

MILESTONE SCIENTIFIC INC.

Form 10-Q

May 15, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarter ended March 31, 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

State or other jurisdiction of Incorporation or organization

13-3545623

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

220 South Orange Avenue, Livingston, NJ 07039

(Address of principal executive offices)

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

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

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

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

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

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

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

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

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

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

As of May 15, 2018, the registrant has a total of 33,468,197 shares of Common Stock, \$0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

MILESTONE SCIENTIFIC INC.

Form 10-Q

TABLE OF CONTENTS

PART I—FINANCIAL INFORMATION

Financial Statements

Item 1.

Condensed Consolidated Balance Sheets March 31, 2018 (Unaudited) and December 31, 2017 (Audited) 4

Condensed Consolidated Statements of Operations for the three months ended March 31, 2018 and 2017 (Unaudited) 5

Condensed Consolidated Statement of Changes in Stockholders' Equity for the three months ended March 31, 2018 (Unaudited) 6

Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2018 and March 31, 2017 (Unaudited) 7

Notes to Condensed Consolidated Financial Statements (Unaudited) 8

Item 2.

Management's Discussion and Analysis of Financial Condition and Results of Operations 21

Item 3.

Quantitative and Qualitative Disclosures About Market Risk 25

Item 4.

Controls and Procedures 25

PART II—OTHER INFORMATION

Item 1.

	Legal Proceedings	26
Item 1A.	Risk Factors	26
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	26
Item 3.	Defaults Upon Senior Securities	26
Item 4.	Mine Safety Disclosures	26
Item 5.	Other Information	26
Item 6.	Exhibits	27
	Signatures	

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 considering 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

	March 31, 2018 (Unaudited)	December 31, 2017 (Audited)
ASSETS		
Current Assets:		
Cash and cash equivalents	\$2,094,238	\$2,636,956
Accounts receivable, net	833,836	1,535,513
Accounts receivable from related party	1,725,450	1,725,450
Notes receivable from financing transaction, current	500,000	500,000
Prepaid expenses and other current assets	494,717	436,410
Deferred cost related party	1,109,671	1,109,671
Inventories, net	3,265,058	3,379,209
Advances on contracts	984,408	697,192
Total current assets	11,007,378	12,020,401
Furniture, fixtures & equipment, net	115,502	141,760
Patents, net	2,552,382	2,789,748
Notes receivable from financing transaction, noncurrent	650,000	650,000
Other assets	26,878	26,878
Total assets	\$14,352,140	\$15,628,787

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities:		
Accounts payable	\$1,556,689	\$977,623
Accounts payable related party	1,075,078	985,678
Accrued expenses and other payables	1,928,654	2,287,908
Deferred profit, related party	714,717	751,500
Deferred revenue, related party	1,725,450	1,725,450
Total current liabilities	7,000,588	6,728,159
Deferred gain from financing transaction	1,400,000	1,400,000
Total liabilities	8,400,588	8,128,159

Commitments and Contingencies

Stockholders' Equity

Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, and 7,000 shares issued and outstanding as of March 31, 2018 and December 31, 2017	7	7
Common stock, par value \$.001; authorized 50,000,000 shares; 33,216,571 shares issued, 1,699,323 shares to be issued and 33,183,238 shares outstanding as of March 31, 2018; 33,191,571 shares issued, 1,401,247 shares to be issued and 33,158,238 shares outstanding as of December 31, 2017;	34,915	34,593
Additional paid-in capital	87,115,071	86,689,084
Accumulated deficit	(80,442,262)	(78,568,284)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	5,796,215	7,243,884
Noncontrolling interest	155,337	256,744
Total stockholders' equity	5,951,552	7,500,628
Total liabilities and stockholders' equity	\$14,352,140	\$15,628,787

See notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended	
	March 31, 2018	March 31, 2017
Revenue		
Product sales, net	\$ 1,805,605	\$ 3,688,988
Cost of products sold	562,676	1,402,285
Gross profit	1,242,929	2,286,703
Selling, general and administrative expenses	3,018,780	2,707,620
Research and development expenses	225,817	105,015
Total operating expenses	3,244,597	2,812,635
Loss from operations	(2,001,668)	(525,932)
Other expenses	(1,700)	(1,209)
Interest income	2,664	758
Loss before provision for income taxes and equity in net losses of equity investments	(2,000,704)	(526,383)
Provision for income taxes	(11,464)	(7,201)
Loss before equity in net losses of equity investments	(2,012,168)	(533,584)
Loss on earnings from China Joint Venture	36,783	(44,401)
Net loss	(1,975,385)	(577,985)
Net loss attributable to noncontrolling interests	(101,407)	(73,117)
Net loss attributable to Milestone Scientific Inc.	\$(1,873,978)	\$(504,868)
Net loss per share applicable to common stockholders—		
Basic	\$(0.06)	\$(0.02)
Diluted	\$(0.06)	\$(0.02)
Weighted average shares outstanding and to be issued—		
Basic	34,766,014	32,004,548
Diluted	34,766,014	32,004,548

See notes to Condensed Consolidated Financial Statements

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	-	-			86,809	-	-	-	86,809
Common stock to be issued to employee for bonuses			323,076	323	339,177	-	-	-	339,500
Net loss	-	-				(1,873,978	)(101,407	)-	(1,975,385)
Balance, March 31, 2018	7,000	\$ 7	34,915,894	\$ 34,915	\$ 87,115,071	\$ (80,442,262	)\$ 155,337	\$ (911,516	)\$ 5,951,552

See notes to Condensed Consolidated Financial Statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	March 31, 2018	March 31, 2017
Cash flows from operating activities:		
Net loss	\$(1,975,385)	\$(577,985)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	27,625	16,860
Amortization of patents	237,366	17,682
Stock compensation	86,809	116,718
Equity income on China joint venture	(36,783)	-
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	701,677	(824,182)
Decrease in accounts receivable related party	-	1,400,801
Decrease in inventories	114,151	68,885
Increase to in advances on contracts	(287,216)	(161,114)
Increase in prepaid expenses and other current assets	(58,307)	(207,613)
Increase in other assets	-	(9,523)
Decrease in deferred cost, related party	-	438,925
Increase (decrease) in accounts payable	579,070	(452,157)
Increase (decrease) in accounts payable related party	89,400	(152,748)
(Decrease) increase in accrued expenses and other payables	(19,757)	96,841
(Decrease) in deferred revenue, related party	-	(645,400)
Net cash used in operating activities	(541,350)	(874,010)
Cash flows from investing activities:		
Purchase of property and equipment	(1,368)	-
Net cash used in investing activities	(1,368)	-
Cash flows from financing activities:		
Net proceeds on Public offering	-	150,836
Proceeds from exercise of stock options	-	62,500
Net cash provided by financing activities	-	213,336
Net decrease in cash and cash equivalents	(542,718)	(660,674)
Cash and cash equivalents at beginning of period	2,636,956	3,602,229
Cash and cash equivalents at end of period	\$2,094,238	\$2,941,555
Supplemental disclosure of cash flow information:		
Shares issued to employees for bonuses	\$339,500	\$195,000
Shares issued to consultants in lieu of cash payments	\$-	\$43,750
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 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 *no* 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.

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 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.

In *December 2016*, we received notification from the FDA that based upon the *510(k)*-application submitted for intra-articular injections, we did *not* adequately document that the device met the equivalency standard required for *510(k)* clearances. Following consultation with the FDA Office of Device Evaluation, we intend to file a new *510(k)* application for the device in *2018*.

NOTE 2- LIQUIDITY AND UNCERTAINTIES

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 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. The capital raised in *December 2016* and *January 2017* provided Milestone Scientific with working capital to continue to develop its medical devices and obtain regulatory approval for *one* of its *CompuFlo®* Epidural Computer Controlled Anesthesia System (the “*CompuFlo* Epidural System”), as well as 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, the generation of revenue from its medical devices and disposables business in the United States (following *June 2017* FDA approval of its *CompuFlo* Epidural System) and worldwide, and a reduction in operating expenses.

Management believes that Milestone Scientific will have sufficient cash reserves to meet its anticipated obligations over the next *twelve* months from the filing date of this quarterly report. However, Milestone Scientific will likely need to raise additional capital prior to the expected generation of sustainable positive cash flow from operating activities and *may* also need to raise additional capital to effectively launch its approved Epidural Device and eventually generate positive cash flow from the medical business.

The Company is subject to several risks like those of development stage companies, including dependence on key individuals and products, the difficulties inherent in the development of a commercial market, the potential need to obtain additional capital necessary to fund the development of its products, and competition from larger companies and other medical device companies that develop similar or substitute products. The Company's sales performance, selling and marketing expenditures to develop sales performance, as well as the status of each of its new product development programs and the resulting operating income (loss), will significantly impact its cash requirements.

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 is a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

2. Basis of Presentation

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

Revenue from product sales are 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 months ended March 31, 2018

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.

Milestone Scientific became the primary beneficiary of Milestone Education as of *January 2017*. Accordingly, the assets and liabilities of Milestone Education are included in the accompanying condensed consolidated financial statements.

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

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

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

Milestone management does not have the ability to control the activities that most significantly impact Milestone China's economics and, therefore, the power criterion has not been met. Management placed the most weight on the relationship and significance of activities of Milestone China to the majority shareholder/CEO of Milestone China. As majority shareholder, majority holder of voting rights, and the active CEO, the 53% investor has the power to direct the activities that most significantly impact the economic performance of Milestone China. Management has concluded that Milestone Scientific is not the primary beneficiary under ASC 810. Accordingly, Milestone China has not been consolidated into the financial statements of Milestone Scientific and continues to be accounted for under the equity method

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 of credit sales are due within 90 days from invoicing. There have *not* been any significant credit losses incurred to date. As of *March 31, 2018* and *December 31, 2017*, accounts receivable was recorded, net of allowance for doubtful accounts of *\$10,000*.

8. Note Receivable

Milestone Scientific values note receivable at historic cost less amount paid against principle. Milestone Scientific estimates losses on the note-based payments and credit quality of the debtor.

9. Product Return and Warranty

Milestone Scientific generally does *not* accept non-defective returns from its customers. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Company's 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, and obsolete inventory is recorded based on past and expected future sales, potential technological obsolescence and product expiration requirements. As of *March 31, 2018*, and *December 31, 2017*, inventory was recorded net of allowance for slow moving inventory of approximately \$220,000.

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 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.

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 will be amortized at the estimated average useful life of the patent. These patents and developed technology are recorded at the acquisition cost.

Patent defense costs, to the extent applicable, are expensed as incurred. 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.

14. Impairment of Long-Lived Assets

As of March 31, 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. There have been no impairment indicators or triggering events and therefore, there were no impairments as of March 31, 2018 and December 31, 2017.

15. Shipping and Handling Costs

Shipping and handling costs, if any, are paid by or billed to customers at the time of shipments. Domestic and international shipments are FOB warehouse; therefore, *no* costs are incurred by Milestone Scientific.

16. 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.

17. 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.

18. 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 3,510,335 and 3,710,335 at *March 31, 2018* and *December 31, 2017*, respectively.

19. 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.

20. Fair Value of Financial Instruments

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

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

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

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

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

21. 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 non-employee options was estimated on the date of grant using the Black Scholes option-pricing model. In accordance with the provisions of ASC 505, Milestone Scientific will re-measure the value of the grant at each presentation date unless there is a significant disincentive for non-performance or until performance has been rendered. For the *three* months *March 31, 2018* and *2017*, Milestone Scientific recognized approximately *\$4,000* of expense, and *\$17,100* of income related to non-employee options, respectively.

22. Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers (Topic 606)” (ASC 606). The standard, including subsequently issued amendments, replaces most existing revenue recognition guidance in U.S. GAAP. The key focus of the new standard is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted this new standard as of January 1, 2018 by using the modified-retrospective method.

In connection with the adoption, we performed a review of our existing revenue arrangements as of January 1, 2018 following the five-step model outlined in ASC 606.

Based on our analysis, there were no changes identified that impacted the amount or timing of revenues recognized under the new guidance as compared to the previous guidance. Additionally, our analysis indicated that there were no changes to how costs to obtain and fulfill our customer contracts would be recognized under the new guidance as compared to the previous guidance.

In February 2016, the FASB issued 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 the exception of short-term leases. The Company will adopt this standard on 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 August 2016, the FASB issued ASU No. 2016-15, "Statement Cash Flows – Classification of Certain Cash Receipts and Cash Payments" (Topic 230). The new standard provides guidance as to the conformity of presentation of certain cash receipts and disbursements. The Company adopted this standard during the quarter ended March 31, 2018 and there was no material impact on the Company's consolidated statements of cash flows.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation – Stock Compensation" (Topic 718). The new standard provides guidance and clarity for modification to equity-based compensation programs. The Company adopted this standard during the quarter ended March 31, 2018 and there was no material impact on the Company's consolidated financial statements.

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.

NOTE 4 — NOTES RECEIVABLE

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

As of *March 2, 2018*, the promissory note was in default. In *April 2018*, Milestone Scientific entered into a Release, Assignment and 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 1.4 million shares of Milestone China's common stock to Milestone Scientific and cancelled the promissory note (see Note 16).

NOTE 5 — INVENTORIES

Inventories at *March 31, 2018* and *December 31, 2017* consist of the following:

	March 31, 2018	December 31, 2017
Dental finished goods	\$2,786,334	\$2,846,272
Medical finished goods, net	453,454	475,285
Component parts and other materials	25,270	57,652
Total	\$3,265,058	\$3,379,209

As of *March 31, 2018*, and *December 31, 2017*, inventory was recorded net of allowance for slow moving inventory of approximately \$220,000.

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 *March 31, 2018* and *December 31, 2017* was \$984,408 and \$697,192 respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE 7 – CONSOLIDATION OF VARIABLE INTEREST ENTITY

Milestone Education is a 50% owned subsidiary of Milestone Scientific which began operations in 2013 to provide training and education to dentists throughout the world. As of *March 31, 2018*, and 2017, approximately 72% and 82% of the revenue earned by Milestone Education is from services performed for Milestone Scientific, respectively. Because of this dependency and relationship, we determined that we had the power to direct the activities that most significantly impact Milestone Education's economic performance, and therefore Milestone Education is consolidated in our financial statements.

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. For the three months ended March 31, 2018, and 2017, Milestone Scientific recorded a loss on its investment in Milestone China of \$0 and \$44,401, respectively, inclusive of the intra-entity deferral of profit. As of March 31, 2018 and December 31, 2017, Milestone Scientific's investment in Milestone China was \$0. As of March 31, 2018, and December 31, 2017, Milestone Scientific's share of cumulative losses of Milestone china were \$3,524,617 and \$3,147,470, respectively, which have been suspended.

As of March 2, 2018, the Note Receivable identified on the Balance Sheet was in default. If Milestone Scientific exercises its rights as a secured party it may be obligated to return to the purchaser up to the \$250,000 received for the Milestone China Shares as surplus. At March 31, 2018, Milestone Scientific did not receive a response from the purchaser of the Milestone China Shares and did not recorded any financial benefit from the sale of Milestone China Shares to date. Refer to Note 4 for subsequent actions.

Milestone Scientific had no related party sales of handpieces and devices to Milestone China and Milestone China's agent for three months ended March 31, 2018. Milestone Scientific had \$1,001,800 of related party sales of handpieces and devices to Milestone China for the three months ended March 31, 2017. Milestone Scientific defers the total revenue and costs of goods sold when devices and handpieces are shipped to Milestone China and Milestone China's agent due to market conditions and Milestone China liquidity concerns until a payment is received.

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-Q

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. At March 31, 2018 and December 31, 2017, the deferred profit was \$714,717 and \$751,500, respectively, which is included in deferred profit, related party in the, condensed consolidated balance sheets.

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

	March 31, 2018	December 31, 2017
Assets:		
Current assets	\$ 10,678,999	\$ 13,127,422
Non-current assets	3,381,262	3,213,520
Total assets:	\$ 14,060,261	\$ 16,340,942
Liabilities:		
Current liabilities	12,414,362	18,468,937
Stockholders' equity	1,645,899	(2,127,995)
Total liabilities and stockholders' equity	\$ 14,060,261	\$ 16,340,942
	March 31, 2018	March 31, 2017
Net sales	\$ 756,956	\$ 427,400
Cost of goods sold	(447,611)	(479,411)
Gross Profit	309,345	(52,011)
Other Expenses	(1,252,213)	(958,055)
Net Losses	\$(942,868)	\$(1,010,066)

NOTE 9 — PATENTS

Patents at *March 31, 2018* and *December 31, 2017* are comprised of the following:

	2018			2017		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Patents-foundation intellectual property	\$1,377,863	\$(805,216)	\$572,647	\$1,377,863	\$(787,821)	\$590,042
Epidural-APAD acquired patents	2,639,647	(659,912)	1,979,735	2,639,647	(439,941)	2,199,706
Total	\$4,017,510	\$(1,465,128)	\$2,552,382	\$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, with a weighted average amortization period of approximately 5 years.

On July 13, 2017, Milestone Scientific consummated a Asset Purchase Agreement (the “Agreement”) with APAD Octrooi B.V. and APAD B.V. (each, a “Seller” and collectively, the “Sellers”) pursuant to which Milestone Scientific acquired certain patent rights and other intellectual property rights related to the Sellers’ computer-controlled injection instrument (the “Purchased Assets”) and has been accounted for as an asset acquisition. On the closing date, Milestone Scientific issued to the Sellers an aggregate of 1,646,358 shares of its common stock, valued at approximately \$2,486,000 for the Purchased Assets which shares are subject to certain post-closing upward or downward adjustments not to exceed twenty-five percent of the initial shares as of the purchase date or 250,000 Euros, as defined in the agreement. As of March 31, 2018, and December 31, 2017, Milestone Scientific has recorded a liability of \$295,000 relating to the estimated additional shares that would have to be issued according this provision in the Agreement. The asset purchase price of approximately \$2,639,000, net of expenses has been capitalized and will amortized over their three-year estimated useful life.

Amortization expense was \$237,366 and \$17,682 for the three months ended March 31, 2018 and 2017, respectively. The annual amortization expense expected to be recorded for existing intangibles assets for the next five years from the balance sheet date of March 31, 2018 are as follows: \$927,000, \$920,000, \$259,000, \$39,000 and \$39,000, respectively.

NOTE 10 — STOCKHOLDERS’ EQUITY

Shares to be Issued

As of *March 31, 2018*, and *December 31, 2017*, there were *1,699,323* and *1,401,247* shares of common stock, respectively, whose issuance has been deferred under the terms of an employment agreements with the Chief Executive Officer, Chief Financial Officer and other employees of Milestone Scientific. Such shares will be issued to each 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 *March 31, 2018*, and *December 31, 2017* there were *5,209,658* and *5,111,582* shares reserved for future issuance and *3,510,335*, and *3,710,335* shares underlying other stock options and warrants outstanding, respectively. At *March 31, 2018* and *December 31, 2017*, there were *1,699,323* 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 *March 31, 2018*, and *December 31, 2017*, no recognition was given to the utilization of the remaining net operating loss carryforwards in each of these periods.

The utilization of Milestone Scientific's net operating losses *may* be subject to a substantial limitation due to the "change of ownership provisions" under Section 382 of the Internal Revenue Code and similar state provisions. Such limitation *may* result in the expiration of the net operating loss carry forwards before their utilization. Milestone Scientific has established a *100%* valuation allowance for all 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 *March 31, 2018*, and *December 31, 2017*, we had *no* uncertain tax positions that required recognition in the consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the Statements of Operations.

No interest and penalties are present for periods open. 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	
	March 31,	
Net Sales:	2018	2017
Dental	\$1,769,105	\$3,688,988
Medical	36,500	-
Total	\$1,805,605	\$3,688,988

Operating (Loss):	2018	2017
Dental	\$357,165	\$1,275,631
Medical	(708,382)	(624,326)
Corporate	(1,650,451)	(1,177,237)
Total	\$(2,001,668)	\$(525,932)

Depreciation and Amortization:	2018	2017
Dental	\$4,141	\$4,468
Medical	16,877	9,360
Corporate	243,973	20,714
Total	\$264,991	\$34,542

Loss before taxes and equity in losses of affiliates:	2018	2017
Dental	\$359,822	\$1,276,099
Medical	(708,954)	(624,796)
Corporate	(1,651,572)	(1,177,686)
Total	\$(2,000,704)	\$(526,383)

Total Assets:	March 31, 2018	December 31, 2017
Dental	\$9,302,960	\$10,255,144
Medical	667,770	655,513
Corporate	4,381,410	4,718,130
	\$14,352,140	\$15,628,787

The following table presents information about our operations by geographic area as *March 31, 2018* and *2017*. Net sales by geographic area are based on the respective locations of our subsidiaries

	March 31, 2018	March 31, 2017
Domestic-US & Canada		
Devices	\$121,048	\$185,645
Handpieces	768,531	1,510,486
Other	28,851	18,941
Total Domestic US & Canada	\$918,430	\$1,715,072
International ROW		
Devices	\$279,468	\$358,670
Handpieces	582,827	583,349
Other	24,880	30,097
Total International-ROW	\$887,175	\$972,116
International-China		
Devices	\$-	\$1,000,000
Handpieces	-	-
Other	-	1,800
Total International	\$-	\$1,001,800
Domestic. International Analysis		
Domestic-US & Canada	\$918,430	\$1,715,072
International -ROW	887,175	972,116
International -China	-	1,001,800
Total Product Sales	\$1,805,605	\$3,688,988

NOTE 13 -- CONCENTRATION

Milestone Scientific has informal arrangements with a third-party manufacturer 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 2017, Milestone Scientific entered into a purchase commitment for the delivery of 2,000 instruments beginning in the 4th quarter of 2017. At March 31, 2018, Milestone Scientific's purchase commitment for this purchase order was \$186,965. In January 2018, Wand Dental entered into a new purchase commitment for the delivery of 2,000 devices beginning in the third quarter of 2018, Milestone Scientific's purchase commitment for this purchase order was \$1,397,440. An advance of \$ 984,408 and \$697,192 was recorded at March 31, 2018 and December 31, 2017, respectively. Consequently, advances on contracts have been classified as current at March 31, 2018 and December 31, 2017. The termination of the manufacturing relationship with any of the above manufacturer could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, whether because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business and results of operations

For the three months ended March 31, 2018, an aggregate of approximately 54% of Milestone Scientific's net product sales were to one customer/distributor. For the three months ended March 31, 2017, an aggregate of approximately 79% of Milestone Scientific's net product sales were to two customer/distributors (one of which, Milestone China, is a related party), 52%, and 27%, respectively. Accounts receivable for the major customer/distributors amounted to an aggregate of approximately \$1,923,950, or 76% of Milestone Scientific's accounts receivable, as of March 31, 2018. Accounts receivable for the major customer/distributors amounted to an aggregate of approximately \$2,555,476, or 78% of Milestone Scientific's accounts receivable, as of December 31, 2017.

NOTE 14 -- RELATED PARTY TRANSACTIONS

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were \$351,280 and \$452,352 for the *three* months ended *March 31, 2018* and *2017*, respectively. As of *March 31, 2018*, and *December 31, 2017*, Milestone Scientific owed \$1,075,078 and \$985,678 this manufacturer, respectively.

Milestone Scientific had *no* related party sales of handpieces and devices to Milestone China and Milestone China's agent for *three* months ended *March 31, 2018*. Milestone Scientific had *\$1,001,800* of related party sales of handpieces and devices to Milestone China for the *three* months ended *March 31, 2017*. Milestone Scientific defers the total revenue and costs of goods sold when devices and handpieces are shipped to Milestone China and Milestone China's agent due to market conditions and Milestone China liquidity concerns until a payment is received.

In August 2016, K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$50,000 for the three months ended March 31, 2018 and 2017.

In *January 2017*, Milestone Scientific entered into a *12-month* agreement with Innovest S.p.A. to provide consulting services. This agreement will renew for successive *12-month* terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were *\$20,000* for the *three* months ended *March 31, 2018* and *2017*.

NOTE 15 — COMMITMENTS

(1) Contract Manufacturing Agreement

Milestone Scientific has informal arrangements with a *third-party* manufacturer 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 2017*, Milestone Scientific entered into a purchase commitment for the delivery of *2,000* instruments beginning in the *4th* quarter of *2017*. At *March 31, 2018*, Milestone Scientific's purchase commitment for this purchase order was *\$186,965*. In *January 2018* Wand Dental entered into a purchase commitment for the delivery of *2,000* instruments beginning in the *3rd* quarter of *2018*, Milestone Scientific's purchase commitment for this purchase order was *\$1,397,440*. An advance of *\$ 984,408* and *\$697,192* was recorded at *March 31, 2018* and *December 31, 2017*, respectively.

(2) Other Commitments

In *February 2018*, Milestone Scientific and Daniel Goldberger, the Company's former President and Chief Executive Officer, who resigned effective *October 2, 2017*, signed a Settlement and Release Agreement with respect to Mr. Goldberger's leaving the Company. The gross settlement was *\$175,000*, and *\$80,555* was paid in *March 2018*. The remainder of the settlement will be paid over a *nine-month* period beginning in *March 2018*.

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. The Director of Clinical Affairs was granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant 8,333 shares of common stock upon the issuance of each additional patent relating to these technologies. If products produced by *third* parties use any of these technologies (under license from us) then the Director of Clinical Affairs will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license.

The Director of Clinical Affairs' royalty fee was \$85,769 and \$131,908 for *three* months ended *March 31, 2018* and *2017*, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$68,751 for *three* months ended *March 31, 2018* and *2017*, respectively.

In *January 2017*, Milestone Scientific entered into a *12-month* agreement with Innovest S.p.A. to provide consulting services. This agreement will renew for successive *12-month* terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were \$20,000 for *three* months ended *March 31, 2018* and *2017*.

NOTE 16 — SUBSEQUENT EVENTS

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 1.4 million shares of Milestone China’s common stock to Milestone Scientific and cancelled the Note. As a result 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 on financing transaction of \$1,400,000, and no gain or loss was recognized on the transaction. See Note 4.

In May 2018, the Company entered a twelve-month Consulting Agreement to provide corporate finance advice, assisting the Company to establish corporate financing goals, and creating public awareness in European markets. The Company shall grant to the Consultant, upon fulfilment of Condition Precedent, an option to buy from the Company 500,000 shares of newly issued common stock at the price of \$1.00; such option being exercisable any time up to the 1st anniversary year of this Agreement. The Condition Precedent is the purchase of at least 400,000 shares of the Company's common stock from the secondary market within 30 days of signing the Consulting Agreement. If the Consultant purchases up to additional 400,000 shares of the Company common stock in the secondary market in the period between 30 to 60 days from the date hereof, the option will increase up to an additional 500,000 shares of newly issued common stock at a price of 1.00, the proportion shall be on a 4 to 5 ratio (e.g., 400,000 shares purchased equals 500,000 shares option).

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.

OVERVIEW

Milestone Scientific is a biomedical technology research and development company that patents, designs, develops and commercializes innovative diagnostic and therapeutic injection technologies and devices for medical, dental, cosmetic and veterinary applications. Since our inception, we have engaged in pioneering proprietary, innovative, computer-controlled injection technologies and solutions for the medical and dental markets. We have focused our resources on redefining the worldwide standard of care for injection techniques by making the experience more comfortable for the patient by reducing the anxiety and stress of receiving injections from the healthcare provider. Our computer-controlled injection systems make injections precise, efficient and virtually painless. Milestone's proprietary *DPS* Dynamic Pressure Sensing technology is our technology platform that advances the development of next-generation devices, regulating flow rate and monitoring pressure from the tip of the needle, through platform extensions for local anesthesia for subcutaneous drug delivery, with specific applications for cosmetic botulinum toxin injections, epidural space identification in regional anesthesia procedures and intra-articular joint injections.

Milestone Scientific remains focused on advancing efforts to achieve the following five primary objectives:

Establishing Milestone's *DPS* Dynamic Pressure Sensing technology platform as the standard-of-care in painless and precise drug delivery, providing for the first time objective

visual and audible in-tissue pressure feedback, and continuing to expand platform applications;

Following obtaining successful FDA clearance of our first medical device in June 2017, Milestone Scientific is transitioning from a research and development organization to

a commercially focused medical device company;

Commercializing our *CompuFlo* Epidural System, a transformative device for epidural anesthesia procedures;

Expanding the global footprint of our *CompuFlo* Epidural System by partnering with distribution companies worldwide; and

Continuing the commercial launch and gain regulatory approval of our proprietary cosmetic injection device for delivery of botulinum toxin (such as *Botox*® and *Dysport*®).

Distribution and Marketing Arrangements

Our dental devices are sold in the United States, Canada, and in over 53 countries abroad. In June 2017, we received FDA regulatory clearance to sell our first medical device, the *CompuFlo* Epidural System in the United States. Since receiving FDA clearance in 2017 our epidural devices have had minimal sales in the United States and Europe.

Dental Market

In the spring of 2009, Milestone Scientific signed a distribution and marketing agreement with China National Medicines Corporation, dba Sinopharm. In early October 2012, the State Food and Drug Administration (“CFDA”) of the People’s Republic of China approved the *Wand STA* System. However, the CFDA’s approval of the *Wand STA* handpieces was not received until May 2014 and the distribution of these handpieces in China began in the fourth quarter of 2014. The distribution and marketing agreement with Sinopharm was terminated in September 2014. Proximate to that time, we entered into a new agreement with Milestone China to be our distributor for the *Wand STA* System and handpieces in China.

In November 2012, Milestone Scientific signed an exclusive distributor and marketing agreement with a well-known U.S. domestic manufacturer and distributor, for the sale and distribution of the *Wand STA* System and handpieces in the United States and Canada. The marketing initiative included participation in United States and Canadian dental shows, as well as pediatric dental shows; an active advertising initiative targeting major dental publications; and direct mailing campaigns to over 150,000 dentists across the United States and Canada. This exclusive distributor and marketing agreement was converted to a non-exclusive agreement as of December 31, 2016.

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. In June 2016, that agreement was replaced by a new agreement with Henry Schein providing for an exclusive distribution arrangement for our dental products in the United States and Canada by a newly formed marketing and sales group at Henry Schein. Under this arrangement, we have a semi-dedicated independent sales force visiting dentists. Henry Schein's exclusive products sales specialist team, which is comprised of 25 sales representatives and supported by over 1,000 field service representatives, will exclusively market and distribute the *Wand STA* System and handpieces, together with a select group of other devices in the United States and Canada.

Our agreement with Henry Schein has minimum purchase orders to maintain exclusivity in the third through tenth years. We believe that this exclusive arrangement will be more effective than previous arrangements relying on Wand Dental's appearances at dental shows and catalog sales.

Medical Market

Having received FDA clearance to sell the *CompuFlo* Epidural System in June 2017, we are in discussions with a small number of regional and national distributors. Our immediate focus is on marketing our epidural device throughout Europe.

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.

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

The following table shows a breakdown of Milestone Scientific's product sales (net), domestically and internationally, by business segment product category:

		Three months ended March 31, 2018			2017					
		Reportable Segments			Reportable Segments					
		Dental	Medical	Total	Dental	Medical	Total			
Domestic US										
/ Canada:										
Device	\$	121,048	\$	-	\$	185,645	\$	-	\$	185,645

Edgar Filing: MILESTONE SCIENTIFIC INC. - Form 10-Q

Handpieces	768,531	-	768,531	1,510,486	-	1,510,486
Other	28,851	-	28,851	18,941	-	18,941
Total						
Domestic	918,430	-	918,430	1,715,072	-	1,715,072
US / Canada						
International						
Rest of the						
World:						
Device	246,968	32,500	279,468	358,670	-	358,670
Handpieces	578,827	4,000	582,827	583,349	-	583,349
Other	24,880	-	24,880	30,097	-	30,097
Total						
International	850,675	36,500	887,175	972,116	-	972,116
Rest of the						
World						
International						
China:						
Device	-	-	-	1,000,000	-	1,000,000
Handpieces	-	-	-	1,800	-	1,800
Other	-	-	-	-	-	-
Total						
International	-	-	-	1,001,800	-	1,001,800
China						
Total						
Product	\$ 1,769,105	\$ 36,500	\$ 1,805,605	\$ 3,688,988	\$ -	\$ 3,688,988
Sales						

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

Current Product Platform

See Item 1. Description of Business.

Results of Operations

The following table sets forth for the consolidated results of operations for the three months ended March 31, 2018 compared to 2017 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

	Three Months Ended			
	March 31, 2018		March 31, 2017	
Operating results:				
Net Sales	\$1,805,605	100 %	\$3,688,988	100 %
Cost of Sales	562,676	31 %	1,402,285	38 %
Gross Profit	1,242,929	69 %	2,286,703	62 %
Operating expenses:				
Selling, general, and administrative	3,018,783	167 %	2,707,620	73 %
Research & development	225,817	13 %	105,015	3 %
Operating Loss	\$(2,001,668)	-111 %	\$(525,932)	-14 %
Other Expenses, net	26,283	1 %	(52,053)	-1 %
Net Loss	(1,975,385)	-109 %	(577,985)	-16 %
Net loss profit attributable to noncontrolling interest	(101,407)	-6 %	(73,117)	2 %
Net loss attributable to Milestone Scientific Inc.	\$(1,873,978)	-104 %	\$(504,868)	-14 %

	Three Months Ended	
	March 31, 2018	March 31, 2017
Cash flow:		
Net cash used in operating activities	\$ (541,350)	\$(874,010)
Net cash used in investing activities	\$(1,368)	\$-
Net cash provided by financing activities	\$ -	\$ 213,336

Three Months ended March 31, 2018 compared to Three Months ended March 31, 2017

Net sales for three months ended March 31, 2018 and 2017 were as follows:

	2018	2017	Increase (Decrease) \$	%
Dental	\$1,769,105	\$3,688,988	\$(1,919,883)	-52.04 %
Medical	36,500	-	36,500	100.00 %
Total	\$1,805,605	\$3,688,988	\$(1,883,383)	-51.05 %

Consolidated revenue for the three months ended March 31, 2018 and 2017 were approximately \$1.8 million and \$3.7 million, respectively. Dental revenue for the three months ended March 31, 2018 and 2017 were approximately \$1.8 million and \$3.7 million, respectively. Dental revenue decreased by approximately \$1.9 million, which is principally related to a decrease in sales to Milestone China (approximately \$1.0 million) and a decrease of approximately \$900,000 in USA and Canada domestic sales. The reduction in shipments to Milestone China is due to Milestone China working through inventory purchases from 2017 and modifications to their business strategy to better serve the China dental market. The USA and Canadian revenue is lower in the first quarter of 2018, as Henry Schein purchased additional inventories in the fourth quarter of 2017, to avoid a price increase effective in the first quarter of 2018. Medical revenue for the three months ended March 31, 2018 and 2017 were \$36,500 and \$0, respectively.

On June 12, 2017 the Company announced that the *CompuFlo* Epidural System received 510(k) marketing clearances from the U.S. Food and Drug Administration (FDA). Milestone is in the process of attending medical device trade shows and attending introductory meetings with medical device distributors within the United States and European markets. The Company's focus is on marketing its *CompuFlo* Epidural System throughout Europe.

Gross Profit for three months ended March 31, 2018 and 2017 were as follows:

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$1,218,026	\$2,286,703	\$(1,068,677)	-46.73 %
Medical	24,903	-	24,903	100.00 %
Total	\$1,242,929	\$2,286,703	\$(1,043,774)	-45.65 %

Consolidated gross profit for the three months ended March 31, 2018 and 2017 were approximately 69% and 62%, respectively. The improvement in gross profit percentage for the three months ended March 31, 2018 is due to the decrease in sales to Milestone China which sales have a reduced gross profit margin as Milestone China is expanding its market penetration. The gross profit dollars decreased by approximately \$1.0 million due to lower revenues in the first quarter 2018.

Selling, general and administrative expenses for three months ended March 31, 2018 and 2017 were as follows:

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$860,861	\$1,008,071	\$(147,210)	-14.60 %
Medical	678,052	589,483	88,569	15.02 %
Corporate	1,479,867	1,110,066	369,801	33.31 %
Total	\$3,018,780	\$2,707,620	\$311,160	11.49 %

Consolidated selling, general and administrative expenses for the three months ended March 31, 2018 and 2017 were approximately \$3 million versus \$2.7 million, respectively. The increase of approximately \$311,000 is predominantly due to the increase in Corporate expenses. Milestone Scientific Corporate SG&A expenses increased by approximately \$370,000 essentially all the increase represents (approx. \$220,000) amortization of the patents acquired in the APAD purchase in 2017.

Research and Development for three months ended March 31, 2018 and 2017 were as follows:

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$-	\$3,000	\$ (3,000)	-100.00 %
Medical	55,233	34,844	20,389	58.52 %
Corporate	170,584	67,171	103,413	153.95 %
Total Sales	\$225,817	\$105,015	\$ 120,802	115.03 %

Consolidated research and development expenses for the three months ended March 31, 2018 and 2017 were approximately \$226,000 and \$105,000, respectively. The increase is due to the development of the cosmetic injection device.

Profit (Loss) from Operations for three months ended March 31, 2018 and 2017 were as follows:

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$357,165	\$1,275,631	\$ (918,466)	-71.94 %
Medical	(708,382)	(624,326)	(84,056)	13.46 %
Corporate	(1,650,451)	(1,177,237)	(473,214)	40.26 %
Total	\$(2,001,668)	\$(525,932)	\$(1,475,736)	280.60 %

The loss from operations for the three months ended March 31, 2018 and 2017 was approximately \$2 million and \$526,000, respectively, an increase of approximately \$1.5 million. This increase is primarily attribute to the reduction in net sales of \$1.8 million, and an increase in selling, general and administrative of \$311,000 as explained above, represents the increase loss of operations for the first quarter 2018.

Liquidity and Capital Resources

At March 31, 2018, Milestone Scientific had cash and cash equivalents of approximately \$2.1 million, total current assets of approximately \$11.0 million and working capital of approximately \$4 million. We believe that our cash on hand, accounts receivable and the anticipated revenues from the dental business will be sufficient to fund our business operations for at least the next 12 months from the filing date of this Form 10-Q.

Milestone Scientific continues to take positive steps to maintain adequate inventory levels and advances on contracts to maintain available inventory to meet our domestic and international sales requirements. For the three months ended March 31, 2018 and 2017, we had cash flows used in operating activities of approximately \$541,000 and \$874,000, respectively.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception. The capital raised in December 2016 and January 2017 provided Milestone Scientific with working capital to continue to develop its medical devices and obtain FDA regulatory clearance of its *CompuFlo* Epidural System, as well as to aggressively 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 Company's development costs should be lower in 2018. The FDA clearance will provide the Company with the opportunity to establish distribution in the USA. At the same time, the Company is looking to establish additional financing opportunities to help with the commercialization of the Epidural device. The intra-articular device will begin the 510K application process in the second quarter of this year. Most of the cost associated with this application will be internal personnel cost and some low level third party review expense.

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

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.

Milestone Scientific believes that the June 2016 exclusive distribution agreement with Henry Schein will continue to improve its domestic revenues in 2018. The dental agreement has provided a substantial increase in US and Canada

dental revenue in 2017 (approximately \$2 million). To further reduce Milestone Scientific's expenditures, Milestone Medical is carefully managing expenses related to obtaining FDA clearance for the intra-articular devices.

Our condensed consolidated balance sheets included in this Quarterly Report reflects a decrease of approximately \$1.0 million in current assets from December 31, 2017 to March 31, 2018. This decrease in current assets was primarily due to a reduction in cash, accounts receivable, and inventory of approximately \$1,358,000. This was offset by increases in prepaid expenses and advances on contracts of an aggregate of approximately \$345,000.

In this Quarterly Report our consolidated balance sheets included an increase in current liabilities of approximately \$364,000 from approximately \$7.0 million to approximately \$6.7 million. The increase is primarily due to an increase in accounts payable of approximately \$579,000, accounts payable related party of approximately \$89,400, deferred profit related party of approximately 55,000 and a decrease in accrued expenses of approximately \$359,000.

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 March 31, 2018 are effective to ensure that information required to be disclosed in the reports Milestone Scientific files

or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to Milestone Scientific's management, including the Interim Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in Milestone Scientific's internal control over financial reporting identified in connection with the evaluation that occurred during Milestone Scientific's last fiscal quarter ended March 31, 2018 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

None.

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

26

Item 6. Exhibits and Financial Statement Schedules

Exhibit No Description

31.1	Rule 13a-14(a) Certification-Chief Executive Officer*
31.2	Rule 13a-14(a) Certification-Chief Financial Officer*
32.1	Section 1350 Certifications-Chief Executive Officer**
32.2	Section 1350 Certifications-Chief Financial Officer**
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*

* Filed herewith.

** Furnished herewith and not filed, in accordance with item 601(32) (ii) of Regulation S-K.

SIGNATURES

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

MILESTONE SCIENTIFIC INC.

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

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

Date: May 15, 2018