

MILESTONE SCIENTIFIC INC.
Form 10-Q
November 14, 2018

FORM 10-Q

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 September 30, 2018

Or

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

For the transition period from _____ to _____

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

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

220 South Orange Avenue, Livingston, NJ 07039

(Address of principal executive offices)

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

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

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$.001 per share	NYSE American

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
Emerging growth company	

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

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

As of November 14, 2018, the registrant has a total of 33,825,701 shares of Common Stock, \$0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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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 because of various factors. Such forward-looking statements should, therefore, be considered regarding 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, 2017 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 INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

ASSETS	September 30, 2018 (Unaudited)	December 31, 2017 (Audited)
Current Assets:		
Cash and cash equivalents	\$414,829	\$2,636,956
Accounts receivable, net	1,014,166	1,535,513
Accounts receivable, related party	1,258,995	1,725,450
Note receivable from financing transaction, current	-	500,000
Prepaid expenses and other current assets	446,264	436,410
Deferred cost, related party	790,190	1,109,671
Inventories, net	2,245,958	3,379,209
Advances on contracts	884,823	697,192
Total current assets	7,055,225	12,020,401
Furniture, fixtures & equipment, net	94,590	141,760
Patents, net	448,528	2,789,748
Note receivable from financing transaction, noncurrent	-	650,000
Other assets	26,878	26,878
Total assets	\$7,625,221	\$15,628,787
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$1,306,523	\$977,623
Accounts payable, related party	1,453,030	985,678
Accrued expenses and other payables	2,003,094	2,179,268
Accrued expenses, related party	64,748	108,640
Deferred profit, related party	492,884	751,500
Deferred revenue, related party	1,258,995	1,725,450
Total current liabilities	6,579,274	6,728,159
Deferred gain from financing transaction	-	1,400,000
Total liabilities	\$6,579,274	\$8,128,159
Commitments and Contingencies		
Stockholders' Equity	\$7	\$7

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Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, and 7,000 shares issued and outstanding		
Common stock, par value \$.001; authorized 50,000,000 shares; 33,748,226 shares issued, 1,909,175 shares to be issued and 33,714,893 shares outstanding as of September 30, 2018; 33,191,571 shares issued, 1,401,247 shares to be issued and 33,158,238 shares outstanding as of December 31, 2017;	35,655	34,593
Additional Paid in Capital	87,971,298	86,689,084
Accumulated deficit	(86,179,797)	(78,568,284)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	915,647	7,243,884
Noncontrolling interest	130,300	256,744
Total stockholders' equity	\$1,045,947	\$7,500,628
Total liabilities and stockholders' equity	\$7,625,221	\$15,628,787

See notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Product sales, net	\$ 1,622,246	\$ 2,853,813	\$ 5,856,351	\$ 9,066,550
Cost of products sold	1,742,451	1,044,540	3,326,341	3,320,411
Gross profit (loss)	(120,205)	1,809,273	2,530,010	5,746,139
Selling, general and administrative expenses	2,886,081	3,205,996	8,748,485	8,996,092
Research and development expenses	1,500	16,884	215,655	241,964
Impairment of long lived assets	1,539,794	-	1,539,794	-
Total operating expenses	4,427,375	3,222,880	10,503,934	9,238,056
Loss from operations	(4,547,580)	(1,413,607)	(7,973,924)	(3,491,917)
Other expenses	(1,784)	(1,046)	(5,239)	(3,278)
Interest income	1,544	3,582	6,135	6,495
Loss before provision for income taxes and equity in net losses of equity investments	(4,547,820)	(1,411,071)	(7,973,028)	(3,488,700)
Provision for income taxes	(1,622)	(6,475)	(17,160)	(18,339)
Loss before equity in net losses of equity investments	(4,549,442)	(1,417,546)	(7,990,188)	(3,507,039)
(Loss) Earnings on earnings from Milestone Education	1,635	-	1,635	-
Earnings (Loss) from China Joint Venture	143,242	-	258,616	(28,941)
Net loss	(4,404,565)	(1,417,546)	(7,729,937)	(3,535,980)
Net loss attributable to noncontrolling interests	11,742	6,605	118,424	138,915
Net loss attributable to Milestone Scientific Inc.	\$(4,392,823)	\$(1,410,941)	\$(7,611,513)	\$(3,397,065)
Net loss per share applicable to common stockholders—				
Basic	\$(0.12)	\$(0.04)	\$(0.22)	\$(0.10)
Diluted	\$(0.12)	\$(0.04)	\$(0.22)	\$(0.10)
Weighted average shares outstanding and to be issued—				
Basic	35,586,995	33,573,676	35,086,822	32,501,221
Diluted	35,586,995	33,573,676	35,086,822	32,501,221

See notes to Condensed Consolidated Financial Statements

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MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(UNAUDITED)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance, January 1, 2018	7,000	\$7	34,592,818	\$34,593	\$86,689,084	\$(78,568,284)	\$256,744	\$(911,516)	\$7,500,628
Stock based compensation	-	-	-	-	247,425	-	-	-	247,425
Common stock to be issued to employee for bonuses	-	-	422,120	422	414,078	-	-	-	414,500
Common stock issued for payment of consulting services	-	-	350,103	349	289,401	-	-	-	289,750
Common stock to be issued to employee for compensation	-	-	47,401	47	44,953	-	-	-	45,000
Common stock issued for Asset Acquisition	-	-	244,959	244	286,357	-	-	-	286,601
Acquired controlling interest in Milestone Education	-	-	-	-	-	-	(8,020)	-	(8,020)
Net loss	-	-	-	-	-	(7,611,513)	(118,424)	-	(7,729,937)
Balance as September 30, 2018	7,000	\$7	35,657,401	\$35,655	\$87,971,298	\$(86,179,797)	\$130,300	\$(911,516)	\$1,045,947

See notes to
Condensed

Consolidated
Financial Statements

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MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Nine Months Ended	
	September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(7,729,937)	\$(3,535,980)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	53,675	44,046
Amortization of patents	801,426	187,209
Impairment to long lived assets	1,539,794	-
Stock compensation	247,425	530,966
Equity (income) loss on China joint venture	(258,616)	28,941
Inventory reserve	728,017	-
Deferred cost reserve	790,189	-
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	521,347	(1,197,252)
Decrease in accounts receivable, related party	466,455	2,001,800
Decrease in other receivables	-	10,000
Decrease in inventories	405,234	436,998
Increase in advances on contracts	(187,631)	(291,342)
Increase in prepaid expenses and other current assets	(9,854)	(260,081)
Increase in other assets	-	(9,523)
Increase (decrease) in accounts payable	328,900	(725,170)
Increase (decrease) in accounts payable, related party	467,352	(332,711)
(Decrease) increase in deferred cost, related party	(470,708)	257,323
Increase in accrued expenses	859,677	1,583,624
Decrease in accrued expenses, related party	(43,892)	-
Decrease in deferred revenue, related party	(466,455)	(289,000)
Net cash used in operating activities	(1,957,602)	(1,560,152)
Cash flows from investing activities:		
Purchase of intangible assets	-	(39,520)
Purchase of property and equipment	(6,505)	(4,749)
Acquisition of Milestone Education	(8,020)	-
Purchase of intangibles assets-Apad	-	(153,647)
Net cash used in investing activities	(14,525)	(197,916)
Cash flows from financing activities:		
Proceeds (payments) financing transaction	(250,000)	250,000
Proceeds from exercise of stock options	-	62,500
Net proceeds on Private Placement Offering	-	150,836
Net cash (used in) provided by financing activities	(250,000)	463,336
Net decrease in cash and cash equivalents	(2,222,127)	(1,294,732)
Cash and cash equivalents at beginning of period	2,636,956	3,602,229

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Cash and cash equivalents at end of period	\$414,829	\$2,307,497
Supplemental disclosure of cash flow information:		
Shares issued to employees for bonuses	\$47,401	\$259,841
Shares issued to consultants in lieu of cash payments	\$350,103	\$422,249
Shares issued for assets acquired	\$-	\$2,484,354
Sale of Milestone China share, financing transaction	\$(1,400,000)	\$1,400,000
See notes to Condensed Consolidated Financial Statements		

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MILESTONE SCIENTIFIC INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1 — ORGANIZATION AND BUSINESS

All references in this report to “Milestone Scientific,” “us,” “our,” “we,” the “Company” or “Milestone” refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., Milestone Advanced Cosmetic Devices, 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 Device*®; 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 dentistry under the trademark *CompuDent*®, and *STA Single Tooth Anesthesia Device*® and in medicine under the trademark *CompuMed*®. *CompuDent*® is suitable for all dental procedures that require local anesthetic. *CompuMed*® is suitable for many medical procedures regularly performed in plastic surgery, hair restoration surgery, podiatry, colorectal surgery, dermatology, orthopedics and many other disciplines. The dental devices are sold in the United States, Canada and in 53 other countries. To date, there have been minimal sales of the Company’s medical devices in the United States and Europe.

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 (the “*CompuFlo* Epidural System”). In June 2017, the FDA approved the *CompuFlo* Epidural System for epidural injections. Milestone Scientific is in the process of meeting with medical device distributors within the United States and foreign markets. Milestone Scientific’s immediate focus is on marketing its epidural device throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k)-application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA Office of Device Evaluation, we filed a new 510(k) application for the device in June 2018. In August 2018, the FDA provided Milestone Scientific with a list of questions on the intra-articular 510(k) application filed in June 2018. Milestone Scientific is in the process of reviewing and responding to FDA questions.

NOTE 2 — GOING CONCERN AND LIQUIDITY

In accordance with Accounting Standard Codification (“ASC”) 205-40, “Presentation of Financial Statements – Going Concern”, 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. Additionally, there has been delayed payments for shipments made to Milestone China in 2017 and 2018. 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. The Company’s continued operations will depend on its ability to raise additional capital through various potential sources until it achieves profitability. 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 recover ability 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) and Milestone Medical (majority owned). Milestone Education was a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. Milestone Scientific purchased the remaining 50% of Milestone Education in September 2018, increasing its ownership of Milestone Education to 100%. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

2. Basis of Presentation

The unaudited condensed consolidated financial statements of Milestone Scientific have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information with the instructions for Form 10Q and Article 10 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, 2017, included in Milestone Scientific's Annual Report on Form 10-K.

3. Reclassifications

Certain reclassifications have been made to the 2017 financial statements to conform to the condensed consolidated 2018 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

4. Revenue Recognition

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

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

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

Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has no obligation on product sales for any installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Scientific's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Sales Returns

We generally do not accept non-defective returns from our customers. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Company's warranty policy. Returns not within the warranty policy are evaluated and the customer is charged for repair.

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 12 for revenues by geographical market, based on the customer's location, and product category for the three and nine months ended September 30, 2018 and 2017.

5. 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. As Milestone Scientific's equity at risk and voting rights were not proportional to their economic interest in Milestone China, Milestone China was determined to be a VIE. Milestone Scientific would be considered the primary beneficiary of the VIE if it has both of the following characteristics:

Power Criterion: The power to direct the activities that most significantly impact the entity's economic performance; and

Losses/Benefits Criterion: The obligation to absorb losses that could potentially be significant or the right to receive benefits that could potentially be significant to the VIE

Milestone 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 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 8.

6. 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.

7. Accounts Receivable

Milestone Scientific sells a significant amount of its product on credit terms to its major distributors. Milestone Scientific estimates losses from the inability of its customers to make payments on amounts billed. Most credit sales are due within 90 days from invoicing. There have not been any significant credit losses incurred to date. As of September 30, 2018, and December 31, 2017, accounts receivable was recorded, net of allowance for doubtful accounts of \$10,000.

8. 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, and obsolete inventory is recorded based on past and expected future sales, potential technological obsolescence and product expiration requirements.

9. 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 noncurrent assets on the Condensed Consolidated Balance Sheets. Under this method of accounting, Milestone Scientific's share of the net earnings or losses of the investee is presented below the income tax line on the Condensed Consolidated Statements of Operations. Milestone Scientific evaluates its equity method investments whenever events or changes in circumstance indicate that the carrying amounts of such investments may be impaired. If a decline in the value of an equity method investment is determined to be other than temporary, a loss is recorded in earnings in the current period.

10. Intangible Assets – Patents and Developed Technology

Patents are recorded at cost to prepare and file the applicable documents with the U.S. Patent and Trademark 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 will be amortized at the estimated average useful life of the patent. These patents and developed technology are recorded at the acquisition cost. See Note 9.

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

confidentiality agreements and restricted access to the facilities will be sufficient to protect the proprietary technology.

11. Impairment of Long-Lived Assets

As of September 30, 2018, Milestone Scientific has reviewed long-lived assets for any impairments. The carrying value of the assets is evaluated in relation to the operating performance and future undiscounted cash flows of the underlying assets when an impairment indicator or triggering event occurs. Milestone Scientific adjusts the net book value of an underlying asset if its fair value is determined to be less than its net book value. At September 30, 2018, Milestone Scientific identified that the APAD Patents purchased in 2017, will not be further developed (due to lack of financial resources) for commercial launch before their estimated useful life expires and have therefore been impaired. The amount of the charge for the three and nine months ended September 30, 2018 was approximately \$1,500,000. There were no impairment charges recorded during the three and nine months ended September 30, 2017.

12. 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.

13. 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.

14. Basic and diluted net loss per common share

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

Since Milestone Scientific had net losses for 2018 and 2017, the assumed effects of the exercise of potentially dilutive outstanding stock options and warrants were not included in the calculation as their effect would have been anti-dilutive. Such outstanding options and warrants totaled 3,518,668 and 3,710,335 at September 30, 2018 and December 31, 2017, respectively.

15. 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.

16. Stock-Based Compensation

Milestone Scientific accounts for stock-based compensation under ASC 718, “Compensation – Stock Compensation”. ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized as expense over the requisite service period as an operating expense, based on the grant-date fair values.

The fair value of the employee and non-employee options was estimated on the date of grant using the Black Scholes option-pricing model. For the three months ended September 30, 2018 and 2017, Milestone Scientific recognized approximately \$72,500 and \$300,000 of expense related to employee options, respectively. For the nine months ended September 30, 2018 and 2017, Milestone Scientific recognized approximately \$236,000 and \$543,000 of expense related to employee options, respectively. For the three months ended September 30, 2018 and 2017, Milestone Scientific recognized approximately \$4,000 of expense and \$6,000 of income related to non-employee options, respectively. For the nine months ended September 30, 2018 and 2017, Milestone Scientific recognized approximately \$11,000 of expense and \$12,000 of income related to non-employee options, respectively

17. Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update (“ASU”) No. 2016-02, “Leases (Topic 842)”. This ASU requires lessees to recognize a right of use asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Under Topic 842, a modified retrospective transition approach is required, and the new standard is applied to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. We expect to adopt the new standard on January 1, 2019 and use the effective date as our date of initial application. Consequently, prior period financial information will not be updated, and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. We are currently evaluating the impact of adopting this guidance on our consolidated balance sheets, results of operations and financial condition.

In February 2018, the FASB issued ASU No. 2018-02, “Income Statement – Reporting Comprehensive Income (Topic 220)”, which amends the previous guidance to allow for certain tax effects “stranded” in accumulated other comprehensive income, which are impacted by the Tax Cuts and Jobs Act (the “Act”), to be reclassified from accumulated other comprehensive income into retained earnings. This amendment pertains only to those items impacted by the new tax law and will not apply to any future tax effects stranded in accumulated other comprehensive income. This standard is effective for fiscal years beginning after December 15, 2018 and allows for early adoption. The Company does not anticipate that the adoption of this standard will have a material impact on the Company’s consolidated balance sheet.

In June 2018, the FASB issued ASU 2018-07 to simplify the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of

Accounting Standards Codification, or ASC, 718 to include share-based payments granted to non-employees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50. The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASC 606. The Company adopted this standard during the quarter ended September 30, 2018 and there was no material impact on the Company's condensed consolidated financial statements.

NOTE 4 — NOTES RECEIVABLE, RELATED PARTY

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

The transaction was accounted for as a secured financing and Milestone Scientific continued to account for its relationship with Milestone China under the equity method of accounting. A note receivable was presented on the Company's condensed consolidated balance sheet along with a deferred gain from financing transaction of \$1,400,000. The carrying value of the forty (40%) percent investment in Milestone China at the transaction date was zero.

As of March 2, 2018, the promissory note was in default. In April 2018, Milestone Scientific entered into a Release, Assignment and Termination Agreement (the "Termination Agreement") with the issuer of the promissory note, pursuant to which, Milestone Scientific repaid the \$250,000 payment made by the issuer and the issuer returned the shares of Milestone China's common stock to Milestone Scientific and cancelled the promissory note. Because of the Termination Agreement and related repayment made by Milestone Scientific, the Company derecognized the outstanding note receivable balance of \$1,150,000 and the related deferred gain from financing transaction of \$1,400,000. No gain or loss was recognized on the transaction.

NOTE 5 — INVENTORIES

Inventories at September 30, 2018 and December 31, 2017 consist of the following:

	September 30, 2018	December 31, 2017
Dental finished goods, net	\$1,855,538	\$2,846,272
Medical finished goods, net	209,329	475,285
Component parts and other materials	181,091	57,652
Total inventories	\$2,245,958	\$3,379,209

As of September 30, 2018, and December 31, 2017, inventory was recorded net of allowance for slow moving and damaged inventory of approximately \$783,000 and \$220,000, respectively.

NOTE 6 — ADVANCES ON CONTRACTS

The advances on contracts represent funding of future STA inventory purchases and Epidural replacements parts. The balance of the advances as of September 30, 2018 and December 31, 2017 was \$884,823 and \$697,192 respectively. The advance are classified as current based on the estimated annual usage of the underlying inventory.

NOTE 7 – CONSOLIDATION OF VARIABLE INTEREST ENTITY

Milestone Education was, until September 2018 (see below), a 50% owned subsidiary of Milestone Scientific which began operations in 2013 to provide training and education to dentists throughout the world. As of September 30, 2018, and 2017, approximately 80% and 81%, respectively, of the revenue earned by Milestone Education is from services performed for Milestone Scientific. Because of this dependency and relationship, we determined that Milestone Scientific had the power to direct the activities that most significantly impact Milestone Education's economic performance, and therefore Milestone Education is consolidated in our financial statements. Milestone Scientific purchased the remaining 50% of Milestone Education in September 2018 for a nominal purchase price. Milestone Scientific acquired the non-controlling interest in the amount of \$8,020.

NOTE 8 – INVESTMENT IN UNCONSOLIDATED AFFILIATE

Milestone China Ltd.

In June 2014, Milestone Scientific invested \$1 million in Milestone China Ltd. (“Milestone China”) by contributing 772 STA Instruments to Milestone China for a 40% ownership interest. Milestone Scientific recorded this investment under the equity method of accounting. As of September 30, 2018, and December 31, 2017, Milestone Scientific's investment in Milestone China was \$0. As of September 30, 2018, and December 31, 2017, Milestone Scientific's share of cumulative losses of Milestone China were \$3,881,726 and \$3,147,470, respectively, which have been suspended.

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 intra-entity profit is required as of the balance sheet date. In accordance with ASC 323, “Investments – Equity Method and Joint Ventures”, Milestone Scientific has deferred 40% of the gross profit associated with recognized revenue from Milestone China that has not been sold to third parties by Milestone China. At September 30, 2018 and December 31, 2017, deferred profit was \$492,884 and \$751,500, respectively, which is included in deferred profit, related party in the condensed consolidated balance sheets. Milestone Scientific recorded earnings and loss on its investment in Milestone China of \$143,242 and \$258,616 for the three and nine months ended September 30, 2018, respectively, and \$0 and (\$28,941) for the three and nine months ended September 30, 2017, respectively, inclusive of the change in intra-entity deferral of profit.

Milestone Scientific defers the total revenue and costs of goods sold when devices and handpieces are shipped to Milestone China and Milestone China's agents due to market conditions and Milestone China liquidity concerns, until a payment is received. As of September 30, 2018, Milestone Scientific had deferred revenues and deferred costs associated with sales to Milestone China and its agents was approximately \$1.3 million and \$790,000, respectively. As of December 31, 2017, Milestone Scientific had deferred revenues and deferred costs associated with sales to Milestone China and its agents was approximately \$1.7 million and \$1.1 million, respectively. Milestone Scientific recognized \$300,000 related party revenue from Milestone China and its agents during the three and nine months ended September 30, 2018. Milestone Scientific recognized \$356,400 and \$1.7 million of related party revenue for the three and nine months ended September 30, 2017. See Note 14 for related party transactions.

As of September 30, 2018, Milestone China missed its schedule payment of \$200,000 in accordance with the previously agreed upon payment terms with Milestone Scientific Inc. which requires \$200,000 per month through November 2018 and a balloon payment of approximately \$1,425,000 during December 2018. 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 \$1,258,995. Additionally, Milestone Scientific recorded a reserve of \$790,189 against the associated deferred cost, related party. These reserves will be

reviewed periodically and adjusted based on updated fact and circumstances.

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

	September 30, 2018	December 31, 2017
Assets:		
Current assets	\$ 13,972,657	\$ 13,127,422
Non-current assets	2,920,936	3,213,520
Total assets:	\$ 16,893,593	\$ 16,340,942
Liabilities:		
Current liabilities	21,122,545	18,468,937
Stockholders' equity	(4,228,952)	(2,127,995)
Total liabilities and stockholders' equity	\$ 16,893,593	\$ 16,340,942

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net sales	\$1,710,473	\$1,382,588	\$3,795,507	\$2,548,140
Cost of goods sold	789,957	556,430	1,888,409	1,445,634
Gross Profit	920,516	826,158	1,907,098	1,102,506
Other Expenses	(1,371,085)	(1,886,180)	(3,742,737)	(3,487,845)
Net Losses	\$(450,569)	\$(1,060,022)	\$(1,835,639)	\$(2,385,339)

NOTE 9 — INTANGIBLE ASSETS, PATENTS

Patents at September 30, 2018 and December 31, 2017 are comprised of the following:

	September 30, 2018				December 31, 2017			
	Cost	Impairment	Accumulated Amortization	Net	Cost	Impairment	Accumulated Amortization	Net
Patents-foundation intellectual property	\$1,377,863	\$-	\$(929,335)	\$448,528	\$1,377,863	\$-	\$(787,821)	\$590,042
Epidural-Apad acquired patents	2,639,647	(1,539,794)	(1,099,853)	-	2,639,647	-	(439,941)	2,199,706
Total	\$4,017,510	\$(1,539,794)	\$(2,029,188)	\$448,528	\$4,017,510	\$-	\$(1,227,762)	\$2,789,748

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. At September 30, 2018, Milestone Scientific identified that the APAD Patents purchased in 2017, will not be developed (due to lack of financial resources) into marketable instruments in the near term. As such, Management has determined that these patents meet the accounting requirements for impairment. The impairment charge for the three and nine months ended September 30, 2018 was \$1,539,794. Amortization expense was \$332,071 and \$151,845 for the three months ended September 30, 2018 and 2017, respectively. Amortization expense was \$801,426 and \$187,209 for the nine months ended September 30, 2018 and 2017, respectively.

NOTE 10 — STOCKHOLDERS' EQUITY

Shares to be Issued

As of September 30, 2018, and December 31, 2017, there were 1,909,175 and 1,401,247 shares of common stock, respectively, whose issuance has been deferred under the terms of an employment agreements with the Interim Chief Executive Officer, Chief Financial Officer and other employees of Milestone Scientific. Such shares will be issued to each such person upon termination of their employment. The number of shares was fixed at the date of grant and were fully vested upon grant date.

Shares Reserved for Future Issuance

As of September 30, 2018, and December 31, 2017 there were 5,300,854 and 5,111,582 shares reserved for future issuance and 3,518,668, and 3,710,335 shares underlying other stock options and warrants outstanding, respectively. At September 30, 2018 and December 31, 2017, there were 1,909,175 shares and 1,401,247 shares, respectively, reserved for issuance in settlement of deferred compensation to officers of Milestone Scientific.

NOTE 11 — INCOME TAXES

Due to Milestone Scientific's history of operating losses, a full valuation allowances have been provided for all of Milestone Scientific's deferred tax assets. As of September 30, 2018, and December 31, 2017, no recognition was given to the utilization of the remaining net operating loss carry-forwards in each of these periods.

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

Accounting for uncertainties in income taxes prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition. At September 30, 2018, and December 31, 2017, we had no uncertain tax positions that required recognition in the consolidated financial statements. Tax returns for the 2014, 2015, 2016 and 2017 years are subject to audit by federal and state jurisdictions.

NOTE 12 — SEGMENT AND GEOGRAPHIC DATA

We conduct our business through two reportable segments dental and medical. These segments offer different products to different customer base.

The following tables present information about our reportable and operating segments:

Sales	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
Net Sales:	2018	2017	2018	2017
Dental	\$1,622,246	\$2,853,813	\$5,780,251	\$9,066,550
Medical	-	-	76,100	-
Total net sales	\$1,622,246	\$2,853,813	\$5,856,351	\$9,066,550
Operating Income (Loss):	2018	2017	2018	2017
Dental	\$(893,148)	\$711,589	\$119,613	\$2,547,599
Medical	(454,306)	(517,938)	(2,008,852)	(1,746,391)
Corporate	(3,200,126)	(1,607,258)	(6,084,685)	(4,293,125)
Total operating Income (loss)	\$(4,547,580)	\$(1,413,607)	\$(7,973,924)	\$(3,491,917)
Depreciation and Amortization:	2018	2017	2018	2017
Dental	\$3,889	\$4,261	\$12,133	\$13,187
Medical	2,530	5,515	21,884	21,436
Corporate	338,565	155,092	821,084	196,632
Total depreciation and amortization	\$344,984	\$164,868	\$855,101	\$231,255
Income (loss) before taxes and equity in earnings of affiliates:	2018	2017	2018	2017
Dental	\$(959,095)	\$714,840	\$125,734	\$2,553,437
Medical	(454,906)	(518,398)	(2,010,595)	(1,747,791)
Corporate	(3,133,819)	(1,607,513)	(6,088,167)	(4,294,346)
	\$(4,547,820)	\$(1,411,071)	\$(7,973,028)	\$(3,488,700)

Total income (loss) before taxes and equity in earnings of
affiliate

Total Assets:	September 30,	December 31,
	2018	2017
Dental	\$6,380,314	\$10,255,144
Medical	384,849	655,513
Corporate	860,058	4,718,130
Total assets	\$7,625,221	\$15,628,787

The following table presents information about our operations by geographic area.

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Domestic-US & Canada				
Devices	\$119,190	\$452,232	\$251,743	\$857,525
Handpieces	369,027	893,496	2,296,533	3,230,567
Other	21,037	12,338	72,265	53,037
Total Domestic US & Canada	\$509,254	\$1,358,066	\$2,620,541	\$4,141,129
International ROW				
Devices	\$299,872	\$340,575	\$952,390	\$1,053,050
Handpieces	506,880	765,821	1,924,901	2,068,007
Other	6,240	32,951	58,519	89,764
Total International-ROW	\$812,992	\$1,139,347	\$2,935,810	\$3,210,821
International-China				
Devices	\$-	\$		