

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 quarter ended March 31, 2019  
Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

Delaware

State or other jurisdiction of Incorporation or organization

13-3545623

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

220 South Orange Avenue, Livingston, NJ 07039

(Address of principal executive offices)

Registrant's telephone number, including area code: 973-535-2717

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 American

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 every Interactive Data File required to be submitted 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 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

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

Emerging growth company

Accelerated filer

Smaller reporting 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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of Exchange on which registered</u>
Common Stock	MLSS	NYSE American

As of May 14, 2019, the registrant has a total of 41,149,313 shares of Common Stock, \$0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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**MILESTONE SCIENTIFIC INC.**  
**Form 10-Q**  
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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, 2018 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 Device®; and The Wand ®.*

**Part I- Financial Information**  
**Item 1. Financial Statements**

MILESTONE SCIENTIFIC AND SUBSIDIARIES  
CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS	March 31, 2019 (Unaudited)	December 31, 2018 (Audited)
Current assets:		
Cash and cash equivalents	\$ 2,739,700	\$ 743,429
Accounts receivable, net	1,512,746	1,978,456
Accounts receivable, related party, net	50,000	100,000
Prepaid expenses and other current assets	595,951	414,541
Deferred cost, related party	24,602	50,000
Inventories, net	1,861,291	1,921,051
Advances on contracts	530,114	648,783
<b>Total current assets</b>	<b>7,314,404</b>	<b>5,856,260</b>
Furniture, fixtures and equipment, net	77,869	82,557
Patents, net	422,021	435,273
Operating lease-right of use assets	129,982	-
Other assets	17,355	26,878
<b>Total assets</b>	<b>\$ 7,961,631</b>	<b>\$ 6,400,968</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,198,624	\$ 1,205,396
Accounts payable, related party	1,400,806	1,663,849
Accrued expenses and other payables	1,548,353	1,481,715
Accrued expenses, related party	110,215	-
Operating lease-current	114,058	-
Deferred profit, related party	431,364	421,800
Deferred revenue, related party	50,000	100,000
Derivative liability	365,785	-
<b>Total current liabilities</b>	<b>5,219,205</b>	<b>4,872,760</b>
Operating lease-non current	15,924	-
<b>Total liabilities</b>	<b>\$ 5,235,129</b>	<b>\$ 4,872,760</b>
Commitments and contingencies		
Stockholders' equity		
Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, and 7,000 shares issued and outstanding (liquidation preference of \$7,000,000 as of March 31, 2019 and December 31, 2018 )	\$ 7	\$ 7
Common stock, par value \$.001; authorized 50,000,000 shares; 40,855,721 shares issued, 2,807,710 shares to be issued and 40,822,388 shares outstanding as of March 31, 2019; 33,859,034 shares issued, 2,470,565 shares to be issued and 33,825,701 shares outstanding as of December 31, 2018;	43,662	36,330
Additional paid in capital	90,398,875	88,414,718
Accumulated deficit	(86,782,681)	(85,999,929)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
<b>Total Milestone Scientific Inc. stockholders' equity</b>	<b>2,748,347</b>	<b>1,539,610</b>
Noncontrolling interest	(21,845)	(11,402)
<b>Total stockholders' equity</b>	<b>2,726,502</b>	<b>1,528,208</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 7,961,631</b>	<b>\$ 6,400,968</b>

See notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)

	March 31, 2019	March 31, 2018
Product sales, net	\$ 1,915,909	\$ 1,805,605
Cost of products sold	618,694	562,676
Gross profit	1,297,215	1,242,929
Selling, general and administrative expenses	2,109,050	3,018,780
Research and development expenses	6,346	225,817
Total operating expenses	2,115,396	3,244,597
Loss from operations	(818,181)	(2,001,668)
Other expenses	(2,264)	(1,700)
Interest income	1,019	2,664
Change in fair value of derivative liability	40,260	-
Loss before provision for income taxes and net losses of equity investments	(779,166)	(2,000,704)
Provision for income taxes	(4,465)	(11,464)
Loss before equity in net earnings (losses) of equity investments	(783,631)	(2,012,168)
(Loss) earnings from China Joint Venture	(9,564)	36,783
Net loss	(793,195)	(1,975,385)
Net loss attributable to noncontrolling interests	(10,443)	(101,407)
Net loss attributable to Milestone Scientific Inc.	\$ (782,752)	\$ (1,873,978)
Net loss per share applicable to common stockholders—		
Basic	\$ (0.02)	\$ (0.06)
Diluted	\$ (0.02)	\$ (0.06)
Weighted average shares outstanding and to be issued—		
Basic	40,531,762	34,766,014
Diluted	40,531,762	34,766,014

See notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES  
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY  
FOR THREE MONTHS ENDED MARCH 31, 2019 AND 2018  
(UNAUDITED)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance as January 1, 2019	7,000	\$ 7	36,329,600	\$ 36,330	\$ 88,414,718	\$ (85,999,929)	\$ (11,402)	\$ (911,516)	\$ 1,528,208
Stock based compensation	-	-	-	-	56,988	-	-	-	56,988
Reclassification of warrants and Shares to be issued to derivative liability (Note 8)	-	-	-	-	(406,045)	-	-	-	(406,045)
Common stock to be issued to employees for bonuses	-	-	175,715	175	61,325	-	-	-	61,500
Common stock to be issued for payment of consulting services	-	-	118,115	118	39,882	-	-	-	40,000
Common stock to be issued to employee for compensation	-	-	22,727	23	7,477	-	-	-	7,500
Common stock to be issued to board of directors for services rendered	-	-	20,588	21	6,979	-	-	-	7,000
Common stock issued in public offering	-	-	6,282,400	6,281	1,968,265	-	-	-	1,974,546
Common stock issued in private offering	-	-	714,286	714	249,286	-	-	-	250,000
Net loss	-	-	-	-	-	(782,752)	(10,443)	-	(793,195)
Balance as March 31, 2019	7,000	\$ 7	43,663,431	\$ 43,662	\$ 90,398,875	\$ (86,782,681)	\$ (21,845)	\$ (911,516)	\$ 2,726,502
	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance, January 1, 2018	7,000	\$ 7	34,592,818	\$ 34,593	\$ 86,689,084	\$ (78,568,284)	\$ 256,744	\$ (911,516)	\$ 7,500,628
Stock based compensation	-	-	-	-	86,809	-	-	-	86,809
Common stock issued to employee for bonuses	-	-	323,076	323	339,177	-	-	-	339,500
Net loss	-	-	-	-	-	(1,873,978)	(101,407)	-	(1,975,385)
Balance, March 31, 2018	7,000	\$ 7	34,915,894	\$ 34,916	\$ 87,115,070	\$ (80,442,262)	\$ 155,337	\$ (911,516)	\$ 5,951,552

See notes to Condensed Consolidated Financial Statements

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

	March 31, 2019	March 31, 2018
Cash flows from operating activities:		
Net loss	\$ (793,195)	\$ (1,975,385)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	12,792	27,625
Amortization of patents	13,252	237,366
Stock compensation	56,988	86,809
Loss (Income) on China joint venture	9,564	(36,783)
Change in fair value of derivative liability	(40,260)	-
Changes in operating assets and liabilities:		
Decrease in accounts receivable	465,710	701,677
Decrease in accounts receivable, related party	50,000	-
Decrease in other receivables	9,523	-
Decrease in operating lease-right of use asset	39,555	-
Decrease in inventories	59,760	114,151
Decrease (increase) in advances on contracts	118,669	(287,216)
Decrease (increase) in prepaid expenses and other current assets	(181,410)	(58,307)
Increase (decrease) in accounts payable	(6,772)	579,070
Increase (decrease) in accounts payable, related party	(263,043)	89,400
Decrease in deferred cost, related party	25,398	-
Increase (decrease) in accrued expenses	182,638	(19,757)
Increase in accrued expenses, related party	110,215	-
Decrease in operating lease right to used liability	(39,555)	-
(Decrease) in deferred revenue, related party	(50,000)	-
Net cash used in operating activities	(220,171)	(541,350)
Cash flows from investing activities:		
Purchase of property and equipment	(8,104)	(1,368)
Net cash used in investing activities	(8,104)	(1,368)
Cash flows from financing activities:		
Net proceeds from Public Placement Offering	1,974,546	-
Net proceeds from Private Placement Offering	250,000	-
Net cash provided by financing activities	2,224,546	-
Net increase (decrease) in cash and cash equivalents	1,996,271	(542,718)
Cash and cash equivalents at beginning of period	743,429	2,636,956
Cash and cash equivalents at end of period	<u>\$ 2,739,700</u>	<u>\$ 2,094,238</u>
Supplemental disclosure of cash flow information:		
Shares issued to board of directors	\$ 61,500	\$ 339,500
Shares issue to board of directors for services rendered	\$ 7,500	\$ -
Shares issued to employees for compensation	\$ 7,000	\$ -
Shares issued to consultants in lieu of cash payments	\$ 40,000	\$ -
Operating lease-right of use asset	\$ 166,292	\$ -
Operating lease right to used liability	\$ (166,292)	\$ -
Derivative liability	\$ (406,045)	\$ -

See notes to Condensed Consolidated Financial Statements

**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, Inc., Milestone Advanced Cosmetic Systems, Inc., Milestone Medical, Inc. and Milestone Education LLC (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 device, using *The Wand*®, a single use disposable handpiece. The device is marketed in the dental market under the trademark *CompuDent*®, and *STA Single Tooth Anesthesia System*® and in the medical market under the trademark *CompuMed*®. *CompuDent*® is suitable for all dental procedures that require local anesthetic. *CompuMed*® is suitable upon regulatory approval, as required, for many medical procedures regularly performed in Plastic Surgery, Hair Restoration Surgery, Podiatry, Colorectal Surgery, Dermatology, Orthopedics and many other disciplines. The dental devices are sold in the United States, Canada and in 60 other countries.

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (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 device throughout the United States and Europe. To date there have been five medical devices sold in the United States and limited amounts sold internationally, although certain medical devices have obtained CE mark approval and can be marketed and sold in most European countries.

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) clearances. Following consultation with the FDA Office of Device Evaluation, we intend to file a new 510(k) application for the device in 2019.

In November 2018, Milestone Scientific received a letter from NYSE American LLC (the “Exchange”) stating that the Company was not in compliance with the continued listing standards as set forth in Section(s) 1003(a)(i), (ii), and (iii) of the NYSE American Company Guide (the “Company Guide”). On December 20, 2018, the Company submitted a plan of compliance (the “Plan”) to the Exchange addressing how it intends to regain compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide by May 20, 2020. On January 24, 2019, the Company received a letter from the Exchange stating that the Company’s Plan has been accepted by the Exchange. The Company is still not in compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide and its listing on the Exchange is being continued pursuant to an extension granted by the Exchange.

In February 2019, Milestone Scientific consummated a public offering and a private placement of Common Stock. The public offering generated gross proceeds of approximately \$2.0 million for the issuance of 5,715,000 shares of common stock and warrants to purchase 1,428,750 shares of common stock. The warrants term is 5 years and they are exercisable at \$.50. Subsequent to the public offering the underwriter exercised its overallotment option and paid approximately \$198,000 for 567,400 additional shares of common and as well as 141,850 warrants.

Also, in February 2019, the Company generated gross proceeds from a private placement of approximately \$250,000 for 714,286 shares of common stock and warrants to purchase 178,571 shares of common stock from Bp4 S.p.A., a principal stockholder of Milestone Scientific, that exercised its right to participate on a pro-rata basis on the recent public offering. Bp4’s CEO is a director of Milestone Scientific and also Chief Executive Officer and Director of Wand Dental, a wholly owned subsidiary of Milestone Scientific. The warrants term is 5 years and they are exercisable at \$.50.



## **NOTE 2- GOING CONCERN AND LIQUIDITY**

The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. Milestone Scientific has incurred operating losses and negative cash flows from operating activities in virtually each year since its inception. At March 31, 2019 cash on hand was \$2.7 million an increase of \$2 million from December 31, 2018. Based on the expected cash needed for operating activities, the Company's current cash and liquidity is not sufficient to finance the operating requirements for at least the next 12 months from the filing date. These factors raise substantial doubt regarding the Company's ability to continue as a going concern.

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 devices and disposables business in the United States and worldwide, and a reduction in operating expenses. However, the Company's continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability, if ever. Management is actively pursuing financing or other strategic plans but can provide no assurances that such financing or other strategic plans will be available on acceptable terms, or at all.

These condensed consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the inability of the Company to continue as a going concern.

## **NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### **1. Principles 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), Milestone Education (wholly owned) and Milestone Medical (majority owned). All significant, intra-entity transactions and balances have been eliminated in 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 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, 2018, included in Milestone Scientific's Annual Report on Form 10-K.

### **3. Reclassifications**

Certain reclassifications have been made to the 2018 financial statements to conform to the condensed consolidated 2019 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

### **4. 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.

## 5. Revenue Recognition

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps:

- i. identification of the promised goods or services in the contract;
- ii. determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
- iii. measurement of the transaction price, including the constraint on variable consideration;
- iv. allocation of the transaction price to the performance obligations based on estimated selling prices; and
- v. recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606.

The Company derives its revenues from the sale of its products, primarily dental instruments, handpieces, and other related products. The Company sells its products through a global distribution network and that includes both exclusive and non-exclusive distribution agreements with related and third parties.

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has no obligation on product sales for any 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.

### Sales Returns

The Company records allowances for product returns as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the customers' return rights and the Company's historical experience with returns and the amount of product in the distribution channel not consumed by patients and subject to return. The Company relies on historical return rates to estimate returns. In the future, if any of these factors and/or the history of product returns change, adjustments to the allowance for product returns may be required.

### Financing and Payment

Our payment terms differ by geography and customer, but payment is generally required within 90 days from the date of shipment or delivery.

### Disaggregation of Revenue

We operate in two operating segments: dental and medical. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. See Note 10 for revenues by geographical market and operating results by segment for three months ended March 31, 2019 and 2018.

## 6. 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.

Because Milestone Scientific has a variable interest in Milestone China, it considered the guidance in ASC 810, "Consolidation" as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. 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 Scientific 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 CEO and a group of significant shareholders, including the Milestone China CEO, of Milestone China which have 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. See Note 6.

#### **7. 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.

#### **8. 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. Most credit sales are due within 90 days from invoicing. There have not been any significant credit losses incurred to date. As of March 31, 2019 and December 31, 2018, accounts receivable was recorded, net of allowance for doubtful accounts of \$10,000.

#### **9. Product Return and Warranty**

Milestone Scientific generally does not accept non-defective returns from its customers, except for certain customers that can return factory sealed purchases (inventory) that still remain in their locations at the time of termination of their Distributor Agreement. 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.

#### **10. Inventories**

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or net realizable value. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess, slow moving, defective, and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence and product expiration requirements. As of March 31, 2019 and December 31, 2018, inventory was recorded net of a valuation allowance for slow moving and defective inventory of approximately \$756,000 and \$763,000, respectively.

#### **11. Equity Method Investments**

Investments in which Milestone Scientific can 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.

#### **12. 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 two to seven years. The costs of maintenance and repairs are charged to operations as incurred.

### **13. Intangible Assets – Patents and Developed Technology**

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 and other developed technology acquired from another business entity are amortized over the remaining estimated useful life of the patent. These patents and developed technology are recorded at the acquisition cost. Patent defense costs, to the extent applicable, are expensed as incurred.

### **14. Impairment of Long-Lived Assets**

Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company's impairment review process is based upon an estimate of future undiscounted cash flow. Factors the Company considers that could trigger an impairment review include the following:

- significant under performance relative to expected historical or projected future operating results,
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business
- significant negative industry or economic trends
- significant technological changes, which would render the technology obsolete

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs.

### **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.

At March 31, 2019 and December 31, 2018, we had no uncertain tax positions that required recognition in the condensed consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the condensed consolidated statements of operations. No interest and penalties are present for periods open. Tax returns for the 2015, 2016, and 2017 years are subject to audit by federal and state jurisdictions.

### **17. Basic and diluted net loss per common share**

Basic earnings (loss) per common share is computed by dividing the net earnings (loss) for the period by the weighted average number of common shares outstanding during the period. In periods where there is net income, we apply the two-class method to calculate basic and diluted net income (loss) per share of common stock, as our Series A Convertible Preferred Stock is a participating security. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. In periods where there is a net loss, the two-class method of computing earnings per share does not apply as our Series A Convertible Preferred Stock does not

contractually participate in our losses. We compute diluted net income (loss) per common share using net income (loss) as the “control number” in determining whether potential common shares are dilutive, after giving consideration to all potentially dilutive common shares, including stock options, warrants, during the period and potential issuance of stock upon the conversion of our Series A Convertible Preferred Stock issued and outstanding during the period, except where the effect of such securities would be antidilutive.

The Company did not include any portion of outstanding options, warrants or convertible preferred stock in the calculation of diluted loss per common share because all such securities are anti-dilutive for all periods presented. The application of the two-class method of computing earnings per share under general accounting principles for participating securities is not applicable during these periods because those securities do not contractually participate in its losses.

Since Milestone Scientific had net losses for 2019 and 2018, the assumed effects of the exercise of potentially dilutive outstanding stock options, warrants and convertible preferred stock were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 8,461,057 and 6,703,553 at March 31, 2019 and December 31, 2018, respectively.

#### 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 can 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 an 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.

The following table provides the carrying value and fair value of the Company’s financial assets measured at fair value on a recurring basis as of March 31, 2019.

	Carrying Value	Level 1	Level 2	Level 3
Derivative Warrants	\$ 336,237	\$ -	\$ -	\$ 336,237
Shares to be issued-liability	29,548	29,548	-	-
Total March 31, 2019	<u>\$ 365,785</u>	<u>\$ 29,548</u>	<u>\$ -</u>	<u>\$ 336,237</u>

The following additional disclosures relate to the changes in fair value of the Company’s Level 3 instruments during the three months ended March 31, 2019:

	March 31, 2019
Balance at beginning of year	\$ -
Warrants issued in connection with public offering (See Note 8)	376,497
Change in fair value of derivative liability	(40,260)
Balance at end of period	<u>\$ 336,237</u>

#### 19. Derivative Liability

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risks; however, the Company has certain financial instruments that qualify as derivatives and are classified as liabilities on the balance sheet. The Company evaluates all its financial instruments to determine if those instruments or any potential embedded components of those

instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC 815, “Derivatives and Hedging”. Derivatives satisfying certain criteria are recorded at fair value at issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense. In addition, upon the occurrence of an event that requires the derivative liability to be reclassified to equity, the derivative liability is revalued to fair value at that date.

## 20. Stock-Based Compensation

Share-based payments to employees, including grants of employee stock options, is recognized in the condensed consolidated statements of operations over the service period, as an operating expense, based on the grant-date fair values.

## 21. Recent Accounting Pronouncements

On January 1, 2019, we adopted Accounting Standards Update No. 2016-02, Leases (Topic 842) (ASU 2016-02), as amended, which supersedes the lease accounting guidance under Topic 840, and generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use (ROU) assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases. In July 2018, the FASB issued ASU 2018-11, Leases, *Targeted Improvements*, (“ASU 2018-11”), which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. ASU 2018-11 provided companies with an option to not restate comparative periods presented in the financial statements. For information regarding the impact of Topic 842 adoption, see *Significant Accounting Policies – Leases* and Note 13 – Commitments.

In June 2016, the FASB issued a new standard ASU No.2016-13, “Financial Instruments – Credit Losses” (Topic 326).: The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2019. We are currently evaluating the impact of adopting this guidance on our consolidated balance sheets, results of operations, and financial condition.

Milestone Scientific adopted this standard on January 1, 2019 and the ASU had an immaterial effect on its financial position, results of operations and cash flows. In July 2017, the FASB issued a new standard ASU No.2017-11, “Earnings Per Share” (Topic 260), “Distinguishing Liabilities from Equity” (Topic 480), “Derivatives and Hedging” (Topic 815). The new standard provides guidance relating to equity-linked instruments that include certain features.

## 22. Leases

On January 1, 2019, we adopted Topic 842 using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application. Results and disclosure requirements for reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts have not been adjusted and continue to be reported in accordance with our historical accounting under Topic 840.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance, which does not require the reassessment of the following: i) whether existing or expired arrangements are or contain a lease, ii) the lease classification of existing or expired leases, and iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. As of the adoption date, the Company identified three operating lease arrangements in which it is a lessee. The adoption of this standard resulted in the recognition of operating lease liabilities and right-of-use assets of \$129 thousand on the Company’s condensed consolidated balance sheets. The adoption of the standard did not have a material effect on the Company’s statements of operations or statements of cash flows. See Note 13.

## NOTE 4 — INVENTORIES

Inventories consist of the following:	March 31, 2019	December 31, 2018
Dental finished goods, net	\$ 1,564,206	\$ 1,609,000
Medical finished goods, net	188,133	188,133
Component parts and other materials	108,952	123,918
Total inventories	<u>\$ 1,861,291</u>	<u>\$ 1,921,051</u>

At March 31, 2019 and December 31, 2018, there is a reserve for slow moving medical finished goods of \$454,183 and damaged slow moving dental finished goods of \$302,073 and \$309,196, respectively. The reserve for the medical finished goods was primarily related to the delay in commercialization of the intra-articular medical instrument.

#### **NOTE 5 — 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 March 31, 2019 and December 31, 2018 is approximately \$530,000 and \$649,000 respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

#### **NOTE 6 – INVESTMENT IN AND TRANSACTIONS WITH UNCONSOLIDATED SUBSIDIARIES**

##### **Milestone China Ltd.**

###### *Ownership*

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.

###### *Related Party Transactions*

Milestone China is Milestone Scientific’s exclusive distributor in China. During 2017 and prior to the payment default during 2018 Milestone Scientific agreed to sell inventory to Milestone China and its agent. During 2018 Milestone Scientific entered into a payment arrangement with Milestone China to satisfy past due receivables from Milestone China and its agents which increased to \$ 2.8 million at the time of the payment arrangement. The payment terms required \$200,000 payments per month beginning in July 2018 through November 2018 and a balloon payment of approximately \$1,425,000 during December 2018. Milestone Scientific only collected \$950,000 under the payment arrangement which resulted in a deferred revenue and deferred cost balance of \$1.8 million and \$1.25 million. Due to the default on the arrangement and Milestone China’s liquidity constraints, Milestone Scientific halted shipments to Milestone China. The Company has adjusted the accounts receivable related party and the deferred revenue related party based on the expected payment realization and recorded a reserve against the related deferred cost of \$1.25 million.

As of March 31, 2019, Milestone Scientific has deferred revenues and deferred costs associated with sales to Milestone China and its agents of \$50,000 and \$24,602, respectively. As of December 31, 2018, Milestone Scientific had deferred revenues and deferred costs associated with sales to Milestone China and its agents of \$100,000 and \$50,000, respectively. Milestone Scientific recognized \$50,000 of related party sales of handpieces to Milestone China and its agent for the three months ended March 31, 2019. For the three months ending March 31, 2018, Milestone recognized no sales to Milestone China and its agent.

###### *Gross Profit Deferral*

Due to timing differences of when the inventory sold to Milestone China is recognized and when Milestone China sells the acquired inventory to third parties, an elimination of the 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 sales to Milestone China until that product is sold to third parties.

At March 31, 2019 and December 31, 2018, the deferred profit was \$431,364 and \$421,800, respectively, which is included in deferred profit, related party in the condensed consolidated balance sheets. For the three months ended March 31, 2019 and 2018, Milestone Scientific recorded a loss and income on equity investment of \$9,564 and \$36,783, respectively, for product sold by Milestone China to third parties.

###### *Equity Method Disclosures*

As March 31, 2019 and December 31, 2018, Milestone Scientific's investment in Milestone China was \$0. As of March 31, 2019 and December 31, 2018, Milestone Scientific’s share of cumulative losses of Milestone China were \$3,984,177 and \$3,380,388, respectively, which have been suspended.

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

	March 31, 2019 (unaudited)	December 31, 2018 (unaudited)
<b>Assets:</b>		
Current assets	\$ 12,989,534	\$ 10,587,648
Non-current assets	4,604,255	4,603,485
<b>Total assets:</b>	<b>\$ 17,593,789</b>	<b>\$ 15,191,133</b>
<b>Liabilities:</b>		
Current liabilities	21,914,957	17,696,033
Stockholders' equity (deficit)	(4,321,168)	(2,504,900)
<b>Total liabilities and stockholders' deficit</b>	<b>\$ 17,593,789</b>	<b>\$ 15,191,133</b>

	March 31, 2019 (unaudited)	March 31, 2018 (unaudited)
Net sales	\$ 604,328	\$ 756,956
Cost of goods sold	235,100	447,611
Gross profit	369,228	309,345
Other expenses	(1,878,704)	(1,252,213)
<b>Net loss</b>	<b>\$ (1,509,476)</b>	<b>\$ (942,868)</b>

**NOTE 7 — PATENTS**

March 31, 2019				
	Cost	Impairment	Accumulated Amortization	Net
Patents-foundation intellectual property	\$ 1,377,863	\$ -	\$ (955,842)	\$ 422,021
<b>Total</b>	<b>\$ 1,377,863</b>	<b>\$ -</b>	<b>\$ (955,842)</b>	<b>\$ 422,021</b>
December 31, 2018				
	Cost	Impairment	Accumulated Amortization	Net
Patents-foundation intellectual property	\$ 1,377,863	\$ -	\$ (942,590)	\$ 435,273
Epidural-APAD acquired patents	2,639,647	(1,539,794)	(1,099,853)	-
<b>Total</b>	<b>\$ 4,017,510</b>	<b>\$ (1,539,794)</b>	<b>\$ (2,042,443)</b>	<b>\$ 435,273</b>

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. Amortization expense was \$13,252 and \$237,366 for the three months ended March 31, 2019 and 2018, respectively.

During 2018, the Company determined that the APAD Patents purchased in 2017 will not be further developed or commercialized before their estimated useful life expires. As such, Management determined that these assets were impaired and a charge of approximately \$1.5 million was recorded.



## NOTE 8— STOCKHOLDERS' EQUITY

### PUBLIC OFFERING AND PRIVATE PLACEMENT

In February 2019, Milestone Scientific consummated a public offering and a private placement of Common Stock. The public offering generated gross proceeds of approximately \$2.0 million for the issuance of 5,715,000 shares of common stock and warrants to purchase 1,428,750 shares of common stock. The warrants term is 5 years and they are exercisable at \$.50. Subsequent to the public offering the underwriter exercised its overallotment option and paid approximately \$198,000 for 567,400 additional shares of common stock and as well as 141,850 warrants.

Also, in February 2019, the Company generated gross proceeds from a private placement of approximately \$250,000 for 714,286 shares of common stock and warrants to purchase 178,571 shares of common stock from Bp4 S.p.A., a principal stockholder of Milestone Scientific, that exercised its right to participate on a pro-rata basis on the recent public offering. Bp4's CEO is a director of Milestone Scientific and also Chief Executive Officer and Director of Wand Dental, a wholly owned subsidiary of Milestone Scientific. The warrants term is 5 years and they are exercisable at \$.50.

### WARRANTS

The following table summarizes information about shares issuable under warrants outstanding at March 31, 2019:

	Warrant shares outstanding	Weighted Average exercise price	Weighted Average remaining life	Intrinsic value
Outstanding at January 1, 2018	1,500,000	\$ 2.55	0.73	-
Issued	1,749,171	\$ 0.50	4.85	-
Exercised	-	-	-	-
Expired or cancelled	-	-	-	-
Outstanding and exercisable at March 31, 2019	<u>3,249,171</u>	<u>\$ 1.45</u>	<u>2.94</u>	<u>\$ -</u>
Exercisable at March 31, 2019	<u>3,249,171</u>	<u>\$ 1.45</u>	<u>2.94</u>	<u>\$ -</u>

### PREFERRED STOCK

In May of 2014, Milestone completed a private placement, which raised gross proceeds in the total of \$10 million, from the sale of \$3 million of Milestone Scientific common stock (two million shares at \$1.50 per share) and \$7 million of our Series A Convertible Preferred Stock ("preferred stock") (7,000 shares at \$1,000 per share). These shares are convertible, at the option of the holder, into the number of shares of common stock equal to the stated value divided by \$2.545, subject to anti-dilution adjustments, at any time before May 14, 2019. These shares are mandatory convertible on May 14, 2019, into the number of shares of common stock equal to the stated value divided by \$2.545 per share or \$1.50 per share if the common stock does not trade at \$3.15 for period of time, as defined by the agreements, both subject to anti-dilution adjustment.

The conversion ratio and anti-dilution adjustment becomes effective if a triggering event occur such as; issuance of stock dividends or distributions, subdivisions, splits, issuance of stock purchase rights, debt and distributions, cash dividends or distributions, self-tender offers and exchange offers, rights plans and issuance below the conversion price, as defined in the Investment Agreement. Generally, each share of preferred stock entitles the holder to vote together with the holders of Milestone Scientific common stock, as a single class, on all matters submitted for the approval of the holders of Milestone Scientific common stock and has the number of votes equal to the number of shares of our common stock into which they are then convertible. In addition, preferred stock is also entitled to share, pari passu, in any cash dividends declared on Milestone Scientific common stock on a converted basis.

As of March 31, 2019, the Preferred Stock would be converted at a value of \$1.17 per share resulting in 5,982,906 shares of common stock at the mandatory conversion date, May 14, 2019, provided that there are no other issuance of common stock that would require further adjustment to the forced conversion price.

## SHARES TO BE ISSUED

As of March 31, 2019 and December 31, 2018, there were 2,127,843 and 1,908,813 shares, respectively, whose issuance has been deferred under the terms of an employment agreements with the Chief Executive Officer, Chief Financial Officer and other employees of Milestone Scientific. Such shares will be issued to each party upon termination of their employment. As of March 31, 2019 and December 31, 2018, there were 679,867 and 561,752 shares, respectively, that will be issued to non-employee for services rendered. The number of shares was fixed at the date of grant and were fully vested upon grant date.

## SHARES AND WARRANTS IN EXCESS OF AUTHORIZED SHARES

On February 6, 2019, as a result of the shares and warrants issued in the public and private offerings, the Company does not have a sufficient number of authorized shares of common stock to cover the exercise and issue of approximately 1,840,000 outstanding equity instruments. Therefore, the warrants issued in the public and private placement are classified as liabilities and will continue to be liability-classified until there are sufficient number of authorized shares of common stock to cover the shares issuable upon exercise of the warrants. As long as the warrants are liability-classified, they will continue to be re-measured each reporting period, with any increase or decrease in value recorded as a loss or gain in the condensed consolidated statement of operations.

The fair value of the warrants are determined using a Black-Scholes option pricing model. The following assumptions were used to value the warrants at the grant date:

	<b>Warrants</b>
Expected Term	5 years
Volatility	85%
Dividend yield	0.00%
Exercise Price	\$ 0.50
Risk-free interest rate	2.50%
Weighted average fair value of warrants granted	\$ 0.22
Number of shares underlying warrants granted	1,749,171

As these warrants are liability-classified, they were revalued at March 31, 2019 using the following assumptions:

	<b>Warrants</b>
Expected Term	4.9
Volatility	85%
Dividend yield	0.00%
Exercise Price	\$ 0.50
Risk-free interest rate	2.23%
Weighted average fair value of warrants granted	\$ 0.19

Additionally, approximately 90,000 of the shares to be issued are also classified as liability until there are sufficient number of authorized shares of common stock to cover the issuance of the shares. These shares were valued at the trading price of a share of the Company's common stock (\$0.33 upon the creation of the liability and as of March 31, 2019) and they will continue to be re-measured each reporting period, with any increase or decrease in value recorded as a loss or gain in the condensed consolidated statement of operations. The Company plans to seek shareholder approval to increase the number of authorized shares of Common Stock at the next Shareholder's meeting.

## NOTE 9 — INCOME TAXES

Due to Milestone Scientific's history of operating losses, full valuation allowances have been provided for all of Milestone Scientific's deferred tax assets. At March 31, 2019 and December 31, 2018, no recognition was given to the utilization of the remaining net operating loss carry forwards 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 its deferred tax assets due to uncertainty as to their future realization.

**NOTE 10 — SEGMENT AND GEOGRAPHIC DATA**

We conduct our business through two reportable segments: dental and medical. These segments offer different products and services to different customer base. The following tables present information about our reportable and operating segments:

	<b>Three months ended March 31</b>	
<b>Sales</b>		
<b>Net Sales:</b>	<b>2019</b>	<b>2018</b>
Dental	\$ 1,915,509	\$ 1,769,105
Medical	400	36,500
Total net sales	<u>\$ 1,915,909</u>	<u>\$ 1,805,605</u>
<b>Operating Income (Loss):</b>	<b>2019</b>	<b>2018</b>
Dental	\$ 491,966	\$ 357,165
Medical	(491,683)	(708,382)
Corporate	(818,464)	(1,650,451)
Total operating loss	<u>\$ (818,181)</u>	<u>\$ (2,001,668)</u>
<b>Depreciation and Amortization:</b>	<b>2019</b>	<b>2018</b>
Dental	\$ 3,936	\$ 4,141
Medical	2,597	16,877
Corporate	19,512	243,973
Total depreciation and amortization	<u>\$ 26,045</u>	<u>\$ 264,991</u>
<b>Income (loss) before taxes and equity in earnings of affiliates:</b>	<b>2019</b>	<b>2018</b>
Dental	\$ 492,985	\$ 359,822
Medical	(492,386)	(708,954)
Corporate	(779,765)	(1,651,572)
Total loss before taxes and equity in earnings of affiliate	<u>\$ (779,166)</u>	<u>\$ (2,000,704)</u>
<b>Total Assets:</b>	<b>March 31, 2019</b>	<b>December 31, 2018</b>
Dental	\$ 4,977,176	\$ 5,169,944
Medical	365,593	328,208
Corporate	2,618,862	902,816
Total assets	<u>\$ 7,961,631</u>	<u>\$ 6,400,968</u>

The following table presents information about our operations by geographic area as March 31, 2019 . Net sales by geographic area are based on the respective locations of our subsidiaries:

	2019		
	Dental	Medical	Total
<b>Domestic US / Canada:</b>			
Device	\$ 123,994	\$ -	\$ 123,994
Handpieces	789,153	400	789,553
Other	16,817	-	16,817
<b>Total Domestic US / Canada</b>	<b>\$ 929,964</b>	<b>\$ 400</b>	<b>\$ 930,764</b>
<b>International Rest of the World:</b>			
Device	\$ 285,345	\$ -	\$ 285,345
Handpieces	631,311	-	631,311
Other	18,889	-	18,889
<b>Total International Rest of the World</b>	<b>\$ 935,545</b>	<b>\$ -</b>	<b>\$ 935,545</b>
<b>International China:</b>			
Device	\$ -	\$ -	\$ -
Handpieces	50,000	-	50,000
Other	-	-	-
<b>Total International China</b>	<b>\$ 50,000</b>	<b>\$ -</b>	<b>\$ 50,000</b>
<b>Total Product Sales</b>	<b>\$ 1,915,509</b>	<b>\$ 400</b>	<b>\$ 1,915,909</b>

The following table presents information about our operations by geographic area as March 31, 2018. Net sales by geographic area are based on the respective locations of our subsidiaries:

	2018		
	Dental	Medical	Total
<b>Domestic US / Canada:</b>			
Device	\$ 121,048	\$ -	\$ 121,048
Handpieces	768,531	-	768,531
Other	28,851	-	28,851
<b>Total Domestic US / Canada</b>	<b>\$ 918,430</b>	<b>\$ -</b>	<b>\$ 918,430</b>
<b>International Rest of the World:</b>			
Device	\$ 246,968	\$ 32,500	\$ 279,468
Handpieces	578,827	4,000	582,827
Other	24,880	-	24,880
<b>Total International Rest of the World</b>	<b>\$ 850,675</b>	<b>\$ 36,500</b>	<b>\$ 887,175</b>
<b>International China:</b>			
Device	\$ -	\$ -	\$ -
Handpieces	-	-	-
Other	-	-	-
<b>Total International China</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Total Product Sales</b>	<b>\$ 1,769,105</b>	<b>\$ 36,500</b>	<b>\$ 1,805,605</b>

## NOTE 11 -- CONCENTRATIONS

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, *CompuDent* and *CompuMed* devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. Consequently, advances on contracts have been classified as current at March 31, 2019 and December 31, 2018. The termination of the manufacturing relationship with any of these 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, because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business and results of operations.

For the three months ended March 31, 2019 and 2018, an aggregate of approximately 52% and 54%, respectively, of Wand Dental's net product sales were to one customer/distributor. Accounts receivable for two customer/distributor amounted to approximately \$2,669,000 or 79%, or 55% and 24% of Milestone Scientific's gross accounts receivable as of March 31, 2019. Accounts receivable, including related party accounts receivable, for the major customer/distributor (i.e., Milestone China, a related party), amounted to approximately \$2,555,000, or 78% of Milestone Scientific's accounts receivable, as of December 31, 2018. As of March 31, 2019, Milestone China owed \$1,867,990 to Milestone Scientific. Due to the delinquent nature of the scheduled payments and Milestone China's further liquidity constraints, Milestone Scientific reduced accounts receivable, related party and deferred revenue, related party by \$1,817,990 in 2018, this allowance remains recorded as of March 31, 2019. Additionally, Milestone Scientific recorded a reserve of \$1,250,928 at March 31, 2019 and December 31, 2018, against the associated deferred cost, related party.

## NOTE 12 -- RELATED PARTY TRANSACTIONS

### United Systems

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), 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 approximately \$338,000 and \$351,000 for the three months ended March 31, 2019 and 2018, respectively. As March 31, 2019 and 2018, Milestone Scientific owed this manufacturer \$1.2 million and \$1.0 million, respectively, which is included in accounts payable, related party on the condensed consolidated balance sheets. In February 2019, Milestone Scientific board of directors granted United Systems (controlling shareholder, Tom Cheng) 285,714 shares of stock at \$0.35 or \$100,000 for consulting services. These shares were included in shares to be issued at March 31, 2019.

During 2018 Milestone Scientific through its wholly owned subsidiary, Wand Dental, entered into an agreement with United Systems. The agreement was a Royalty Agreement for handpieces sold to Milestone China by United Systems. United Systems will pay Wand Dental a royalty equal to the net profit that Wand Dental would have received if the handpieces were sold directly to Milestone China or its Agent. As of March 31, 2019 and December 31, 2018, Wand Dental has deferred royalty income of \$342,540 that will be recognized at the earlier of when payment of the royalties is received from United Systems or when collectability is deemed to be assured and is included in accounts receivable, related party and deferred revenue, related party on the condensed consolidated balance sheets.

Also, during the year ended December 31, 2018, a Distribution Agreement between Wand Dental and United Systems was entered into. Under the Distribution Agreement United Systems purchased 1,000 STA instruments in June 2018, for delivery to Milestone China. Due to the related party nature and collectability concerns Wand Dental has deferred the sale. During 2018, Milestone Scientific had recorded deferred revenues and deferred costs associated with the sale to United Systems of \$750,000 and \$686,365, respectively. Milestone Scientific entered into a payment arrangement with Milestone China to satisfy past due receivables from Milestone China and its agents which increased to \$ 2.8 million at the time of the payment arrangement. The payment terms required \$200,000 payments per month beginning in July 2018 through November 2018 and a balloon payment of approximately \$1,425,000 during December 2018.

As of March 31, 2019 Milestone Scientific only collected \$950,000 under the payment arrangement. Due to the default on the arrangement and Milestone China's liquidity constraints, Milestone Scientific halted shipments to Milestone China. The Company has adjusted the accounts receivable related party and the deferred revenue related party based on the expected payment realization and recorded a reserve against the related deferred cost of \$1.25 million which includes the sales to United Systems. The amounts due from United Systems described above are included in the adjustments and reserves for Milestone China. See Note 6.

## Milestone China

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. See Note 6 for a description of related party transactions with Milestone China.

## Other

In August 2016, K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$25,000 for the three months ended March 31, 2019 and 2018, respectively.

In January 2017, Milestone Scientific entered into a twelve-month agreement with Innovest S.p.A., a significant stockholder of Milestone Scientific, to provide consulting services. This agreement will renew for successive twelve-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were \$20,000 for the three months ended March 31, 2019, and 2018 respectively.

The Director of Clinical Affairs' royalty fee was approximately \$91,490 and \$85,769 for the three months ended March 31, 2019 and 2018, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$68,751 for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019 and December 31, 2018, Milestone Scientific owed the Director Clinical Affairs for royalties of approximately \$309,000 and \$364,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

## NOTE 13 — COMMITMENTS

### (1) Contract Manufacturing Agreement

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, CompuDent® and CompuMed® devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. In January 2018, Wand Dental entered into a new purchase commitment for the delivery of 1,000 devices beginning in the first quarter of 2019, Milestone Scientific's purchase commitment for this purchase order was \$748,295 at March 31, 2019, however an advance of \$477,379 was recorded against this purchase order. At March 31, 2019, Milestone Scientific owes \$270,916 related to this purchase order. An advance of approximately \$530,000 and \$649,000 was recorded at March 31, 2019, and December 31, 2018, respectively.

### (2) Leases

#### Operating Leases

In June 2015, the Company amended its original office lease of approximately 6,851 square feet for its headquarters in Livingston, New Jersey. Under the amendment, the Company leased an additional 774 square feet of rentable area of the building and extends the term of the lease through January 31, 2020 at a monthly cost of \$12,522. The Company has an option to further extend the term of the lease, however, this option was not included in the determination of the lease's right-of-use asset or lease liability. Per the terms of the lease agreement, the Company does not have a residual value guarantee. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities:

- As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company has utilized its incremental borrowing rate based on the long-term borrowing costs of comparable companies in the Medical Device industry.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined lease component, all contract consideration was allocated to the combined lease component.
- The expected lease terms include noncancelable lease periods. Renewal option periods are not included in the determination of the lease terms as they were not reasonably certain to be exercised.

The components of lease expense as of March 31, 2019 were as follows:

	March 31, 2019
<b>Lease cost</b>	
Operating lease cost	\$ 39,555
Total lease cost	\$ 39,555
<b>Other information</b>	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 39,555
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ -
Weighted-average remaining lease term - operating leases	.9 years
Weighted-average discount rate - operating leases	9.2%

Maturities of lease liabilities due under these lease agreements as of March 31, 2019 are as follows:

	Operating Leases
2019 (excluding the 3 months ended March 31, 2019)	
2020	\$ 118,664
2021	\$ 15,976
2022	\$ -
2023	\$ -
Thereafter	\$ -
Total lease payments	\$ 134,640
Less: interest	\$ (4,658)
Total operating lease liabilities as of March 31, 2019	<u>\$ 129,982</u>

The Company adopted ASU 2016-02 on January 1, 2019 as noted above, and as required, the following disclosure is provided for periods prior to adoption. Future annual minimum lease payments and operating lease commitments as of December 31, 2018 were as follows:

	Total	Less than 1 Year	1-3 Years	3-5 Years
Operating Lease Obligations	\$ 238,939	\$ 16,419	\$ -	\$ -

### (3) Other Commitments

The technology underlying the Safety Wand® 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 covering 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 approximately \$91,490 and \$85,769 for the three months ended March 31, 2019 and 2018, respectively.

### NOTE 14— SUBSEQUENT EVENTS

On May 2, 2019, Milestone Scientific Inc. filed an S-3 Shelf Registration Statement with the Securities and Exchange Commission for the issuance of up to \$30 million of the Company's Common Stock, Preferred Stock, Warrants, units and debt securities replacing the S-3 Shelf Registration Statement originally filed in May 2016, which expired on March 4, 2019.

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

The following discussions of the 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 annual report. Certain statements in this discussion and elsewhere in this report constitute forward-looking statements, within the meaning of section 21E of the Exchange Act, that involve risks and uncertainties. The actual results may differ materially from those anticipated in these forward-looking statements. See "Risk Factors" in Form 10-K at December 31, 2018.

### OVERVIEW

Our common stock was listed on the NYSE American on June 1, 2015 and trades under the symbol "MLSS". We have developed a proprietary, computer-controlled anesthetic delivery instrument, using *The Wand*, a single use disposable handpiece. The instrument is marketed in dental sector under the trademark *CompuDent*®, and *STA Single Tooth Anesthesia System* and in medical sector 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 several other disciplines. The dental instruments are sold in the United States, US territories, Canada, and in over 58 other countries abroad. In June 2017, the FDA approved our 510(k) applications 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 Europe. There have been five medical instruments sold in the United States in 2018 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 November 2018, Milestone Scientific received a letter from NYSE American LLC (the "Exchange") stating that the Company was not in compliance with the continued listing standards as set forth in Section(s) 1003(a)(i), (ii), and (iii) of the NYSE American Company Guide (the "Company Guide"). On December 20, 2018, the Company submitted a plan of compliance (the "Plan") to the Exchange addressing how it intends to regain compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide by May 20, 2020.

On January 24, 2019, the Company received a letter from the Exchange stating that the Company's Plan has been accepted by the Exchange. The Company is still not in compliance with Section(s) 1003(a)(i), (ii) and (iii) of the Company Guide and its listing on the Exchange is being continued pursuant to an extension granted by the Exchange. If the Company is not in compliance with the continued listing standards by May 20, 2020, or if the Company does not make progress consistent with the Plan, the Exchange will initiate delisting procedures as appropriate. The Company may appeal a staff delisting determination in accordance with Section 10 and Part 12 of the Company Guide.

In 2019, we remained focused on advancing efforts to achieve our three primary objectives; in our medical sector; those being

- Identify distributors in the United States for the Epidural instruments, now that FDA clearance has been received;
- Worldwide distribution of the *CompuFlo* Epidural Computer Controlled Anesthesia System; and
- Complete the Cosmetic device and obtain European Regulatory Approve (CE market clearance).

### Wand STA Dental Market

Since its market introduction in early 2007, the Wand/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.

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.

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, up to 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 are currently in the field selling the instrument.



Henry Schein also plans to increase the number of exclusive product specialist in 2019 and to train an additional customer service representative to support dentists across North America through its exclusive product sales customer call center, as business volume increases.

On the global front, we have granted exclusive marketing and distribution rights for the Wand/STA Instrument to select dental suppliers in various international regions in Asia, Africa, South America and Europe. They include FM Produkty Dla Stomatologii in Poland 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 Wand/STASingle Tooth Anesthesia System(STA System). In May 2014, the CFDA also approved the Wand STA handpieces for sale in China.

#### **Medical Market**

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.

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (FDA) for both intra-articular and epidural injections with the CompuFlo Epidural System. In June 2017, the FDA approved the CompuFlo Epidural System for epidural injections. Milestone Scientific is in the process of meeting with medical device distributors within the United States and foreign markets. Milestone Scientific's immediate focus is on marketing its epidural device 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) clearances. Following consultation with the FDA Office of Device Evaluation, we filed a new 510(k) application for the device in June 2018. In August 2018, the FDA provided Milestone Scientific with a list of questions on the intra-articular 510(k) application filed in June 2018. Due to the delay in responding to FDA questions Milestone Scientific will be required file a new 510(K) application.

In February and March 2018, Milestone Scientific hired an Executive VP of Global Sales and Marketing and a Vice President of US Sales to fill a significant gap in our commercialization efforts of the CompuFlo Epidural System. In October 2018, Milestone Medical signed a Distributor Agreement in the U.S. This agreement provides that this Distributor will purchase and hold an inventory of the CompuFlo Epidural System and disposables for sale. At this time there have been no minimum purchase established with the Distributor. This Distributor purchased five CompuFlo Epidural Systems and disposables after executing the Agreement.

We have entered into a limited number of distributor arrangements in Europe and the Middle East for our CompuFlo Epidural System. Our distribution strategy is initially aimed at having KOLs use and accept the device and initiates their own studies.

The following table shows a breakdown of Milestone Scientific's product sales (net), domestically and internationally, by business segment product category for the period ending March 31, 2019 and 2018:

	2019			2018		
	Dental	Medical	Total	Dental	Medical	Total
<b>Domestic US / Canada:</b>						
Device	\$ 123,994	\$ -	\$ 123,994	\$ 121,048	\$ -	\$ 121,048
Handpieces	789,153	400	789,553	768,531	-	768,531
Other	16,817	-	16,817	28,851	-	28,851
<b>Total Domestic US / Canada</b>	<b>\$ 929,964</b>	<b>\$ 400</b>	<b>\$ 930,764</b>	<b>\$ 918,430</b>	<b>\$ -</b>	<b>\$ 918,430</b>
<b>International Rest of the World:</b>						
Device	\$ 285,345	\$ -	\$ 285,345	\$ 246,968	\$ 32,500	\$ 279,468
Handpieces	631,311	-	631,311	578,827	4,000	582,827
Other	18,889	-	18,889	24,880	-	24,880
<b>Total International Rest of the World</b>	<b>\$ 935,545</b>	<b>\$ -</b>	<b>\$ 935,545</b>	<b>\$ 850,675</b>	<b>\$ 36,500</b>	<b>\$ 887,175</b>
<b>International China:</b>						
Device	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Handpieces	50,000	-	50,000	-	-	-
Other	-	-	-	-	-	-
<b>Total International China</b>	<b>\$ 50,000</b>	<b>\$ -</b>	<b>\$ 50,000</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
<b>Total Product Sales</b>	<b>\$ 1,915,509</b>	<b>\$ 400</b>	<b>\$ 1,915,909</b>	<b>\$ 1,769,105</b>	<b>\$ 36,500</b>	<b>\$ 1,805,605</b>

### Current Product Platform

See Note 1 Organization and Business.

### Results of Operations

The following table sets forth the consolidated results of operations for the three months ended March 31, 2019 compared to 2018. The trends suggested by this table may not be indicative of future operating results:

	2019	2018
<b>Operating results:</b>		
Product sales, net	\$ 1,915,909	\$ 1,805,605
Cost of products sold	618,694	562,676
Gross profit	1,297,215	1,242,929
<b>Operating expenses:</b>		
Selling, general and administrative expenses	2,109,050	3,018,780
Research and development expenses	6,346	225,817
Loss from operations	(818,181)	(2,001,668)
Other income, net	24,986	26,283
Net loss	(793,195)	(1,975,385)
Net loss attributable to noncontrolling interests	(10,443)	(101,407)
Net loss attributable to Milestone Scientific Inc.	\$ (782,752)	\$ (1,873,978)
<b>Cash flow:</b>		
	March 31, 2019	March 31, 2018
Net cash used in operating activities	\$ (220,171)	\$ (541,350)
Net cash used in investing activities	(8,104)	(1,368)
Net cash provided by financing activities	2,224,546	-

**Three months ended March 31, 2019 compared to Three months ended March 31, 2018**

**Net sales for 2019 and 2018 were as follows:**

	2019	2018	Increase	Decrease	%
Dental	\$ 1,915,509	\$ 1,769,105	\$ 146,404		8.2%
Medical	400	36,500	(36,100)		-98.90%
Total sales, net	<u>\$ 1,915,909</u>	<u>\$ 1,805,605</u>	<u>\$ 110,304</u>		<u>6.11%</u>

Consolidated revenue for the three months ended March 31, 2019 and 2018, were approximately \$1.9 million and \$1.8 million, respectively. The increase of 8% is primarily due to a 5% increase in Rest of World (ROW) revenue, principally due to increase in handpieces pricing to distributors. We are in the process of attending medical device trade shows and attending introductory meetings with medical device distributors within the United States and European markets.

**Gross Profit for 2019 and 2018 were as follows:**

	2019	2018	Increase	Decrease	%
Dental	\$ 1,296,842	\$ 1,218,026	\$ 78,816		6.47%
Medical	373	24,903	(24,530)		-98.50%
Total gross profit	<u>\$ 1,297,215</u>	<u>\$ 1,242,929</u>	<u>\$ 54,286</u>		<u>4.37%</u>

Consolidated gross margin for the three months ended March 31, 2019 and 2018, was approximately 68% and 69%, respectively.

**Selling, general and administrative expenses for 2019 and 2018 were as follows:**

	2019	2018	Increase	Decrease	%
Dental	\$ 804,180	\$ 860,861	\$ (56,681)		-6.58%
Medical	486,406	678,052	(191,646)		-28.26%
Corporate	818,464	1,479,867	(661,403)		-44.69%
Total selling, general and administrative expenses	<u>\$ 2,109,050</u>	<u>\$ 3,018,780</u>	<u>\$ (909,730)</u>		<u>-30.14%</u>

Consolidated selling, general and administrative expenses for the three months ended March 31, 2019 and 2018, were approximately \$2.1 million and \$3 million, respectively. The decrease of approximately \$0.9 million is categorized in several areas. Salaries, bonus, and recruiting fees decreased by approximately \$138,000 due to the reduction of personnel in the Medical Segment during 2018. Executive pension expense decreased by approximately \$50,000 in the first quarter of 2019 as the liability was finalized in 2018. Patent amortization decreased by approximately \$224,000 in 2018 compared to 2019 due to the write-down of the APAD patent (impairment in 2018). Professional legal and accounting fees decrease by approximately \$218,000 due to a reduction in special event analysis and non-renewal of a consulting agreement with a third party. Additional, international expense decreased approximately \$80,000 in the first quarter of 2019 as management placed a hold on incentive compensation.

**Research and Development for 2019 and 2018 were as follows:**

	2019	2018	Increase	Decrease	%
Dental	\$ 696	\$ -	\$ 696		100%
Medical	5,650	55,233	(49,583)		-89.77%
Corporate	-	170,584	(170,584)		-100.00%
Total research and development	<u>\$ 6,346</u>	<u>\$ 225,817</u>	<u>\$ (219,471)</u>		<u>-97.19%</u>

Consolidated research and development expenses for the three months ended March 31, 2019 and 2018, were approximately \$6,000 and \$226,000, respectively. The decrease is due to a reduction in development costs associated with the Epidural and Intra Articular devices.

**Profit (Loss) from Operations for 2019 and 2018 were as follows:**

	2019	2018	Increase	Decrease	%
Dental	\$ 491,966	\$ 357,165	\$ 134,801		37.74%
Medical	(491,683)	(708,382)	216,699		-30.59%
Corporate	(818,464)	(1,650,451)	831,987		-50.41%
Total loss from operations	<u>\$ (818,181)</u>	<u>\$ (2,001,668)</u>	<u>\$ 1,183,487</u>		<u>59.31%</u>

The loss from operations was approximately \$818,000 and \$2 million for the first quarter ending March 31, 2019 and 2018 respectively. The decrease in the loss quarter over quarter is due to a decrease in selling, general and administration expenses of approximately \$1 million and a reduction of approximately \$219,000 in research and development as noted in the previous section of this report. The dental segments are still the primary revenue and gross profit generator for the Company. The dental segment continues to gain revenue on a steady basis in the United States and Rest of the World and manage expenses during the process. Costs in the medical segment are beginning to increase as personnel are expanded in the U.S. to focus on our domestic Epidural device business.

**Liquidity and Capital Resources**

At March 31, 2019 Milestone Scientific had cash and cash equivalents of approximately \$2.7 million and working capital of approximately \$2.1 million versus working capital of \$1 million at December 31, 2018. For the three months ended March 31, 2019, we had negative cash flows from operating activities of approximately \$220,000 compared to \$541,000 for the three months ended March 31, 2018. Based on current and expected cash to be used in operating activities substantial doubt exists about the Company's ability to continue as a going concern for at least the next twelve months from the financial reporting date.

Management believes that the current cash flow and support from the dental business will not be able to mitigate the expected selling expenditures for the Epidural medical device commercialization, as well as other operating expenditures and new product development programs, over the next twelve months from the financial reporting date. Without additional funding a delay, scale back or elimination of some or all of the Company's medical commercial strategy or development programs could be required, all of which could have a material adverse impact on the Company.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception. The capital raised in February 2019 (a capital raise in a public and private offering) provides Milestone Scientific with working capital to continue marketing of the CompuFlo Epidural instrument and to market its dental devices. 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 reduction in operating expenses.

Now that the *CompuFlo* Epidural System has obtained FDA clearance in the United States (June 2017), the development costs were reduced in 2019 but the selling costs are expected to continue to increase. The FDA clearance has provided the Company with the opportunity to establish distribution in the USA. At the same time, the Company is looking to establish additional financing to support the Epidural device commercialization process. The intra-articular device will restart the 510K application process later this year.

**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, 2018 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 have been no changes in Milestone Scientific's internal control over financial reporting that occurred during Milestone Scientific's last fiscal quarter 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**

Milestone Scientific is not involved in any material litigation.

##### **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 February 2019, our board of directors granted United Systems (controlling shareholder, Tom Cheng) 285,714 shares of stock at \$.35 or \$100,000 for consulting services.

These securities were issued in reliance upon the exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"). These securities may not be offered or sold in the United States absent registration under or exemption from the Act and any applicable state securities laws.

##### **Item 3. Default upon Senior Securities**

Milestone Scientific is not involved in any material litigation.

##### **Item 4. Mine Safety Disclosure**

Not applicable.

##### **Item 5. Other Information**

None

## Item 6. Exhibits and Financial Statement Schedules

Exhibit No	Description
31.1	<a href="#"><u>Rule 13a-14(a) Certification-Chief Executive Officer*</u></a>
31.2	<a href="#"><u>Rule 13a-14(a) Certification-Chief Financial Officer*</u></a>
32.1	<a href="#"><u>Section 1350 Certifications-Chief Executive Officer**</u></a>
32.2	<a href="#"><u>Section 1350 Certifications-Chief Financial Officer**</u></a>
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 herewith and not filed, in accordance with item 601(32) (ii) of Regulation S-K.

SIGNATURES

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

**MILESTONE SCIENTIFIC INC.**

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

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

Date: May 14, 2019

**Rule 13a-14(a)/15d-14(a) Certification**

I, Leonard Osser, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Milestone Scientific Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2019

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



**Rule 13a-14(a)/15d-14(a) Certification**

I, Joseph D'Agostino, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Milestone Scientific Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2019

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

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Milestone Scientific Inc. ("Milestone") on Form 10-Q for the period ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard Osser, Interim Chief Executive Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone.

Date May 14, 2019

/s/ Leonard Osser

\_\_\_\_\_  
Leonard Osser  
Interim Chief Executive Officer  
(Principal Executive Officer)

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Milestone Scientific Inc. ("Milestone") on Form 10-Q for the period ending March 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph D'Agostino Chief Operating Officer and Chief Financial Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone.

Date May 14, 2019

/s/ Joseph D'Agostino

Joseph D'Agostino  
Chief Operating Officer  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.  
Is over financial reporting.