

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 June 30, 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:

Title of each class
Common Stock, par value \$.001 per share

Name of each exchange on which registered
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

Accelerated filer

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

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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

Title of each class
Common Stock

Trading Symbol(s)
MLSS

Name of Exchange on which registered
NYSE American

As of August 14, 2019, the registrant has a total of 47,490,155 shares of Common Stock, \$0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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
(Unaudited)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,337,593	\$ 743,429
Accounts receivable, net	1,658,919	1,978,456
Accounts receivable, related party, net	-	100,000
Prepaid expenses and other current assets	406,563	414,541
Deferred cost, related party	-	50,000
Inventories, net	1,270,480	1,921,051
Advances on contracts	530,114	648,783
Operating lease-right of use assets	92,830	-
Total current assets	6,296,499	5,856,260
Furniture, fixtures and equipment, net	65,668	82,557
Patents, net	408,767	435,273
Other assets	17,355	26,878
Total assets	\$ 6,788,289	\$ 6,400,968
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,192,823	\$ 1,205,396
Accounts payable, related party	1,283,367	1,663,849
Accrued expenses and other payables	1,464,846	1,481,715
Accrued expenses, related party	125,428	-
Operating lease liabilities-current	92,830	-
Deferred profit, related party	372,700	421,800
Deferred revenue, related party	-	100,000
Derivative liability	1,418,863	-
Total current liabilities	5,950,857	4,872,760
Total liabilities	\$ 5,950,857	\$ 4,872,760
Commitments and contingencies		
Stockholders' equity		
Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, 0 and 7,000 shares issued and outstanding as of June 30, 2019 and December 31, 2018.	\$ -	\$ 7
Common stock, par value \$.001; authorized 50,000,000 shares; 47,132,220 shares issued, 0 shares to be issued and 47,098,886 shares outstanding as of June 30, 2019 ; 33,859,034 shares issued, 2,470,565 shares to be issued and 33,825,701 shares outstanding as of December 31, 2018;	47,132	36,330
Additional paid in capital	89,559,585	88,414,718
Accumulated deficit	(87,823,965)	(85,999,929)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	871,236	1,539,610
Noncontrolling interest	(33,804)	(11,402)
Total stockholders' equity	\$ 837,432	\$ 1,528,208
Total liabilities and stockholders' equity	\$ 6,788,289	\$ 6,400,968

See notes to Condensed Consolidated Financial Statements

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

	For the three months ended June 30, 2019	For the three months ended June 30, 2018	For the six months ended June 30, 2019	For the six months ended June 30, 2018
Product sales, net	\$ 2,257,851	\$ 2,428,498	\$ 4,173,759	\$ 4,234,103
Cost of products sold	752,183	1,021,573	1,370,876	1,584,250
Gross profit	1,505,668	1,406,925	2,802,883	2,649,853
Selling, general and administrative expenses	2,517,970	2,821,837	4,627,023	5,840,601
Research and development expenses	95,529	9,775	101,875	235,592
Total operating expenses	2,613,499	2,831,612	4,728,898	6,076,193
Loss from operations	(1,107,831)	(1,424,687)	(1,926,015)	(3,426,340)
Other expenses	(2,563)	(1,756)	(4,825)	(3,457)
Interest income	188	1,926	1,207	4,590
Change in fair value of derivative liability	12,462	-	52,722	-
Loss before provision for income taxes and net losses of equity investments	(1,097,744)	(1,424,517)	(1,876,911)	(3,425,207)
Provision for income taxes	(14,163)	(4,075)	(18,627)	(15,538)
Loss before equity in net earnings (losses) of equity investments	(1,111,907)	(1,428,592)	(1,895,538)	(3,440,745)
(income)loss from earnings from China Joint Venture	(58,664)	(78,591)	(49,100)	(115,374)
Net loss	(1,053,243)	(1,350,001)	(1,846,438)	(3,325,371)
Net loss attributable to noncontrolling interests	11,959	6,994	22,402	108,657
Net loss attributable to Milestone Scientific Inc.	(1,041,284)	(1,343,007)	(1,824,036)	(3,216,714)
Net loss per share applicable to common stockholders—				
Basic	\$ (0.02)	\$ (0.04)	\$ (0.04)	\$ (0.09)
Diluted	\$ (0.02)	\$ (0.04)	\$ (0.04)	\$ (0.09)
Weighted average shares outstanding and to be issued—				
Basic	45,366,237	35,297,906	41,904,581	34,939,306
Diluted	45,366,237	35,297,906	41,904,581	34,939,306

See notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2019 AND 2018
(UNAUDITED)

	Preferred Stock Shares	Preferred Stock	Common Stock Share	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Treasury Stock	Total
Balance, January 1, 2019	<u>7,000</u>	<u>\$ 7</u>	<u>36,329,600</u>	<u>\$ 36,330</u>	<u>\$ 88,414,718</u>	<u>\$ (85,999,929)</u>	<u>\$ (11,402)</u>	<u>\$ (911,516)</u>	<u>\$ 1,528,208</u>
Stock based compensation	-	-	-	-	56,988	-	-	-	56,988
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
Reclassification of warrants and Shares to be issued to derivative liability (Note 8)	-	-	-	-	(406,045)	-	-	-	(406,045)
Net loss	-	-	-	-	-	(782,752)	(10,443)	-	(793,195)
Balance, March 31, 2019	<u>7,000</u>	<u>\$ 7</u>	<u>43,663,431</u>	<u>\$ 43,662</u>	<u>\$ 90,398,875</u>	<u>\$ (86,782,681)</u>	<u>\$ (21,845)</u>	<u>\$ (911,516)</u>	<u>\$ 2,726,502</u>
Stock based compensation	-	-	-	-	44,712	-	-	-	44,712
Common stock to be issued for payment of consulting services	-	-	265,140	265	139,735	-	-	-	140,000
Common stock to be issued to employee for compensation	-	-	41,667	42	14,958	-	-	-	15,000
Common stock to be issued to board of directors for services rendered	-	-	82,442	82	29,918	-	-	-	30,000
Conversion of Preferred Shares to Common Stock (Mandatory)	(7,000)	(7.00)	5,982,906	5,983	(5,976)	-	-	-	-
Reclassification of warrants and Shares to be issued to derivative liability (Note 8)	-	-	(2,903,366)	(2,902)	(1,062,637)	-	-	-	(1,065,539)
Net loss	-	-	-	-	-	(1,041,284)	(11,959)	-	(1,053,243)
Balance, June 30, 2019	-	\$ -	47,132,220	\$ 47,132	\$ 89,559,585	\$ (87,823,965)	\$ (33,804)	\$ (911,516)	\$ 837,432

	Preferred Stock Shares	Preferred Stock	Common Stock Share	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Treasury Stock	Total
Balance, January 1, 2018	<u>7,000</u>	<u>\$ 7</u>	<u>34,592,818</u>	<u>\$ 34,593</u>	<u>\$ 86,689,084</u>	<u>\$ (78,568,284)</u>	<u>\$ 256,744</u>	<u>\$ (911,516)</u>	<u>\$ 7,500,628</u>
Stock based compensation					\$ 86,809	-	-	-	86,809
Common stock to be issued to employees for bonuses			323,076	\$ 323	\$ 339,177	-	-	-	339,500
Common stock for Asset Acquisition						\$ (1,873,707)	\$ (101,663)		(1,975,370)
Net loss									-
Balance, March 31, 2018	<u>7,000</u>	<u>\$ 7</u>	<u>34,915,894</u>	<u>\$ 34,916</u>	<u>\$ 87,115,070</u>	<u>\$ (80,441,991)</u>	<u>\$ 155,081</u>	<u>\$ (911,516)</u>	<u>\$ 5,951,567</u>
Stock based compensation	-	-	-	-	84,092	-	-	-	84,092
Common stock to be issued to employees for bonuses	-	-	79,307	79	59,921	-	-	-	60,000
Common stock to be issued for payment of consulting services	-	-	296,046	294	249,455	-	-	-	249,749
Common stock to be issued to employee for compensation	-	-	37,267	37	37,463	-	-	-	37,500
Common stock for Asset Acquisition	-	-	244,959	245	286,357	-	-	-	286,602
Net loss	-	-	-	-	-	(1,343,007)	(6,994)	-	(1,350,001)
Balance, June 30, 2018	<u>7,000</u>	<u>\$ 7</u>	<u>35,573,473</u>	<u>\$ 35,571</u>	<u>\$ 87,832,358</u>	<u>\$ (81,784,998)</u>	<u>\$ 148,087</u>	<u>\$ (911,516)</u>	<u>\$ 5,319,509</u>

See notes to Condensed Consolidated Financial Statements

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

	For the six months ended June 30, 2019	For the six months ended June 30, 2018
Cash flows from operating activities:		
Net loss	\$ (1,846,437)	\$ (3,325,371)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	24,993	40,762
Amortization of patents	26,506	469,356
Stock compensation	101,700	170,901
Income from earnings on China joint venture	(49,100)	(115,374)
Inventory reserve	(2,061)	290,349
Change in fair value of derivative liability	(52,722)	-
Amortization of right-of-use assets	79,109	-
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	319,537	(304,632)
Decrease (increase) in accounts receivable, related party	100,000	(1,092,540)
Decrease in other receivables	9,523	-
Decrease in inventories	652,631	778,530
Decrease (increase) in advances on contracts	118,669	(164,590)
Decrease (increase) in prepaid expenses and other current assets	7,978	(48,343)
(Decrease) increase in accounts payable	(12,573)	511,632
(Decrease) increase in accounts payable, related party	(380,482)	243,360
Increase (decrease) in deferred cost, related party	50,000	(686,365)
Increase in accrued expenses	284,128	623,014
Increase in accrued expenses, related party	125,428	-
(Decrease) increase in deferred revenue, related party	(99,997)	1,092,540
Decrease in operating lease-right of use asset	(79,109)	-
Net cash used in operating activities	(622,279)	(1,516,771)
Cash flows from investing activities:		
Purchase of intangible assets	-	(4,531)
Purchase of property and equipment	(8,104)	-
Net cash used in investing activities	(8,104)	(4,531)
Cash flows from financing activities:		
(Payments for) financing transaction	-	(250,000)
Net proceeds from Public Placement Offering	1,974,547	-
Net proceeds from Private Placement Offering	250,000	-
Net cash provided by financing activities	2,224,547	(250,000)
Net increase (decrease) in cash and cash equivalents	1,594,164	(1,771,302)
Cash and cash equivalents at beginning of period	743,429	2,636,956
Cash and cash equivalents at end of period	<u>\$ 2,337,593</u>	<u>\$ 865,654</u>
Supplemental disclosure of cash flow information:		
Shares issued to employee for bonuses	\$ 61,500	\$ 399,500
Shares issue to board of directors for services rendered	\$ 37,000	\$ -
Shares issued to employees for compensation	\$ 22,500	\$ -
Shares issued to consultants in lieu of cash payments	\$ 180,000	\$ 249,749
Common stock issued for asset acquisition	\$ -	\$ 286,602
Sale of Milestone China share, financing transaction	\$ -	\$ (1,400,000)
Initial recognition of operating lease-right of use assets	\$ (166,292)	\$ -
Initial recognition of operating lease right to used liabilities	\$ 166,292	\$ -
Derivative liability for shares over allotment	\$ 1,471,585	\$ -

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*® has regulatory approval for epidural medical procedures, and is expected to be suitable, 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, US territories, 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’s Office of Device Evaluation, we intend to file a new 510(k) application for the device in 2019, providing the Company secures additional funding.

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. 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 terms are 5 years and they are exercisable at \$0.50. 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 terms are 5 years and they are exercisable at \$0.50.

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 June 30, 2019 cash on hand was \$2.3 million. 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 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 the three and six months ended June 30, 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. As of June 30, 2019 and December 31, 2018, accounts receivable (non-related party) 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 June 30, 2019 and December 31, 2018, inventory was recorded net of a valuation allowance for slow moving and defective inventory of approximately \$754,000 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.

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.

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; and
- 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 June 30, 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.

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 5,053,832 and 6,703,553 at June 30, 2019 and December 31, 2018, respectively.

18. Fair Value of Financial Instruments

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 or liabilities (see Note 8) measured at fair value on a recurring basis as of June 30, 2019.

	<u>Carrying Value</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Derivative Warrants	\$ 370,747	-	-	\$ 370,747
Shares to be issued-liability	1,045,212	1,045,212	-	-
Total June 30, 2019	<u>\$ 1,415,959</u>	<u>\$ 1,045,212</u>	<u>\$ -</u>	<u>\$ 370,747</u>

The following additional disclosures relate to the changes in fair value of the Company's Level 3 instruments during the six months ended June 30, 2019 :

	<u>June 30, 2019</u>
Balance at beginning of year	\$ -
Warrants issued in connection with public offering (See Note 8)	376,497
Change in fair value of derivative liability	(5,750)
Balance at end of period	<u>\$ 370,747</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), by ASU 2018-11, 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 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 \$166,292 in 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. For information regarding the impact of Topic 842 adoption, see Note 13 – Commitments.

On August 28, 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-13, Fair Value Measurement: Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (Topic 820), which changes the fair value measurement disclosure requirements of ASC 820. This ASU removes certain disclosure requirements regarding the amounts and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy and the policy for timing of transfers between the levels. This ASU also adds disclosure requirements regarding unrealized gains and losses included in Other Comprehensive Income for recurring Level 3 fair value measurements and the range and weighted average of unobservable inputs used in Level 3 fair value measurements. ASU 2018-13 is effective for all entities with fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of ASU 2018-13. The Company is currently evaluating the impact of adopting this standard.

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 sheet, results of operation and financial condition.

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. It is effective for fiscal years and interim periods, beginning after December 15, 2018. Milestone Scientific adopted this standard in on January 1, 2019. The adoption of this ASU will have immaterial effect on its presentation within the statement of Cash Flows.

NOTE 4 — INVENTORIES

Inventories consist of the following:	June 30, 2019	December 31, 2018
Dental finished goods, net	\$ 1,035,167	\$ 1,609,000
Medical finished goods, net	153,769	188,133
Component parts and other materials	81,544	123,918
Total inventories	<u>\$ 1,270,480</u>	<u>\$ 1,921,051</u>

At June 30, 2019 and December 31, 2018, there is a reserve for slow moving medical finished goods of \$452,120 and \$454,183, respectively, and damaged or 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 June 30, 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 amounted to \$ 2.8 million at the time of the payment arrangement. The payment terms required payments of \$200,000 per month beginning in July 2018 through November 2018 and a balloon payment of approximately \$1,425,000 during December 2018. Milestone Scientific 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, respectively. Due to the default on the arrangement and Milestone China’s liquidity constraints, Milestone Scientific halted shipments to Milestone China and 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 during the fourth quarter of 2018.

Milestone Scientific recognized revenue associated with sales to Milestone China and its agents of \$50,000 and \$100,000 for the three and six months ended June 30, 2019, respectively. For the three and six months ended June 30, 2018, Milestone Scientific recognized no revenue associated with sales to Milestone China and its agents.

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 previously recognized revenue from sales to Milestone China until that product is sold to third parties.

At June 30, 2019 and December 31, 2018, the deferred profit was \$372,200 and \$421,800, respectively, which is included in deferred profit, related party in the condensed consolidated balance sheets. For the three and six months ended June 30, 2019, Milestone Scientific recorded income on equity investment of \$58,664 and \$49,100 respectively, for product sold by Milestone China to third parties. For the three and six months ended June 30, 2018, Milestone Scientific recorded an income on equity investment of \$78,591 and \$115,374 respectively, for product sold by Milestone China to third parties.

Equity Method Disclosures

As June 30, 2019 and December 31, 2018, Milestone Scientific's investment in Milestone China was \$0. As of June 30, 2019 and December 31, 2018, Milestone Scientific’s share of cumulative losses of Milestone China were \$4,223,449 and \$3,380,388, respectively, which have been suspended.

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

	June 30, 2019 (unaudited)	December 31, 2018 (unaudited)
Assets:		
Current assets	\$ 13,966,781	\$ 10,587,648
Non-current assets	4,974,387	4,603,485
Total assets:	<u>\$ 18,941,168</u>	<u>\$ 15,191,133</u>
Liabilities:		
Current liabilities	\$ 23,276,964	\$ 17,696,033
Stockholders' deficit	(4,335,796)	(2,504,900)
Total liabilities and stockholders' deficit	<u>\$ 18,941,168</u>	<u>\$ 15,191,133</u>

	For the three months ended June 30, 2019 (unaudited)	For the three months ended June 30, 2018 (unaudited)	For the six months ended June 30, 2019 (unaudited)	For the six months ended June 30, 2018 (unaudited)
Net sales	\$ 1,149,474	\$ 1,328,079	\$ 1,753,802	\$ 2,085,034
Cost of goods sold	324,300	650,840	559,400	1,098,452
Gross profit	825,174	677,239	1,194,402	986,582
Other expenses	(1,423,353)	(1,119,440)	(3,302,057)	(2,371,652)
Net loss	\$ (598,179)	\$ (442,201)	\$ (2,107,655)	\$ (1,385,070)

NOTE 7 — PATENTS

	June 30, 2019			
	Cost	Impairment	Accumulated Amortization	Net
Patents-foundation intellectual property	\$ 1,377,863	\$ -	\$ (969,096)	\$ 408,767
Total	\$ 1,377,863	\$ -	\$ (969,096)	\$ 408,767

	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)	-
Total	\$ 4,017,510	\$ (1,539,794)	\$ (2,042,443)	\$ 435,273

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. Amortization expense was approximately \$13,000 and \$26,500 for the three and six months ended June 30, 2019, respectively. Amortization expense was approximately \$232,000 and \$469,000 for the three and six months ended June 30, 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 \$0.50. 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 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' terms are 5 years and they are exercisable at \$0.50

WARRANTS

The following table summarizes information about shares issuable under warrants outstanding at June 30, 2019 :

	Warrant shares outstanding	Weighted Average exercise price	Weighted Average remaining life	Intrinsic value
Outstanding at January 1, 2019	1,592,775	\$ 2.55	\$ 0.48	-
Issued	1,749,171	\$ 0.50	\$ 4.60	-
Exercised	-	-	-	-
Expired or cancelled	-	-	-	-
Outstanding and exercisable at June 30, 2019	3,341,946	\$ 1.48	\$ 2.60	-

PREFERRED STOCK

In May 2014, Milestone completed a private placement, which raised gross proceeds 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 occurs 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 as converted basis.

On May 14, 2019, the mandatory conversion date, the Preferred Stock was converted at a rate of \$1.17 per common share resulting in the issuances of 5,982,906 shares of common stock.

SHARES TO BE ISSUED

As of June 30, 2019 2,185,910 shares to be issued to employees were classified as liability until there are sufficient number of authorized shares of common stock to cover the issuance of the shares. As of December 31, 2018, there were 1,908,813 shares, 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 June 30, 2019, 717,456 shares to be issued to non-employees were classified as liability until there are sufficient number of authorized shares of common stock to cover the issuance of the shares. As of December 31, 2018, there were 561,752 shares, respectively, that will be issued to non-employees 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

As a result of the shares and warrants issued in the public and private offerings as well as other issuances of common stock during 2019, the Company does not have a sufficient number of authorized shares of common stock to cover the exercise and issue of approximately 4,850,000 outstanding equity instruments. Therefore, the warrants issued in the public and private placements during 2019 and 2016 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 is determined using a Black-Scholes option pricing model. The following assumptions were used to value the warrants at the reclassification to liability date:

	2016 Warrants	2019 Warrants
Expected Term	0.4 years	5 years
Volatility	100%	85%
Dividend yield	0.00%	0.00%
Exercise Price	\$ 2.55	\$ 0.50
Risk-free interest rate	2.09%	2.50%
Weighted average fair value of warrants granted	-	\$ 0.22
Number of shares underlying warrants granted	201,044	1,749,171

As these warrants are liability-classified, they were revalued at June 30, 2019 using the following assumptions:

	2016 Warrants	2019 Warrants
Expected Term	0.4 years	4.6 years
Volatility	100%	84%
Dividend yield	0.00%	0.00%
Exercise Price	\$ 2.55	\$ 0.50
Risk-free interest rate	2.09%	1.76%
Weighted average fair value of warrants granted	\$ -	\$ 0.21

For the three and six months ended June 30, 2019 the gain(loss) on the liability classified warrants was approximately (\$34,000) and \$6,000, respectively.

Additionally, approximately 2,900,000 of shares to be issued are classified as liabilities until there are sufficient number of authorized shares of common stock to cover the issuance of such shares. These shares were valued at the trading price of a share of the Company's common stock (\$0.36 as of June 30, 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. For the three and six months ended June 30, 2019 the gain(loss) on the liability classified shares to be issued was approximately \$47,000, respectively. 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 June 30, 2019 and December 31, 2018.

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:

	Three months ended June 30		Six months ended June 30	
	2019	2018	2019	2018
Sales				
Net Sales:				
Dental	\$ 2,242,751	\$ 2,388,898	\$ 4,158,259	\$ 4,158,003
Medical	15,100	39,600	15,500	76,100
Total net sales	<u>\$ 2,257,851</u>	<u>\$ 2,428,498</u>	<u>\$ 4,173,759</u>	<u>\$ 4,234,103</u>
Operating Income (Loss):				
Dental	\$ 629,474	\$ 723,084	\$ 1,121,440	\$ 1,080,249
Medical	(664,658)	(846,164)	(1,156,341)	(1,554,546)
Corporate	(1,072,647)	(1,301,607)	(1,891,114)	(2,952,043)
Total operating loss	<u>\$ (1,107,831)</u>	<u>\$ (1,424,687)</u>	<u>\$ (1,926,015)</u>	<u>\$ (3,426,340)</u>
Depreciation and Amortization:				
Dental	\$ 3,950	\$ 4,103	\$ 7,886	\$ 8,244
Medical	5,999	2,478	12,170	19,355
Corporate	15,507	238,546	31,445	482,519
Total depreciation and amortization	<u>\$ 25,456</u>	<u>\$ 245,127</u>	<u>\$ 51,501</u>	<u>\$ 510,118</u>
Income (loss) before taxes and equity in earnings of affiliates:				
Dental	\$ 627,051	\$ 725,007	\$ 1,120,035	\$ 1,084,829
Medical	(664,007)	(846,737)	(1,156,393)	(1,555,691)
Corporate	(1,060,788)	(1,302,787)	(1,840,553)	(2,954,345)
Total loss before taxes and equity in earnings of affiliate	<u>\$ (1,097,744)</u>	<u>\$ (1,424,517)</u>	<u>\$ (1,876,911)</u>	<u>\$ (3,425,207)</u>
Total Assets:			June 30, 2019	December 31, 2018
Dental			\$ 5,409,961	\$ 5,169,944
Medical			276,787	328,208
Corporate			1,101,541	902,816
Total assets			<u>\$ 6,788,289</u>	<u>\$ 6,400,968</u>

The following table presents information about our operations by geographic area for the three and six months June 30, 2019 and 2018. Net sales by geographic area are based on the respective locations of our subsidiaries:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Domestic-US & Canada				
Devices	\$ 146,289	\$ 11,505	\$ 270,285	\$ 132,553
Handpieces	1,030,391	1,158,975	1,819,544	1,927,506
Other	32,463	22,377	49,279	51,228
Total Domestic US & Canada	\$ 1,209,143	\$ 1,192,857	\$ 2,139,108	\$ 2,111,287
International ROW				
Devices	\$ 339,570	\$ 367,450	\$ 624,915	\$ 652,518
Handpieces	631,129	839,194	1,262,839	1,418,021
Other	28,009	28,997	46,897	52,277
Total International-ROW	\$ 998,708	\$ 1,235,641	\$ 1,934,651	\$ 2,122,816
International-China				
Devices	\$ -	\$ -	\$ -	\$ -
Handpieces	50,000	-	100,000	-
Other	-	-	-	-
Total International	\$ 50,000	\$ -	\$ 100,000	\$ -
Domestic, International Analysis				
Domestic-US & Canada	\$ 1,209,143	\$ 1,192,857	\$ 2,139,108	\$ 2,111,287
International -ROW	998,708	1,235,641	1,934,651	2,122,816
International -China	50,000	-	100,000	-
Total Product Sales	\$ 2,257,851	\$ 2,428,498	\$ 4,173,759	\$ 4,234,103

NOTE 11 – CONCENTRATIONS

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, *CompuDent*, *CompuMed* devices and handpieces, 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 June 30, 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 and six months ended June 30, 2019 an aggregate of approximately 52% and 50%, respectively, of Wand Dental's net product sales were to one customer/distributor. For the three and six months ended June 30, 2018 an aggregate of approximately 44% and 43%, respectively, of Wand Dental's net product sales were to one customer/distributor. Accounts receivable for two customer/distributor amounted to approximately \$2,850,461 or 82%, or 52% and 30% of Milestone Scientific's gross accounts receivable as of June 30, 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 June 30, 2019, Milestone China owed \$1,817,990 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 June 30, 2019. Additionally, Milestone Scientific has a reserve of \$1,250,928 at June 30, 2019 and December 31, 2018, against the associated deferred cost, related party which was recorded in 2018.

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 \$167,000 and \$505,600 for the three and six months ended June 30, 2019, respectively. Purchases from this manufacturer were approximately \$222,000 and \$574,000 for the three and six months ended June 30, 2018 respectively. As June 30, 2019 and December 31, 2018, Milestone Scientific owed this manufacturer approximately \$1.0 million, 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 as of June 30, 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 June 30, 2019 and December 31, 2018, Wand Dental had 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 was executed between Wand Dental and United Systems. 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 amounted to \$ 2.8 million at the time of the payment arrangement. The payment terms required payments of \$200,000 per month beginning in July 2018 through November 2018 and a balloon payment of approximately \$1,425,000 during December 2018. 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

Milestone Scientific owns a 40% interest in Milestone China. See Note 6.

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 and \$50,000 for the three and six months ended June 30, 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 and \$40,000 for the three and six months ended June 30, 2019 and 2018, respectively.

The Director of Clinical Affairs' royalty fee was approximately \$108,000 and \$199,000 for the three and six months ended June 30, 2019, respectively. The Director of Clinical Affairs' royalty fee was approximately \$116,956 and 202,481 for the three and six months ended June 30, 2018, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$78,000 for the three and six months ended June 30, 2019 respectively. Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$107,751 for the three and six months ended June 30, 2018 respectively. As of June 30, 2019 and December 31, 2018, Milestone Scientific owed the Director Clinical Affairs for royalties of approximately \$410,000 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 2019. As of June 30, 2019 we have an open purchase order of \$819,725 for 1,000 instruments and have advanced \$482,680 as of June 30, 2019 against these purchase commitment

(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 extended 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 June 30, 2019 were as follows:

Lease cost	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Operating lease cost	\$ 39,554	\$ 79,109
Total lease cost	\$ 39,554	\$ 79,109
Other information		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases		\$ 79,109
Right-of-use assets obtained in exchange for new operating lease liabilities		-
Weighted-average remaining lease term - operating leases		.06 years
Weighted-average discount rate - operating leases		9.2%

Maturities of lease liabilities due under these lease agreements as of June 30, 2019 are as follows:

	Operating Leases
2019 (excluding the 6 months ended June 30, 2019)	\$ 79,109
2020	15,976
2021	-
2022	-
2023	-
Thereafter	-
Total lease payments	\$ 95,085
Less: interest	\$ (2,255)
Total operating lease liabilities as of June 30, 2019	\$ 92,830

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	\$ 175,557	\$ 159,138	\$ 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. See Note-12- other.

NOTE 14— SUBSEQUENT EVENTS

In July 2019, Milestone Scientific Board of Directors approved the issuance of 200,000 Restricted Common Shares to a third party advisor to provide strategic planning and an opportunity for maximizing shareholder value for the company.

In July 2019, Milestone Scientific hired an Investor Relations Consultant for a term of 18 months. Compensation under the agreement will be 150,000 restricted shares.

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 60 other countries abroad. In June 2017, the FDA approved our 510(k) application for marketing clearance in the United States of our *CompuFlo* Epidural Computer Controlled Anesthesia System. We are in the process of introductory meetings with medical device distributors within the United States and Europe. There have been five medical instruments sold in the United States to date 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 remain 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 sale's 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.

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's 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, which we intend to do in 2019, subject to available funding.

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.

In April 2019, Milestone Scientific entered an Agreement with American 3B Scientific, a leading supplier of didactic material for education, for the development and sale of a CompuFlo® Epidural Training Instrument. This instructional instrument utilizes the pressure sensing technology and will be utilized as a training instrument to improve epidural placement success. The first sale of this new medical instrument occurred in May 2019, for three instruments and three disposable kits.

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 KOL's 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 product category for the period ending June 30, 2019 and 2018:

	Three months ended June 30,		Six months ended June 30,	
	2019	2018	2019	2018
Domestic-US & Canada				
Devices	\$ 146,289	\$ 11,505	\$ 270,285	\$ 132,553
Handpieces	1,030,391	1,158,975	1,819,544	1,927,506
Other	32,463	22,377	49,279	51,228
Total Domestic US & Canada	\$ 1,209,143	\$ 1,192,857	\$ 2,139,108	\$ 2,111,287
International ROW				
Devices	\$ 339,570	\$ 367,450	\$ 624,915	\$ 652,518
Handpieces	631,129	839,194	1,262,839	1,418,021
Other	28,009	28,997	46,897	52,277
Total International-ROW	\$ 998,708	\$ 1,235,641	\$ 1,934,651	\$ 2,122,816
International-China				
Devices	\$ -	\$ -	\$ -	\$ -
Handpieces	50,000	-	100,000	-
Other	-	-	-	-
Total International	\$ 50,000	\$ -	\$ 100,000	\$ -
Total Product Sales	\$ 2,257,851	\$ 2,428,498	\$ 4,173,759	\$ 4,234,103

Results of Operations

The following table sets forth the consolidated results of operations for the three and six months ended June 30, 2019 compared to 2018. The trends suggested by this table may not be indicative of future operating results:

	For three months ended June 30,		For six months ended June 30,	
	2019	2018	2019	2018
Operating results:				
Product sales, net	\$ 2,257,851	\$ 2,428,498	\$ 4,173,759	\$ 4,234,103
Cost of products sold	752,183	1,021,573	1,370,876	1,584,250
Gross profit	1,505,668	1,406,925	2,802,883	2,649,853
Operating expenses:				
Selling, general and administrative expenses	2,517,970	2,821,837	4,627,023	5,840,601
Research and development expenses	95,529	9,775	101,875	235,592
Loss from operations	(1,107,831)	(1,424,687)	(1,926,015)	(3,426,340)
Other income, and loss on earning net	54,588	74,686	79,577	100,969
Net loss	(1,053,243)	(1,350,001)	(1,846,438)	(3,325,371)
Net loss attributable to noncontrolling interests	11,959	6,994	22,402	108,657
Net loss attributable to Milestone Scientific Inc.	\$ (1,041,284)	\$ (1,343,007)	\$ (1,824,036)	\$ (3,216,714)
Cash flow:				
			June 30, 2019	June 30, 2018
Net cash used in operating activities			\$ (622,279)	\$ (1,516,771)
Net cash used in investing activities			(8,104)	(4,531)
Net cash provided by financing activities			2,224,547	(250,000)

For the three months ended June 30, 2019 compared to three months ended June 30, 2018

Net sales for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	\$ 2,242,751	\$ 2,388,898	\$ (146,147)	(6.12)%
Medical	15,100	39,600	(24,500)	(61.87)%
Total sales, net	\$ 2,257,851	\$ 2,428,498	\$ (170,647)	(7.03)%

Consolidated revenue for the three months ended June 30, 2019 and 2018, were approximately \$2.3 million and \$2.4 million, respectively. The decrease of approximately \$171,000 is primarily due to non-recurring order for handpieces and devices in 2018 from a Distributor in Mexico of approximately \$400,000. 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	\$ 1,499,329	\$ 1,613,059	\$ (113,730)	(7.05)%
Medical	6,339	(206,134)	212,473	(103.08)%
Total gross profit	\$ 1,505,668	\$ 1,406,925	\$ 98,743	7.02%

Consolidated gross margin for the three months ended June 30, 2019 and 2018, was approximately 67% and 58%, respectively. The consolidated gross margin for the three months ended June 30, 2019 did not require inventory write downs or reserve of \$290,000 as compared to the three months ended June 30, 2018.

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

	2019	2018	Increase Decrease	%
Dental	\$ 870,548	\$ 957,464	\$ (86,916)	(9.08)%
Medical	574,772	630,254	(55,482)	(8.80)%
Corporate	1,072,650	1,234,119	(161,469)	(13.08)%
Total selling, general and administrative expenses	\$ 2,517,970	\$ 2,821,837	\$ (303,867)	(10.77)%

Consolidated selling, general and administrative expenses for the three months ended June 30, 2019 and 2018, were approximately \$2.5 million and \$2.8 million, respectively. The decrease of approximately \$300,000 is categorized in several areas. Salaries, bonus, and recruiting fees decreased by approximately \$434,000 due to the reduction of bonuses in 2019. Executive pension expense decreased by approximately \$50,000 in the second quarter of 2019 as the Company's funding commitment was finalized in 2018. Employee recruiting expense increased by approximately \$70,000 as the Company is searching for specific commercial personnel. Patent amortization decreased by approximately \$218,000 in 2019 compared to 2018 due to the impairment of the APAD patent in the third quarter of 2018. Intellectual regulatory quality control increased by approximately \$92,000 as the Company prepares for changes in the European regulatory registration requirements. Professional legal and accounting fees increased by approximately \$143,000, related to a foreign operations, and additional consulting agreement with a third party. Additionally, marketing expense increased by approximately \$53,000 to support dental and medical revenues.

Research and Development for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	\$ -	\$ -	\$ -	0.00%
Medical	95,529	9,775	85,754	877.28%
Corporate	-	-	-	0.00%
Total research and development	<u>\$ 95,529</u>	<u>\$ 9,775</u>	<u>\$ 85,754</u>	<u>877.28%</u>

Consolidated research and development expenses for the three months ended June 30, 2019 and 2018, were approximately \$96,000 and \$10,000, respectively. The increase is due to an instrument modification to certain Epidural instruments in the development of an Epidural training instrument. The Epidural training instrument is not approved for use on humans or in a clinical setting.

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

	2019	2018	Increase Decrease	%
Dental	\$ 629,474	\$ 723,084	\$ (93,610)	(12.95)%
Medical	(664,658)	(846,164)	181,506	(21.45)%
Corporate	(1,072,647)	(1,301,607)	228,960	(17.59)%
Total loss from operations	<u>\$ (1,107,831)</u>	<u>\$ (1,424,687)</u>	<u>\$ 316,856</u>	<u>(22.24)%</u>

The loss from operations was approximately \$1 million and \$1.4 million for the three months ending June 30, 2019 and 2018 respectively. The decrease in loss quarter over quarter is due to an increase of gross profit of approximately \$100,000, a reduction in general administrative expense of approximately \$300,00 and increase in research and development expense of approximately \$100,000.

For the six months ended June 30, 2019 compared to six months ended June 30, 2018

Net sales for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	\$ 4,158,259	\$ 4,158,003	\$ 256	0.01%
Medical	15,500	76,100	(60,600)	(79.63)%
Total sales, net	<u>\$ 4,173,759</u>	<u>\$ 4,234,103</u>	<u>\$ (60,344)</u>	<u>(1.43)%</u>

Consolidated revenue for the six months ended June 30, 2019 and 2018 was approximately 4.2 million, respectively. The dental revenue for the six months ended June 30, 2018 included a non-recurring order for handpieces and devices in 2018 from a Distributor in Mexico of approximately \$400,000. 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	\$ 2,796,171	\$ 2,831,085	\$ (34,914)	(1.23)%
Medical	6,712	(181,232)	187,944	(103.70)%
Total gross profit	<u>\$ 2,802,883</u>	<u>\$ 2,649,853</u>	<u>\$ 153,030</u>	<u>5.78%</u>

Consolidated gross margin for the six months ended June 30, 2019 and 2018, was approximately 67% and 63%, respectively

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

	2019	2018	Increase Decrease	%
Dental	\$ 1,674,731	\$ 1,818,325	\$ (143,594)	(7.90)%
Medical	1,061,178	1,308,306	(247,128)	(18.89)%
Corporate	1,891,114	2,713,970	(822,856)	(30.32)%
Total selling, general and administrative expenses	\$ 4,627,023	\$ 5,840,601	\$ (1,213,578)	(20.78)%

Consolidated selling, general and administrative expenses for the six months ended June 30, 2019 and 2018, were approximately \$4.6 million and \$5.8 million, respectively. The decrease of approximately \$1.2 million is categorized in several areas. Bonuses decreased by \$620,000 based on management decision to curtail bonuses awards for the remainder of 2019. Also the Executive Pension expense decreased by \$101,000 as the Company's funding commitment was finalized in 2018. International consulting decreased by approximately \$77,000 as management decided to reduce these services in 2019. Stock based compensation decreased by \$65,000 as management did not provide stock options in 2018 to the executive team. Amortization expense for patents decreased by \$442,000 due to the impairment of the Apad patents in 2018. Professional fees decreased by \$188,000 relating to legal and accounting projects that ended in 2018. Marketing expenses increased by \$52,000 in the area of promotions and trials. Due to the quality control regulatory changes in the European community we incurred an increase in cost of approximately \$116,000 for the six months ended June 30, 2019.

Research and Development for 2019 and 2018 were as follows:

	2019	2018	Increase Decrease	%
Dental	\$ -	\$ -	\$ -	0.00%
Medical	101,875	65,008	36,867	56.71%
Corporate	-	170,584	(170,584)	(100.00)%
Total research and development	\$ 101,875	\$ 235,592	\$ (133,717)	(56.76)%

Research and development expenses for the six months ended June 30, 2019 and 2018, were approximately \$101,000 and \$236,000, respectively. The decrease is due management discretion and curtailment in the development of several new projects that were being worked on during 2018. Management decided make modification to some Epidural instruments for the development of an Epidural trainer instruments. CompuFlo® Epidural Trainer (CompuFlo Trainer), an instructional instrument that uses pressure sensing technology to improve epidural placement success. The CompuFlo Epidural Trainer is for training purposes only and not intended for clinical use.

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

	2019	2018	Increase Decrease	%
Dental	\$ 1,121,440	\$ 1,080,249	\$ 41,191	3.81%
Medical	(1,156,341)	(1,554,546)	398,205	(25.62)%
Corporate	(1,891,114)	(2,952,043)	1,060,929	(35.94)%
Total loss from operations	\$ (1,926,015)	\$ (3,426,340)	\$ 1,500,325	(43.79)%

The loss from operations was approximately \$1.9 million and \$3.4 million for six months ended June 30, 2019 and 2018 respectively. The decrease in the loss of approximately \$1.5 million relates to an increase in gross profit of approximately \$150,000, a reduction in administrative expenses of approximately \$1.2 million and reduction in research and development expenses of approximately \$135,000. The dental segment is still the primary revenue and gross profit generator for the Company. The dental segment continues to generate 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 June 30, 2019 Milestone Scientific had cash and cash equivalents of approximately \$2.3 million and working capital of approximately \$345,000 versus working capital of \$1 million at December 31, 2018. For the six months ended June 30, 2019, we had negative cash flows from operating activities of approximately \$620,000. 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) provided 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 is anticipated to restart the 510K application process later this year, if funding is available.

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 June 30, 2019 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 (whose controlling shareholder, Tom Cheng, is a significant shareholder of the Company) 285,714 shares of stock at \$0.35 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	<u>Rule 13a-14(a) Certification-Chief Executive Officer*</u>
31.2	<u>Rule 13a-14(a) Certification-Chief Financial Officer*</u>
32.1	<u>Section 1350 Certifications-Chief Executive Officer**</u>
32.2	<u>Section 1350 Certifications-Chief Financial Officer**</u>
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: August 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: August 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: August 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 June 30, 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 August 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 June 30, 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 August 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.