additional patent relating to these technologies. If products produced by third parties use any of these technologies (under license from us) then the Director of Clinical Affairs will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license. Milestone Scientific expensed the Director of Clinical Affairs' royalty fee of \$110,764 and \$300,643 during the three and six months ended June 30, 2016, respectively. Milestone Scientific expensed the Director of Clinical Affairs' royalty fee of \$84,947 and \$196,431, during the three and six months ended June 30, 2015, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$68,757 and \$137,502 for the three and six months ended June 30, 2016. Additionally, Milestone Scientific

expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$78,000 for the three and six months ended June 30, 2015, respectively.

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

Subsequent Events

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

In July 2016, Milestone Scientific raised \$250,000 in additional capital from the sale of 104,200 shares of common stock at \$2.40 per share. The transaction was covered by the prospectus supplement, filed with the SEC on July 22, 2016, to our shelf registration statement on Form S-3 (SEC File No.: 333-209466).

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

ITEM 2.

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

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

OVERVIEW

Milestone Scientific Inc. ("Milestone Scientific", "our", "us" or "we") was officially listed on the NYSE MKT on June 1, 2015.

In 2016, Milestone Scientific remains focused on advancing efforts to achieve our two primary objectives; those being:

-

Enhancing our global reach by partnering with distribution companies in the medical sector and

-

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

STA Instrument Growth

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

Global Distribution Network

United States and Canadian Market

In June 2016 we established new distribution arrangements for our dental products for the United States and Canada with Henry Schein Inc. (“Henry Schein”), a global leader of distribution in the dental supplies. Under these arrangements we will, for the first time, have a dedicated independent sales force visiting dentists. We believe that these arrangements will be more effective than previous arrangements relying on appearances at dental shows and catalog sales.

International Market

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

In early October 2012, the State Food and Drug Administration (SFDA) of the People’s Republic of China approved Milestone Scientific’s *Single Tooth Anesthesia System*® (STA System). In May 2014, the CFDA, (previously the SFDA), granted registration approval of the *STA* handpieces in China. We have established exclusive distribution arrangements with Milestone China, Ltd, a 40% owned subsidiary of ours, which has placed our dental instruments in clinics serving major cities in China.

Shortly before the end of the second quarter 2009, we announced that we were refining our international marketing strategy to gain greater access to and penetration of the international dental markets for the *STA Instrument*, *CompuDent*® and related disposable handpieces. The new sales strategy provides for increasing hands-on oversight and support of our existing international distribution network, while also attracting new distributors throughout Europe, Asia and South America.

In September 2014, Milestone Medical Inc., a subsidiary of Milestone Scientific (“Milestone Medical”), received CE clearance to distribute their epidural and intra-articular instruments in European Community (EU). Milestone Medical is actively pursuing distributors for the instruments in the EU community. Milestone Medical signed a distribution agreement in March 2015, with a Polish Medical distributor for the distribution of the epidural instrument starting in April 2015.

In July 2016, Milestone Scientific filed for 510(k) marketing clearance with the United States Food and Drug Administration (FDA) for marketing clearance of the Milestone Medical epidural instrument. This clearance is necessary to begin commercialization of the epidural instrument in the United States.

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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 June 30,

Six Months Ended June 30,

2016

2015

2016

2015

DOMESTIC

Instruments

\$ 190,504	21.0 %	\$ 153,325	18.2 %	\$ 852,149	32.3 %	\$ 602,290	35.2 %
------------	--------	------------	--------	------------	--------	------------	--------

Handpieces

695,761	76.7 %	673,062	80.0 %	1,753,685	66.4 %	1,105,124	64.7 %
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Other

20,652	2.3 %	15,229	1.8 %	34,126	1.3 %	1,762	0.1 %
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Total Domestic

\$ 906,917	100.0 %	\$ 841,616	100.0 %	\$ 2,639,960	100.0 %	\$ 1,709,176	100.0 %
------------	---------	------------	---------	--------------	---------	--------------	---------

INTERNATIONAL

Instruments

\$ 535,335	36.6 %	\$ 136,430	14.8 %	\$ 1,559,050	48.8 %	\$ 814,044	28.8 %
------------	--------	------------	--------	--------------	--------	------------	--------

Handpieces

882,135	60.2 %	757,079	81.8 %	1,537,124	48.1 %	1,971,531	69.7 %
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Other

47,323	3.2 %	31,634	3.4 %	100,062	3.1 %	42,212	1.5 %
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Total International

\$ 1,464,793	100.0 %	\$ 925,143	100.0 %	\$ 3,196,236	100.0 %	\$ 2,827,787	100.0 %
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DOMESTIC/INTERNATIONAL ANALYSIS

Domestic

\$ 906,917	37.8 %	\$ 841,616	47.6 %	\$ 2,639,960	45.2 %	\$ 1,709,176	37.7 %
------------	--------	------------	--------	--------------	--------	--------------	--------

International

1,464,793	62.2 %	925,143	52.4 %	3,196,236	54.8 %	2,827,787	62.3 %
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Total Product Sales

\$ 2,371,710	100.0 %	\$ 1,766,759	100.0 %	\$ 5,836,196	100.0 %	\$ 4,536,963	100.0 %
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Milestone Scientific earned gross profit of approximately \$1.6 million and \$3.7 million in the three and six months ended June 30, 2016. Milestone Scientific earned gross profit of approximately \$1.2 million and \$3.0 million in the three and six months ended June 30, 2015. However, the revenues and related gross profits have not been sufficient to support overhead, new product introduction and research and development expenses. Although Milestone Scientific anticipates expending funds for research and development in 2016, these amounts will vary based on the operating results for each quarter. Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception, except for 2013. At June 30, 2016, Milestone Scientific has sufficient cash reserves to meet all of its anticipated obligations for at least the next twelve months, including a limited amount of financing for the operation of Milestone Medical until additional financing is consummated in 2016. Milestone Scientific is actively pursuing the continued generation of positive cash flows from operating activities through increase in revenue, assessment of current contracts and current negotiations.

In 2016, Milestone Scientific plans to further support increased sales and marketing activity through our current distributors and newly appointed distributors of the *STA* instruments and handpieces in the international market. In the U.S. and Canada, Milestone Scientific will utilize Henry Schein's Exclusive Product Division providing best in class, web based training for the initial contact with customers and to train Henry Schein marketing training personnel. Individual practitioners and group practices domestically, and to refined and directed advertising to dental professionals, to support and broaden our global distribution network.

Results of Operations

The following table sets forth for the consolidated results of operations for the three and six months ended June 30, 2016 compared to 2015 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

Three Months Ended June 30,

Six Months Ended June 30

2016

2015

2016

2015

Total revenue

\$ 2,371,710	100 %	\$ 1,766,759	100 %	\$ 5,836,196	100 %	\$ 4,536,963	100 %
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Cost of products sold

789,801	33 %	570,729	32 %	2,157,990	37 %	1,503,877	33 %
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Gross Profit

1,581,909	67 %	1,196,030	68 %	3,678,206	63 %	3,033,086	67 %
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Selling, general and administrative expenses

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3,290,998 91 % 2,590,897 99 % 6,292,109 93 % 4,488,978 99 %

Research and development expenses

309,335 9 % 18,820 1 % 452,780 7 % 28,938 1 %

Operating expenses

3,600,333 100 % 2,609,717 100 % 6,744,889 100 % 4,517,916 100 %

Loss from operations

(2,018,424) -85 % (1,413,687) -80 % (3,066,683) -53 % (1,484,830) -33 %

Interest income and expense

(1,004) 0 % (1,130) 0 % (1,936) 0 % 80 0 %

Total other expenses, net

(1,004) 0 % (1,130) 0 % (1,936) 0 % 80 0 %

Loss before provision for income tax and equity in net earnings of equity investments

(2,019,428) -256 % (1,414,817) -248 % (3,068,619) -142 % (1,484,750) -99 %

Provision for Income Tax

(16,791) -1 % (13,646) -1 % (63,624) -1 % (13,646) 0 %

Loss before equity in net earnings of equity investments

(2,036,219) -86 % (1,428,463) -81 % (3,132,243) -54 % (1,498,396) -33 %

Loss on earnings from Milestone Medical

- 0 % (525,938) -30 % - 0 % (976,099) -22 %

Loss on earnings from Education Joint venture

- 0 % (3,621) 0 % - 0 % (7,836) 0 %

(Loss) Gain on earnings from China Joint Venture

(57,882) -2 % (160,654) -9 % (222,719) -4 % (63,979) -1 %

Loss in equity investments

(57,882) -2 % (690,213) -39 % (222,719) -4 % (1,047,914) -23 %

Net loss

(2,094,101) -88 % (2,118,676) -120 % (3,354,962) -57 % (2,546,310) -56 %

Less: Net loss attributable to the noncontrolling interests

(507,262) -15 % (45,727) 2 % (976,308) -16 % (53,987) 1 %

Net loss attributable to Milestone Scientific Inc.

\$ (1,586,839) -67 % \$ (2,072,949) -117 % \$ (2,378,654) -41 % \$ (2,492,323) -55 %

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

The following paragraphs will describe the results of 2016 compared to 2015.

Total revenues for the three months ended June 30, 2016 and 2015 were approximately \$2.4 and \$1.8 million, respectively. The total revenue increased by approximately \$600,000 or 34%, which was equally related to the increase in instrument and handpieces sales worldwide. Domestic sales in the United States increased by approximately \$65,000 in 2016. It is important to note that in the second quarter of 2016 Henry Schein continued to purchase instruments and handpieces as a non-exclusive distributor in USA and Canada. International Instruments sales increased by \$398,000 over the same period in 2015 principally due to a shipment of STA instruments to China. Handpieces increase by \$126,000 for the same period in 2015. International sales increased by approximately \$540,000. In the USA, Milestone Scientific has concluded its exclusive distributor and marketing agreement with Aseptico Inc. This exclusive agreement was changed to a non-exclusive agreement on December 31, 2015. The term of this non-exclusive agreement expired on March 31, 2016. Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. In June 2016, Milestone Scientific entered an exclusive distributor agreement with Henry Schein pursuant to which it will have a dedicated independent sales force to market our dental products in the USA and Canada. We believe that the agreement with Henry Schein will lead to increased domestic sales of STA instruments and handpieces in the third and fourth quarters of 2016.

The gross margin in 2016 decreased to 67% versus 68% in 2015. This decrease in gross profit margin is due to a special price reduction given to a distributor in a key market for instruments in an effort to stimulate growth in the 2016 sales volume. Although the gross margin percentage decreased 1%, gross profit dollars in 2016 increased to approximately \$1.6 million from approximately \$1.2 million in 2015 or, by approximately \$400,000 over the same period year over year.

Selling, general and administrative expenses for the three months ended June 30, 2016 were approximately \$3.3 million versus \$2.6 million in 2015. This increase of approximately \$700,000 is predominantly due to the consolidation of Milestone Medical commencing on December 31, 2015. In 2015, Milestone Medical was accounted for under the equity method, as such their line item expenses were recorded as a one line entry in the Statement of

Operations as a Loss on Earnings from Milestone Medical of approximately \$525,000. The total operating expense for Milestone Scientific for the quarter ending June 30, 2016 and 2015 was \$3.6 million and \$2.6 million, respectively, after giving effect to proforma consolidation of Milestone Medical in 2015 the net increase was \$400,000.

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20

On a consolidated basis, giving effect to the consolidation of Milestone Medical, Milestone Education and Wand Dental, selling, general and administrative expenses increased by approximately \$200,000 for the three months ended June 30, 2016 as compared to the same prior year period. Salaries and other compensation expense decreased by \$300,000 for the three months ended June 30, 2016 as compared to the same prior year period due to a temporary decrease in personnel, this expense is expected to increase in future quarters as we fill existing open positions to grow our business. The hiring of a replacement Senior Brand Manager, and an increase in our Clinical Hygienist staff to train our current and new customers is anticipated in the future. Marketing and trade show expenses and travel and other expenses accounted for the increase in the second quarter 2016 versus the second quarter of 2015 by providing additional trade show costs for dental and medical sectors of the business. The cost were offset by reduction in travel and administrative cost.

Research and development expenses for the three month ended June 30, 2016 and 2015 were \$309,000 and \$19,000, respectively. As previously stated, the increase is due to the consolidation of Milestone Medical in 2016. The increase is due to other research and development projects that are in process related to the medical instrument.

The loss from operations for the three months ended June 30, 2016 and 2015 was \$2 million and \$1.4 million, respectively. The additional loss of \$600,000 is primarily the result of the consolidation Milestone Medical in 2016.

There was a loss on the China Joint Venture of \$57,882 and of \$160,654 for the three months ended June 30, 2016 and 2015, respectively. The China Joint Venture is in its initial operating and expansion cycle in China, and as such will continue to have losses in 2016.

For the reasons explained above, and after factoring in the positive effects of net loss attributable to non-controlling interest, the net loss for the three months June 30, 2016 was \$1.6 million as compared to the net loss for the three months ended June 30, 2015 of \$2.1 million.

Six months ended June 30, 2016 compared to six months ended June 30, 2015

Total revenues for the six months ended June 30, 2016 and 2015 were approximately \$5.8 and \$4.5 million, respectively. The total dental revenue increased by approximately \$1.3 million or 29% which was primarily related to the increase in instrument sales worldwide. Domestic sales in the United States increased by approximately \$930,000 in 2016. This increase in revenue is in both STA instruments and handpieces. It is important to note that in the first half of 2016 Henry Schein continued to purchased instruments and handpieces as a non-exclusive distributor in USA and Canada. International Instruments sales increased by \$745,000 over the same period in 2015 due to a shipment of STA instruments to China. Handpieces decreased by \$434,000 over the same period in 2015. This decrease is due to the slow first quarter sales, we do not believe that this trend will continue in the remaining months of 2016. International sales increased by approximately \$368,000. In the USA, Milestone Scientific has concluded its exclusive distributor and marketing agreement with Aseptico Inc. This exclusive agreement was changed to a non-exclusive

agreement in December 31, 2015. The term of this non-exclusive agreement expired on March 31, 2016. Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. This agreement was enhanced to an exclusive distribution agreement in June 2016 pursuant to which it will have a dedicated independent sales force to market our dental products in the USA and Canada. We believe that the agreement with Henry Schein will lead to increased domestic sales of STA instruments and handpieces in the third and fourth quarters of 2016.

The gross margin in 2016 decreased to 63% versus 67% in 2015. This decrease in gross profit margin is due to a special price reduction given to a distributor in a key market for instruments in an effort to stimulate growth in the 2016 sales volume. Although the gross margin percentage decreased 4%, gross profit dollars in 2016 increased to approximately \$3.7 million from approximately \$3.0 million in 2015 or, by approximately \$645,000 over the same period year over year.

Selling, general and administrative expenses for the six months ended June 30, 2016 were approximately \$6.3 million versus \$4.5 million in 2015. This increase of approximately \$1.8 million is predominantly due to the consolidation of Milestone Medical in the first half of 2016. In 2015, Milestone Medical was accounted for under the equity method, as such their line item expenses were recorded as a one line entry in the Statement of Operations as a Loss on Earnings from Milestone Medical. The total operating expense for Milestone Medical for the six months ending June 30, 2016 and 2015 was \$1.8 million and \$2 million, respectively. The major reduction in the total operating expense for Milestone Medical was a reduction in Research and Development Expense of approximately \$232,000.

On the consolidated basis, giving effect to the consolidation of Milestone Medical, Milestone Education and Wand Dental, selling, general and administrative expenses increased by approximately \$84,000. Salaries and other compensation expense represents the major decrease in expense (\$270,000). However, in the remainder of 2016 the company will increase in personnel which is required to grow our business, to replacement Senior Brand Manager, and an increase in our Clinical Hygienist staff to train our current and new customers. Other cost increase; other administrative cost increased by \$173,000 due to increased royalties on sales of the dental group. Marketing and travel expense increased \$183,000 as the company is expanding our efforts internationally to grow our distributor based in the world wide market for our dental and medical instruments.

Research and development expenses for the six months ended June 30, 2016 and 2015 were approximately, \$453,000 and \$29,000, respectively. As previously stated, the increase is due to the consolidation of Milestone Medical in 2016. On a proforma consolidated basis, 2015 research and development expenses would have been \$384,000.

The loss from operations for the six months ended June 30, 2016 and 2015 were approximately \$3.1 million and \$1.5 million, respectively. The additional loss of \$1.6 million is primarily the result of the consolidation Milestone Medical in 2016.

There was a loss on the China Joint Venture of \$222,719 and loss of \$63,979 for the six months ended June 30, 2016 and 2015, respectively. The China Joint Venture is in its initial operating and expansion cycle in China, and as such will continue to have losses in 2016.

For the reasons explained above, and after factoring in the positive effects of net loss attributable to non-controlling interest, the net loss for the six months June 30, 2016 was \$2.4 million as compared to the net loss for the six months ended June 30, 2015 of \$2.5 million.

Liquidity and Capital Resources

Looking at the current balance sheet for Milestone Scientific and subsidiaries cash is approximately \$3.2 million, current assets decreased by approximately \$130,000. Milestone Scientific raised \$2 million in a private placement in June 2016. Current liabilities increased to approximately \$4.0 million versus approximately \$3.6 million for June 30, 2016 and 2015, respectively. Working Capital decreased by \$477,000 to \$7,700,000. Milestone Scientific believes that its cash on hand and anticipated revenues from the dental business will be sufficient to operate the ongoing business for at least the next 12 months. As noted previously, the funding for Milestone Medical will be limited during 2016.

Milestone Scientific continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements. Cash flows from operating activities for the six months ended June 30, 2016 and 2015 were approximately a negative \$2.8 million and \$2.4 million, respectively.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception, except for the year ended December 31, 2013. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through increases in revenues based upon management's assessment of present contracts, and current negotiations and reductions in operating expenses. The consolidation of Milestone Medical in December 2015 and the lack of capital raising activities by Milestone Medical in 2015 created a unique

situation for Milestone Scientific advancing into 2016. However, as noted previously, Milestone Scientific is not obligated to continue its financial support of Milestone Medical, but the timeline for Milestone Medical 510K FDA clearance is expected in 2016. Milestone Scientific expects that clearance to commercialize the epidural and intra articular instruments in 2016 will significantly improve the capital raising opportunities and financial picture.

Milestone Scientific believes that with the new distribution agreement with Henry Schein (effective January 1, 2016), the world's largest supplier of medical, dental and veterinary supplies and devices, that dental revenues are projected to improve in the upcoming 12 months. To further reduce Milestone Scientific's expenditures, Milestone Medical expenses related to FDA clearance for the epidural and intra-articular instruments can be controlled as required to meet Milestone Scientific's budget. By limiting the FDA related expenses and increasing the dental instrument revenue through the new distribution agreement and performing a detailed cash flow projection of the consolidated company and its subsidiaries, management believes that Milestone Scientific will have sufficient cash reserves to meet all of its anticipated obligations over the next twelve months.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4.

Controls and Procedures

Milestone Scientific's management, including the Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of Milestone Scientific's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report (the "Evaluation Date"). Based upon that evaluation, Milestone Scientific's Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of the Evaluation Date are effective to ensure that information required to be disclosed in the reports Milestone Scientific files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Milestone Scientific's management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding disclosure.

There were no changes in Milestone Scientific's internal control over financial reporting identified in connection with the evaluation that occurred during Milestone Scientific's last fiscal quarter ended June 30, 2016 that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific's internal controls over financial reporting.

PART II – OTHER INFORMATION

ITEM 1.

LEGAL PROCEEDINGS

None.

ITEM 1A.

RISK FACTORS

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

ITEM 2.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In June 2016, we raised \$2 million of additional capital through a private placement of one million shares of our common stock at a price of \$2.00 per share to an accredited investor. The offering was exempt from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act and a legend restricting the resale, transfer, or other disposition of such shares other than in compliance with the Act was imprinted on the stock certificate evidencing such shares.

In May 2016, we issued 75,000 shares of common stock for aggregate consideration of \$168,675 for consulting services. The issuance was exempt from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act and a legend restricting the resale, transfer, or other disposition of such shares other than in compliance with the Act was imprinted on the stock certificate evidencing such shares.

In April 2016, we initiated a share exchange program pursuant to which we would exchange one share of common stock for every two outstanding shares of Milestone Medical common stock. As of June 30, 2016, 3,965,000 shares of common stock has been issued in exchange for 7,931,000 shares of Milestone Medical common stock. An additional 532,542 shares were issued but not outstanding as of June 30, 2016. As a result of these exchanges, Milestone Scientific owns approximately 86% of Milestone Medical at June 30, 2016. The issuances were exempt from the registration requirements of the Act pursuant to Sections 4(a)(2) and 4(a)(5) of the Act and a legend restricting the resale, transfer, or other disposition of such shares other than in compliance with the Act was imprinted on the stock certificates evidencing such shares.

ITEM 3.

DEFAULT UPON SENIOR SECURITIES

None.

ITEM 4.

MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5.

OTHER INFORMATION

None.

ITEM 6.

EXHIBITS

Exhibit NO.

Description

10.1

Exclusive Distribution and Supply Agreement, dated as of June 20, 2016, among Milestone Scientific Inc., Wand Dental, Inc. and Henry Schein, Inc.(1)

31.1

Chief Executive Officer Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002.*

31.2

Chief Financial Officer Certification pursuant to section 302 of the Sarbanes-Oxley Act of 2002.*

32.1

Chief Executive Officer Certification pursuant to section 906 of the Sarbanes-Oxley Act of 2002.**

32.2

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

101.INS

XBRL Instance Document.*

101.SCH

XBRL Taxonomy Extension Schema Document.*

101.CAL

XBRL Taxonomy Extension Calculation Linkbase Document.*

101.LAB

XBRL Taxonomy Extension Label Linkbase Document.*

101.PRE

XBRL Taxonomy Extension Presentation Linkbase Document.*

101.DEF

XBRL Taxonomy Extension Definition Linkbase Document.*

*

Filed herewith.

**

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

(1)

Incorporated herein by reference to Milestone Scientific's Current Report on Form 8-K filed with the SEC on June 30, 2016.

23

SIGNATURES

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

MILESTONE SCIENTIFIC INC.

/s/ Leonard Osser

Leonard Osser

Chief Executive Officer

(Principal Executive Officer)

/s/ Joseph D'Agostino

Joseph D'Agostino

Chief Operating Officer

Chief Financial Officer

(Principal Financial Officer)

Date: August 11, 2016