

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

---

**MILESTONE SCIENTIFIC INC.**

**Form 10-Q**

**TABLE OF CONTENTS**

**PART I—FINANCIAL INFORMATION**

Item 1. Financial Statements

Condensed Consolidated Balance Sheets as of September 30, 2018 (Unaudited) and December 31, 2017 (Audited) 4

Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2018 and 2017 (Unaudited) 5

Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2018 (Unaudited) 6

Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and September 30, 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 20

Item 3. Quantitative and Qualitative Disclosures About Market Risk 27

Item 4. Controls and Procedures 27

**PART II—OTHER INFORMATION**

Item 1. Legal Proceedings 27

Item 1A. Risk Factors 27

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 28

Item 3. Defaults Upon Senior Securities 28

Item 4. Mine Safety Disclosures 28

Item 5. Other Information	28
Item 6. Exhibits	29
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 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

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

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 September 30,		Nine Months Ended 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

5

## 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

6

---

## 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

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

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		

7

---

**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
<b>Operating Income (Loss):</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
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)
<b>Depreciation and Amortization:</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
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
<b>Income (loss) before taxes and equity in earnings of affiliates:</b>	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
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

<b>Total Assets:</b>	<b>September 30,</b>	<b>December 31,</b>
	<b>2018</b>	<b>2017</b>
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.

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	2018	2017	2018	2017
<b>Domestic-US &amp; Canada</b>				
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
<b>Total Domestic US &amp; Canada</b>	<b>\$ 509,254</b>	<b>\$ 1,358,066</b>	<b>\$ 2,620,541</b>	<b>\$ 4,141,129</b>
<b>International ROW</b>				
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
<b>Total International-ROW</b>	<b>\$ 812,992</b>	<b>\$ 1,139,347</b>	<b>\$ 2,935,810</b>	<b>\$ 3,210,821</b>
<b>International-China</b>				
Devices	\$-	\$-	\$-	\$ 1,000,000
Handpieces	300,000	356,400	300,000	712,800
Other	-	-	-	1,800
<b>Total International</b>	<b>\$ 300,000</b>	<b>\$ 356,400</b>	<b>\$ 300,000</b>	<b>\$ 1,714,600</b>
<b>Domestic. International Analysis</b>				
Domestic-US & Canada	\$ 509,254	\$ 1,358,066	\$ 2,620,541	\$ 4,141,129
International -ROW	812,992	1,139,347	2,935,810	3,210,821
International -China	300,000	356,400	300,000	1,714,600
<b>Total Product Sales</b>	<b>\$ 1,622,246</b>	<b>\$ 2,853,813</b>	<b>\$ 5,856,351</b>	<b>\$ 9,066,550</b>

### NOTE 13 -- CONCENTRATION

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, *CompuDent*® and *CompuMed*® devices, pursuant to which they manufacture these products under specific purchase orders but without any long-

term contract or minimum purchase commitment. Consequently, advances on contracts have been classified as current at September 30, 2018 and December 31, 2017, respectively. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business and results of operations.

For the three months ended September 30, 2018, an aggregate of approximately 35% of Milestone Scientific's net product sales were to one customer/distributor. For the nine months ended September 30, 2018, an aggregate of approximately 48% of Milestone Scientific's net product sales were to one customer/distributor. For the three months ended September 30, 2017, an aggregate of approximately 67% of Milestone Scientific's net product sales were to two customers/ distributors (one of which, Milestone China, is a related party), 54%, and 13%, respectively. For the nine months ended September 30, 2017, an aggregate of approximately 72% of Milestone Scientific's net product sales were to two customers/distributors (one of which, Milestone China, is a related party), 53%, and 19%, respectively.

Accounts receivable, including related party accounts receivable for the major customer/distributors, (one of which, Milestone China, is a related party), amounted to approximately \$1,695,967 (net of allowance for doubtful accounts), or 55% and 19% of Milestone Scientific's accounts receivable as of September 30, 2018. Accounts receivable, including related party accounts receivable, for the major customer/distributors (one of which, Milestone China, is a related party), amounted to approximately \$2,555,476, or 53% and 25% of Milestone Scientific's accounts receivable, as of December 31, 2017.

## **NOTE 14 -- RELATED PARTY TRANSACTIONS**

### **United Systems**

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were \$361,727 and \$900,000 for the three and nine months ended September 30, 2018, respectively. Purchases from this manufacturer were \$721,225 and \$1,690,582 for the three and nine months ended September 30, 2017, respectively. As of September 30, 2018, and December 31, 2017, Milestone Scientific owed this manufacturer \$1,285,681 and \$985,678, respectively, which is included in accounts payable, related party on the condensed consolidated balance sheet.

During the nine months ended September 30, 2018 Milestone Scientific through its wholly owned subsidiary, Wand Dental, entered into an agreement with United Systems. The agreement was a Royalty Agreement for handpieces sold to Milestone China by United Systems. United Systems will pay Wand Dental a royalty equal to the net profit that Wand Dental would have received if the handpieces were sold directly to Milestone China or its Agent. As of September 30, 2018, Wand Dental has deferred royalty income of \$342,540 that will be recognized at the earlier of when payment of the royalties is received from United Systems or when collectability is deemed to be assured and is included in accounts receivable, related party and deferred revenue, related party on the condensed consolidated balance sheet.

Also, during the nine months ended September 30, 2018, a Distribution agreement between Wand Dental and United Systems was formed. Under the Distribution agreement United Systems purchased 1,000 STA instruments in June 2018, for delivery to Milestone China. Due to the related party nature and collectability concerns Wand Dental has deferred the sale. Milestone Scientific has deferred approximately \$750,000 of related party sales of devices to Milestone China under the agreement with United Systems as of September 30, 2018. As of September 30, 2018, Milestone Scientific recorded accounts receivable, related party and deferred revenue, related party of \$750,000 and deferred cost, related of \$686,365, respectively. The deferred revenue, accounts receivable and deferred cost from this transaction are included in accounts receivable, deferred revenue and deferred cost related party related to Milestone China disclosed below.

### **Milestone China**

As of March 2, 2018, the promissory note (See note 4) 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.

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 it’s 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 8 for further information.

### **Other**

In August 2016, K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$25,000 and \$75,000 for the three and nine months ended September 30, 2018 and 2017, respectively.

In January 2017, Milestone Scientific entered into a twelve-month agreement with Innovest S.p.A., a significant stockholder of Milestone Scientific, to provide consulting services. This agreement will renew for successive twelve-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were \$20,000 and \$60,000 for the three and nine months ended September 30, 2018 and 2017, respectively.

## NOTE 15 — COMMITMENTS

### (1) Contract Manufacturing Agreement

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, CompuDent® and CompuMed® devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. In January 2018, Wand Dental entered into a new purchase commitment for the delivery of 2,000 devices beginning in the third quarter of 2018, Milestone Scientific's purchase commitment for this purchase order was \$1,152,888 at September 30, 2018, however an advance of \$884,823 was recorded against this purchase order at September 30, 2018. Milestone Scientific still owes \$268,065 related to this purchase order. An advance of \$884,823 and \$697,192 was recorded at September 30, 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, of which \$147,222 was paid through September 2018. The remainder of the settlement will be paid over the next two-month period ending in November 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. 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 \$77,907 and \$284,437 for three and nine months ended September 30, 2018, respectively. The Director of Clinical Affairs' royalty fee was \$122,606 and \$446,098 for three and nine months ended September 30, 2017, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$146,751 for three and nine months ended September 30, 2018, respectively, and \$68,751 and \$206,253 for three and nine months ended September 30, 2017, respectively. As of September 30, 2018,

and December 31, 2017 Milestone Scientific owes the Director Clinical Affairs for royalties of approximately \$232,000 and \$108,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

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 fulfillment of the Condition Precedent (as set forth below), 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 first anniversary year of the Consulting Agreement.

The Condition Precedent is the purchase by the Consultant 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's common stock in the secondary market in the period between 30 to 60 days from the date of the Consulting Agreement, the option will increase up to an additional 500,000 shares of newly issued common stock at a price of \$1.00 per share, the proportion shall be on a 4 to 5 ratio (e.g., 400,000 shares purchased equals 500,000 shares option). This Consulting Agreement was terminated in July 2018, on basis that the consultant did not fulfill the condition precedent.

## **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 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

Obtaining regulatory approval of our proprietary cosmetic injection device for delivery of botulinum toxin (such as Botox® and Dysport®) and subsequent commercial launch.

### **Distribution and Marketing Arrangements**

Our dental devices are sold in the United States, Canada, and in 53 other countries. 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 were 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, and have entered into a small number of agreements with, regional and national distributors. Our immediate focus is on marketing our epidural device in the U.S. and 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.

In October 2018, Milestone Scientific signed its first USA Stocking Distributor Agreement for the *CompuFlo* Epidural device. This distributor purchases devices and disposables subsequent to signing the agreement.

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 Key Opinion Leaders (KOL) use and accept the device and initiate their own studies. This having been accomplished we are now placing devices in key institutions.

The following table shows a breakdown of Milestone Scientific's product sales (net), domestically and internationally, by business segment product category for three months ended September 30, 2018 and 2017:

	Three months ended September 30, 2018			Three months ended September 30, 2017		
	Dental	Medical	Total	Dental	Medical	Total
Domestic US / Canada: Device	\$ 119,190	\$ -	\$ 119,190	\$ 452,232	\$ -	\$ 452,232

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

Handpieces	369,027	-	369,027	893,496	-	893,496
Other	21,037	-	21,037	12,338	-	12,338
Total Domestic US / Canada	\$509,254	\$ -	\$509,254	\$1,358,066	\$ -	\$1,358,066
International Rest of the World:						
Device	\$299,872	\$ -	\$299,872	\$340,575	\$ -	\$340,575
Handpieces	506,880	-	506,880	765,821	-	765,821
Other	6,240	-	6,240	32,951	-	32,951
Total International Rest of the World	\$812,992	\$ -	\$812,992	\$1,139,347	\$ -	\$1,139,347
International China:						
Device	\$-	\$ -	\$-	\$-	\$ -	\$-
Handpieces	300,000	-	300,000	356,400	-	356,400
Other	-	-	-	-	-	-
Total International China	\$300,000	\$ -	\$300,000	\$356,400	\$ -	\$356,400
Total Product Sales	\$1,622,246	\$ -	\$1,622,246	\$2,853,813	\$ -	\$2,853,813

The following table shows a breakdown of Milestone Scientific's product sales (net), domestically and internationally, by business segment product category for the nine months ended September 30, 2018 and 2017:

	Nine months ended September 30, 2018			Nine months ended September 30, 2017		
	Dental	Medical	Total	Dental	Medical	Total
Domestic US / Canada:						
Device	\$251,743	\$-	\$251,743	\$857,525	\$ -	\$857,525
Handpieces	2,296,533	-	2,296,533	3,230,567	-	3,230,567
Other	72,265	-	72,265	53,037	-	53,037
Total Domestic US / Canada	\$2,620,541	\$-	\$2,620,541	\$4,141,129	\$ -	\$4,141,129
International Rest of the World:						
Device	\$876,290	\$70,500	\$946,790	\$1,053,050	\$ -	1,053,050
Handpieces	1,924,901	5,600	1,930,501	2,068,007	-	2,068,007
Other	58,519	-	58,519	89,764	-	89,764
Total International Rest of the World	\$2,859,710	\$76,100	\$2,935,810	\$3,210,821	\$ -	\$3,210,821
International China:						
Device	\$-	\$-	\$-	\$1,000,000	\$ -	\$1,000,000
Handpieces	300,000	-	300,000	712,800	-	712,800
Other	-	-	-	1,800	-	1,800
Total International China	\$300,000	\$-	\$300,000	\$1,714,600	\$ -	\$1,714,600
Total Product Sales	\$5,780,251	\$76,100	\$5,856,351	\$9,066,550	\$ -	\$9,066,550

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 FDA marketing clearance for the *CompuFlo* Epidural System, Milestone Scientific is initiating marketing and sales efforts in the U.S. 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 September 30, 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 September			
	30, 2018		2017	
Operating results:				
Product sales, net	\$1,622,246	100 %	\$2,853,813	100%
Cost of products sold	1,742,451	107 %	1,044,540	37 %
Gross profit (loss)	(120,205 )	-7 %	1,809,273	63 %
Operating expenses:				
Selling, general and administrative expenses	2,886,081	178 %	3,205,996	112%
Research and development expenses	1,500	0 %	16,884	1 %
Impairment of long lived assets	1,539,794	95 %	-	0 %
Loss from operations	(4,547,580)	-280%	(1,413,607)	-50 %
Other income, net	143,015	9 %	(3,939 )	0 %
Net loss	(4,404,565)	-272%	(1,417,546)	-50 %
Net loss attributable to noncontrolling interests	11,742	1 %	6,605	0 %
Net loss attributable to Milestone Scientific Inc.	\$(4,392,823)	-271 %	\$(1,410,941)	-49 %

22

The following table sets forth for the consolidated results of operations for the nine months ended September 30, 2018 compared to 2017 as a percentage of product sales, net. The trends suggested by this table may not be indicative of future operating results:

	Nine Months Ended September 30,			
	2018		2017	
Operating results:				
Product sales, net	\$5,856,351	100 %	\$9,066,550	100%
Cost of products sold	3,326,341	57 %	3,320,411	37 %
Gross profit	2,530,010	43 %	5,746,139	63 %
Operating expenses:				
Selling, general and administrative expenses	8,748,485	149 %	8,996,092	99 %
Research and development expenses	215,655	4 %	241,964	3 %
Impairment of long lived assets	1,539,794	26 %	-	0 %
Loss from operations	(7,973,924)	-136%	(3,491,917)	-39 %
Other income, net	243,987	4 %	(44,063 )	0 %
Net loss	(7,729,937)	-132%	(3,535,980)	-39 %
Net loss attributable to noncontrolling interests	118,424	2 %	138,915	2 %
Net loss attributable to Milestone Scientific Inc.	\$(7,611,513)	-130%	\$(3,397,065)	-37 %

Cash flow:	September 30, 2018	September 30, 2017
Net cash used in operating activities	\$(1,957,602)	\$(1,560,152)
Net cash used in investing activities	(14,525 )	(197,916 )
Net cash provided by financing activities	(250,000 )	463,366

### Three Months Ended September 30, 2018 compared to Three Months Ended September 30, 2017

Net sales for three months ended September 30, 2018 and 2017 were as follows:

	2018	2017	Increase Decrease	%
Dental	\$1,622,248	\$2,853,813	\$(1,231,565)	-43.16%
Medical	-	-	-	-
Total sales, net	\$1,622,248	\$2,853,813	\$(1,231,565)	-43.16%

Consolidated revenue for the three months ended September 30, 2018 and 2017 were approximately \$1.6 million and \$2.8 million, respectively. Dental revenue decreased approximately \$1.2 million during the three months ended September 2018 compared to 2017. This decrease was primarily related to a decrease of approximately \$848,000 related to a delay in the quarterly re-stocking order for handpieces and devices from Henry Schein. The third quarter re-stocking order was received and shipped in October 2018 in the amount \$773,000. International dental revenue decreased approximately \$326,000 for the three months ended September 2018 compared to 2017. China revenue decreased for three months ended September 30, 2018 by approximately \$56,000 compared to 2017, as for the quarter ending September 30, 2018, the Company recognized \$300,000 in revenue previously deferred until payment was received by Milestone Scientific.

**Gross profit for three months ended September 30, 2018 and 2017 were as follows:**

	2018	2017	Increase Decrease	%
Dental	\$(120,205)	\$1,809,273	\$(1,929,478)	-106.64 %
Medical	-	-	-	0.00 %
Total gross profit	\$(120,205)	\$1,809,273	\$(1,929,478)	-106.64 %

Consolidated gross profit for the three months ended September 30, 2018 included a reserve of approximately \$273,000 for certain dental handpieces. A claim has been made for reimbursement of this purchase to the broker and manufacture that provided the handpieces to the Company. The gross profit percentages for three months ended September 30, 2018 and 2017 were approximately -7% and 63%, respectively. For the three months ended September 30, 2018, the Company recorded an allowance for handpieces and devices sold to Milestone China of approximately \$790,000.

**Selling, general and administrative expenses for three months ended September 30, 2018 and 2017 were as follows:**

	2018	2017	Increase Decrease	%
Dental	\$772,943	\$1,097,684	\$(324,741)	-29.58 %
Medical	454,306	501,054	(46,748 )	-9.33 %
Corporate	1,658,832	1,607,258	51,574	3.21 %
Total selling, general and administrative expenses	\$2,886,081	\$3,205,996	\$(319,915)	-9.98 %

Consolidated selling, general and administrative expenses for the three months ended September 30, 2018 and 2017 were \$2.8 million and \$3.2 million, respectively. The decrease of approximately \$320,000 is primarily related to an decrease compensation, marketing and professional fees of approximately \$373,000 offset by a decrease in general expense, and employee related expenses of approximately \$53,000 for the three months ending September 30, 2018.

Additionally, during the quarter Milestone Scientific charged approximately \$1.5 million to the Corporate segment for an impairment of long-lived assets (Apad patents).

**Research and Development for three months ended September 30, 2018 and 2017 were as follows:**

2018	2017	%
------	------	---

			Increase Decrease		
Dental	\$-	\$-	\$-	0.00	%
Medical	-	16,884	(16,884)	-100.00	%
Corporate	1,500	-	1,500	100.00	%
Total research and development	\$1,500	\$16,884	\$(15,384)	-91.12	%

Consolidated research and development expenses for the three months ended September 30, 2018 and 2017 were approximately \$1,500 and \$17,000, respectively. The decrease is due to a delay in the development of the cosmetic injection device during the second quarter of 2018.

**Loss from Operations for three months ended September 30, 2018 and 2017 were as follows:**

	2018	2017	Increase Decrease	%
Dental	\$(893,148)	\$711,589	\$(1,604,737)	-225.51%
Medical	(454,306)	(517,938)	63,632	12.29%
Corporate	(3,200,126)	(1,607,258)	(1,592,868)	-99.10%
Total loss from operations	\$(4,547,580)	\$(1,413,607)	\$(3,133,973)	-221.70%

The loss from operations for the three months ended September 30, 2018 and 2017 was approximately \$4.5 million and \$1.4 million, respectively, an increase of approximately \$3.1 million. As noted above, third quarter sales decreased by approximately \$1.2 million and gross profit by approximately \$1.9 million offset by a reduction of approximately \$320,000 in selling, general and



administrative expenses and increase of approximately \$1.5 million for the write-down of long-lived assets (Patents) accounted for the loss from operations for the three months ending September 30, 2018. The dental segment of the business continues to control expenses for a stable market. Costs in the medical segment are increasing as personnel are expanded in the U.S. to focus on our domestic Epidural device business.

### **Nine months ended September 30, 2018 compared to nine months ended September 30, 2017**

**Net sales for nine months ended September 30, 2018 and 2017 were as follows:**

	2018	2017	Increase Decrease	%
Dental	\$5,780,251	\$9,066,550	\$(3,286,299)	-36.25 %
Medical	76,100	-	76,100	100.00%
Total sales, net	\$5,856,351	\$9,066,550	\$(3,210,199)	-35.41 %

Consolidated net sales for the nine months ended September 30, 2018 and 2017 were approximately \$5.8 million and \$9.1 million, respectively. Dental revenue for the nine months ended September 30, 2018 and 2017 were \$5.7 million and \$9.1 million, respectively. Dental revenue decreased \$3.2 million during the nine months ended September 30, 2018, compared to 2017.

The domestic dental revenue decrease of approximately \$1.5 million is related to a delay in the quarterly re-stocking order for handpieces and devices from Henry Schein and their focus on working through the inventory purchased in the fourth quarter of 2017. The third quarter re-stocking order was received and shipped in October 2018 in the amount of \$773,000. Henry Schein's inventory of handpieces was less than a half month supply as of September 30, 2018. The receipt of the re-stocking order post-September 30 resulted in out stock positioning for Henry Schein's customers in October 2018 until the order was shipped. International dental revenue excluding China decreased by approximately \$350,000 for the nine months ended September 2018 compared to 2017. China revenue decreased for nine months ended September 30, 2018 by approximately \$1.4 million compared to 2017, as the Company recognized \$300,000 in revenue previously deferred until payment was received by Milestone Scientific. Milestone China is working through inventory purchases from 2017 and making modifications to their business strategy to better serve the Chinese dental market.

**Gross Profit (loss) for nine months ended September 30, 2018 and 2017 were as follows**

	2018	2017	Increase Decrease	%
--	------	------	----------------------	---

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

Dental	\$2,710,882	\$5,746,139	\$(3,035,257)	-52.82 %
Medical	(180,872 )	-	(180,872 )	-100.00%
Total gross profit	\$2,530,010	\$5,746,139	\$(3,216,129)	-55.97 %

Consolidated gross profit for the nine months ended September 30, 2018 and 2017 were approximately 43% and 63% respectively. The gross profit dollars in 2018 decreased to \$2.5 million from \$5.7 million in 2017, or by \$3.2 million over the same period year over year. The gross profit dollars decrease relates to a decrease of approximately \$3.2 million in revenue, reserve for slow moving inventory of approximately \$289,000 and a reserve of approximately \$273,000 for certain dental handpieces. A claim has been made for reimbursement of this purchase to the broker and manufacture that provided the handpieces to the Company. For the three months ended September 30, 2018, the company recorded an allowance for handpieces and devices sold to Milestone China of approximately \$790,000.

**Selling, general and administrative expenses for nine months ended September 30, 2018 and 2017 were as follows:**

	2018	2017	Increase Decrease	%
Dental	\$2,591,269	\$3,195,540	\$(604,271)	-18.91 %
Medical	1,762,972	1,629,598	133,374	8.18 %
Corporate	4,394,244	4,170,954	223,290	5.35 %
Total selling, general and administrative expenses	\$8,748,485	\$8,996,092	\$(247,607)	-2.75 %

Consolidated selling, general and administrative expenses for the nine months ended September 30, 2018 and 2017 were approximately \$8.7 million and \$9.0 million respectively. The decrease of approximately \$247,000 is primarily related to an decrease in compensation, marketing and professional fees of approximately \$653,000 and a decrease in general expense, and employee related expenses of approximately \$406,000 for the three months ending September 30, 2018.

Additionally, during the quarter Milestone Scientific charged approximately \$1.5 million to the Corporate segment for an impairment of long-lived assets (Apad patents).

**Research and Development for nine months ended September 30, 2018 and 2017 were as follows:**

	2018	2017	Increase Decrease	%
Dental	\$-	\$3,000	\$(3,000 )	-100.00%
Medical	65,008	116,793	(51,785 )	-44.34 %
Corporate	150,647	122,171	28,476	23.31 %
Total research and development	\$215,655	\$241,964	\$(26,309 )	-10.87 %

Consolidated research and development expenses for the nine months ended September 30, 2018 and 2017 were approximately \$215,000 and \$241,000, respectively. The decrease is due a delay in the development of the cosmetic injection device during the second and third quarter of 2018.

**Profit (Loss) from Operations for nine months ended September 30, 2018 and 2017 were as follows:**

	2018	2017	Increase Decrease	%
Dental	\$119,613	\$2,547,599	\$(2,427,986)	-95.30 %
Medical	(2,008,852)	(1,746,391)	(262,461 )	-15.03 %
Corporate	(6,084,685)	(4,293,125)	(1,791,560)	-41.73 %
Total loss from operations	\$(7,973,924)	\$(3,491,917)	\$(4,482,007)	-128.35 %

The loss from operations for the nine months ended September 30, 2018 and 2017 was approximately \$8 million and \$3.5 million, respectively, an increase of approximately \$4.5 million. As noted above, sales and gross profit decreased by approximately \$3.2 million for the nine months ending September 30, 2018. The decrease in gross profit is related to a reserve for slow moving inventory of approximately \$289,000 and a reserve of approximately \$273,000 for certain dental handpieces. A claim has been made for reimbursement of this purchase to the broker and manufacture that provided the handpieces to the Company. For the nine months ended September 30, 2018, the Company recorded an allowance for handpieces and devices sold to Milestone China of approximately \$790,000.

Additionally, during the quarter Milestone Scientific charged approximately \$1.5 million to the Corporate segment for an impairment of long-lived assets (Apad patents). The dental segment of the business continues to control expenses for a stable market. Costs in the medical segment are increasing as personnel are expanded in the U.S. to focus on our domestic Epidural device business.

## Liquidity and Capital Resources

At September 30, 2018, Milestone Scientific had cash and cash equivalents of \$0.4 million, total current assets of approximately \$7 million and working capital of approximately \$0.5 million. Based on the delayed payment for shipments made to Milestone China in 2017 and 2018, substantial doubt exists about the company's liquidity and ability to continue as a going concern as of September 30, 2018.

Management as of September 30, 2018, believes that without the collection of the Milestone China Accounts Receivable (a reserve for non-collectability was established of approximately \$1.3 million), and provided that the Company's sales performance, selling expenditures for its Epidural medical device, and the new product development programs deviate from management's plan, the Company will not be able to meet its anticipated obligations over the next twelve months from the financial reporting date. Significant deviations, together with limitations on funding could require a delay, scale back or elimination of some or all of the Company's development programs which could have a material adverse impact on the Company.

Milestone Scientific has incurred annual operating losses and negative cash flows from operating activities since its inception. The capital raised in 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 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, 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 U.S. At the same time, the Company is looking to establish additional financing opportunities to help with the commercialization of the Epidural device. In June 2018, Milestone Scientific filed a new 510(k) application for its intra-articular device. Most of the cost associated with this application were internal personnel cost and some low level third party review expense.

Milestone Scientific believes that the FDA clearance of its 510(k) applications 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 exclusive distribution agreement with Henry Schein will continue to improve its domestic revenues in 2018. 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 reflect a decrease of approximately \$4.9 million in current assets from December 31, 2017 to September 30, 2018. This decrease in current assets was primarily due to a reduction in cash, accounts receivable related party (due to a reserve for doubtful accounts), notes receivable, inventory (reserve for production problems with a dental accessory) and a charge for Impairment on the APAD patents (approximately \$1.5 million), in the aggregate of approximately \$5.1 million. This was partially offset by increases in and advances on contracts of approximately \$.2 million.

In this Quarterly Report our consolidated balance sheets included a decrease in current liabilities of approximately \$150,000 from approximately \$6.7 million to approximately \$6.5 million. This decrease is primarily due to a decrease in accrued expenses, accrued expenses related party, deferred revenue and deferred profit related party of approximately \$945,000 and an increase in accounts payable and accounts payable related party of approximately \$796,000.

### **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 September 30, 2018 are effective to ensure that information required to be disclosed in the reports Milestone Scientific files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to Milestone Scientific’s management, including the Interim Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. There have been no changes in Milestone Scientific’s internal control over financial reporting that occurred during Milestone Scientific’s last fiscal quarter that have materially affected, or that are reasonably likely to materially affect, Milestone Scientific’s internal controls over financial reporting.

## **PART II – OTHER INFORMATION**

#### **Item 1. Legal Proceedings**

Milestone Scientific is not involved in any material litigation.

#### **Item 1A. Risk Factors**

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

**Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

In September 2018, the Company issued 18,497 shares of its common stock to an investor relation firm in connection with the provision of investor relations services to the Company.

In September 2018, the Company issued 28,572 and 9,494 shares of its common stock, respectively, to two consultants to the to the Company.

All of the above shares were issued pursuant to the exemption provided under Section 4(a)(2) the Securities Act of 1933, as amended.

**Item 3. DEFAULT UPON SENIOR SECURITIES**

None.

**Item 4. Mine Safety Disclosure**

Not applicable.

**Item 5. Other Information**

None

**Item 6. Exhibits and Financial Statement Schedules**

Exhibit No. Description

- 31.1 Rule 13a-14(a) Certification- Interim Chief Executive Officer \*
- 31.2 Rule 13a-14(a) Certification- Chief Operating Officer, Chief Financial Officer (Principal Financial and Accounting Officer )\*
- 32.1 Section 1350 Certifications- Interim Chief Executive Officer \*\*
- 32.2 Section 1350 Certifications- Chief Operating Officer, Chief Financial Officer (Principal Financial and Accounting 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 and Chief Financial Officer  
(Principal Financial and Accounting Officer)

Date: November 14, 2018