

MILESTONE SCIENTIFIC INC.  
Form 10-Q  
August 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 June 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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes No

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

As of August 14, 2018, the registrant has a total of 33,660,970 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 June 30, 2018 (Unaudited) and December 31, 2017 (Audited) 4

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

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

Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2018 and June 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 21

Item 3.

Quantitative and Qualitative Disclosures About Market Risk 28

Item 4.

Controls and Procedures 28

**PART II—OTHER INFORMATION**

Item 1.

Legal Proceedings 28

Item 1A.		
	Risk Factors	28
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	June 30, 2018	December 31, 2017
	<u>(Unaudited)</u>	<u>(Audited)</u>
Current Assets:		
Cash and cash equivalents	\$865,654	\$2,636,956
Accounts receivable, net	1,840,145	1,535,513
Accounts receivable, from related party	2,817,990	1,725,450
Note receivable from financing transaction, current	-	500,000
Prepaid expenses and other current assets	484,753	436,410
Deferred cost, related party	1,796,036	1,109,671
Inventories, net	2,310,330	3,379,209
Advances on contracts	861,782	697,192
Total current assets	10,976,690	12,020,401
Furniture, fixtures & equipment, net	105,529	141,760
Patents, net	2,320,392	2,789,748
Note receivable from financing transaction, noncurrent	-	650,000
Other assets	26,878	26,878
Total assets	13,429,489	15,628,787

## LIABILITIES AND STOCKHOLDERS' EQUITY

## Current Liabilities:

Accounts payable	\$ 1,365,491	\$ 853,859
Accounts payable, related party	1,352,802	1,109,442
Accrued expenses and other payables	1,937,571	2,287,908
Deferred profit, related party	636,126	751,500
Deferred revenue, related party	2,817,990	1,725,450
Total current liabilities	8,109,980	6,728,159
Deferred gain from financing transaction	-	1,400,000
Total liabilities	\$ 8,109,980	\$ 8,128,159

## Commitments and Contingencies

## Stockholders' Equity

Series A convertible preferred stock, par value \$.001, authorized 5,000,000 shares, and 7,000 shares issued and outstanding as of June 30, 2018 and December 31, 2017	\$ 7	\$ 7
Common stock, par value \$.001; authorized 50,000,000 shares; 33,660,970 shares issued, 1,912,503 shares to be issued and 33,627,637 shares outstanding as of June 30,	35,571	34,593

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

2018; 33,191,571 shares issued, 1,401,247 shares to be issued and 33,158,238 shares outstanding as of December 31, 2017;

Additional Paid in Capital	87,832,358	86,689,084
Accumulated deficit	(81,784,998)	(78,568,284)
Treasury stock, at cost, 33,333 shares	(911,516 )	(911,516 )
Total Milestone Scientific Inc. stockholders' equity	5,171,422	7,243,884
Noncontrolling interest	148,087	256,744
Total stockholders' equity	5,319,509	7,500,628
Total liabilities and stockholders' equity	\$ 13,429,489	\$ 15,628,787

See notes to Condensed Consolidated Financial Statements



## MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Product sales, net	\$2,428,498	\$2,523,750	\$4,234,103	\$6,212,738
Cost of products sold	1,021,573	873,586	1,584,250	2,275,871
Gross profit	1,406,925	1,650,164	2,649,853	3,936,867
Selling, general and administrative expenses	2,821,837	3,082,534	5,840,601	5,790,161
Research and development expenses	9,775	120,065	235,592	225,080
Total operating expenses	2,831,612	3,202,599	6,076,193	6,015,241
Loss from operations	(1,424,687 )	(1,552,435 )	(3,426,340 )	(2,078,374 )
Other expenses	(1,756 )	(1,024 )	(3,457 )	(1,763 )
Interest income	1,926	2,154	4,590	2,442
Loss before provision for income taxes and equity in net losses of equity investments	(1,424,517 )	(1,551,305 )	(3,425,207 )	(2,077,695 )
Provision for income taxes	(4,075 )	(4,664 )	(15,538 )	(11,865 )
Loss before equity in net losses of equity investments	(1,428,592 )	(1,555,969 )	(3,440,745 )	(2,089,560 )
Earnings (Loss) on earnings from China Joint Venture	78,591	15,460	115,374	(28,941 )
Net loss	(1,350,001 )	(1,540,509 )	(3,325,371 )	(2,118,501 )
Net loss attributable to noncontrolling interests	6,994	61,684	108,657	134,808
Net loss attributable to Milestone Scientific Inc.	\$(1,343,007 )	\$(1,478,825 )	\$(3,216,714 )	\$(1,983,693 )
Net loss per share applicable to common stockholders—				
Basic	(0.04 )	(0.05 )	(0.09 )	(0.06 )
Diluted	(0.04 )	(0.05 )	(0.09 )	(0.06 )
Weighted average shares outstanding and to be issued—				
Basic	35,297,906	32,399,997	34,939,306	32,122,482
Diluted	35,297,906	32,399,997	34,939,306	32,122,482

See notes to Condensed Consolidated Financial Statements

## MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY

(UNAUDITED)

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling interest	Treasury Stock	Total
Balance, January 1, 2018	7,000	\$ 7	34,592,818	\$34,593	\$86,689,084	\$(78,568,284)	\$256,744	\$(911,516)	\$7,500,628
Stock based compensation	-	-	-	-	170,901	-	-	-	170,901
Common stock to be issued to employee for bonuses	-	-	402,383	402	399,098	-	-	-	399,500
Common stock issued for payment of consulting services	-	-	296,046	294	249,455	-	-	-	249,749
Common stock to be issued to employee for compensation	-	-	37,267	37	37,463	-	-	-	37,500
Common stock issued for Asset Acquisition	-	-	244,959	245	286,357	-	-	-	286,602
Net loss	-	-	-	-	-	(3,216,714 )	(108,657 )	-	(3,325,371)
Balance as June 30, 2018	7,000	\$ 7	35,573,473	\$35,571	\$87,832,358	\$(81,784,998)	\$148,087	\$(911,516)	\$5,319,509

See notes to Condensed Consolidated  
Financial Statements

## MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Six Months Ended June	
	30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(3,325,371)	\$(2,118,501)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	40,762	31,023
Amortization of patents	469,356	35,364
Stock compensation	170,901	237,858
Equity (income) loss on China joint venture	(115,374 )	28,941
Inventory reserve	290,349	-
Changes in operating assets and liabilities:		
Increase in accounts receivable	(304,632 )	(617,347 )
Increase (decrease) in accounts receivable, related party	(1,092,540)	2,358,200
Decrease in other receivables	-	10,000
Decrease in inventories	778,530	104,348
Increase to in advances on contracts	(164,590 )	(150,604 )
Decrease (increase) in prepaid expenses and other current assets	(48,343 )	(454,562 )
Increase in other assets	-	(9,523 )
Increase (decrease) in accounts payable	511,632	(355,471 )
Increase (decrease) in accounts payable, related party	243,360	(853,620 )
(Decrease) in deferred cost, related party	(686,365 )	438,925
(Decrease) increase in accrued expenses and other payables	623,014	1,007,983
Increase (decrease) in deferred revenue, related party	1,092,540	(645,400 )
Net cash used in operating activities	(1,516,771)	(952,386 )
Cash flows from investing activities:		
Purchase of intangible assets	(4,531 )	(39,199 )
Purchase of property and equipment	-	(3,349 )
Net cash used in investing activities	(4,531 )	(42,548 )
Cash flows from financing activities:		
Net proceeds on Private Placement Offering	-	150,836
Proceeds from exercise of stock options	-	62,500
Proceeds (payments) financing transaction	(250,000 )	125,000
Net cash provided by financing activities	(250,000 )	338,336
Net decrease in cash and cash equivalents	(1,771,302)	(656,598 )
Cash and cash equivalents at beginning of period	2,636,956	3,602,229
Cash and cash equivalents at end of period	\$865,654	\$2,945,631

Supplemental disclosure of cash flow information:

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

Shares issued to employees for bonuses	\$399,500	\$194,885
Shares issued to consultants in lieu of cash payments	\$249,749	\$422,249
Common stock issued for asset acquisition	\$286,602	\$-
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 no medical devices sold in the United States and limited amounts sold internationally, as certain medical devices have previously obtained CE mark approval and can be marketed and sold in most European countries.

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (FDA) for both intra-articular and epidural injections with the *CompuFlo*® Computer Controlled Anesthesia System (the “*CompuFlo* Epidural System”). In June 2017, the FDA approved the *CompuFlo* Epidural System for epidural injections. Milestone Scientific is in the process of introductory meetings with medical device distributors within the United States and foreign markets. Milestone Scientific’s immediate focus is on marketing its epidural device throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k)-application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA Office of Device Evaluation, we 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- LIQUIDITY AND UNCERTAINTIES

In accordance with Accounting Standard Codification (“ASC”) 205-40, “Presentation of Financial Statements – Going Concern”, the Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Milestone Scientific has incurred operating losses and negative cash flows from operating activities in virtually each year since its inception. The capital raised in December 2016 and January 2017 provided Milestone Scientific with working capital to continue to develop its medical devices and obtain regulatory approval for one of its *CompuFlo*® Epidural Computer Controlled Anesthesia System (the “*CompuFlo* Epidural System”), as well as to market its dental devices. Milestone Scientific is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue from its dental business worldwide, the generation of revenue from its medical devices and disposables business in the United States and worldwide, and a reduction in operating expenses.

Management believes that Milestone Scientific will have sufficient liquidity to meet its anticipated obligations over the next twelve months from the filing date of this quarterly report. However, should the Company's sales performance, selling expenditures for the U.S. Epidural medical device launch, issues collecting the China affiliate receivable and the new product development programs deviate from Managements’ plan, the Company may 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.

The Company is subject to several risks like those of development stage companies, including dependence on key individuals and products, the difficulties inherent in the development of a commercial market including the China market (see Note 8), the potential need to obtain additional capital necessary to fund the development of its products, and competition from larger companies and other medical device companies that develop similar or substitute products.

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

### **1. Principles of Consolidation**

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and include the accounts of Milestone Scientific and its wholly owned and majority owned subsidiaries, including, Wand Dental (wholly owned), Milestone Advanced Cosmetic (majority owned) and Milestone Medical (majority owned). Milestone Education is a variable interest entity of which Milestone Scientific is the primary beneficiary and is consolidated into Milestone Scientific's financial statements. All significant, intra-entity transactions and balances have been eliminated in the consolidation.

### **2. Basis of Presentation**

The unaudited condensed consolidated financial statements of Milestone Scientific have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information with the instructions for Form 10Q and Article 10 of Regulation S-X. Accordingly, they do not include all 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 recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation
- v. is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606

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

Revenue from product sales 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 six months ended June 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 an increasing variable interest in Milestone China, it considered the guidance in ASC 810, "Consolidation" as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. As Milestone 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 significant shareholder of Milestone China which has the power to direct the activities that most significantly impact the economic performance of Milestone China. Management has concluded that Milestone Scientific is not the primary beneficiary under ASC 810. Accordingly, Milestone China has not been consolidated into the financial statements of Milestone Scientific and continues to be accounted for under the equity method. 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 June 30, 2018, and December 31, 2017, accounts receivable was recorded, net of allowance for doubtful accounts of \$10,000. See Note 8 for related party receivables with China affiliate.

## **8. Note Receivable**

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

## **9. 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.

## **10. 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.

## **11. 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.

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

As of June 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. There have been no impairment indicators or triggering events and therefore, there were no impairments as of June 30, 2018 and December 31, 2017.

### **13. 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.

### **14. 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.

## **15. 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 June 30, 2018 and December 31, 2017, respectively.

## **16. 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.

## **17. 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 June 30, 2018 and 2017, Milestone Scientific recognized approximately \$82,000 and \$110,000 of expense related to employee options, respectively. For the six months ended

June 30, 2018 and 2017, Milestone Scientific recognized approximately \$164,000 of expense and \$244,000 of expense related to employee options, respectively. For the three months ended June 30, 2018 and 2017, Milestone Scientific recognized approximately \$3,000 and \$11,000 of expense related to non-employee options, respectively. For the six months ended June 30, 2018 and 2017, Milestone Scientific recognized approximately \$7,000 of expense and \$6,000 of income related to non-employee options, respectively.

## **18. Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)”. This ASU requires lessees to recognize a right of use asset and lease liability on the balance sheet for all leases, except for short-term leases. The Company will adopt this standard on January 1, 2019. We are currently evaluating the impact of adopting this guidance on our consolidated balance sheets, results of operations and financial condition.

In 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 Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2018-07 to simplify the accounting for share-based payments to nonemployees 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 nonemployees 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 June 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 during the three months ended June 30, 2018. No gain or loss was recognized on the transaction.

#### **NOTE 5 — INVENTORIES**

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

	June 30, 2018	December 31, 2017
Dental finished goods, net	\$1,922,647	\$2,846,272
Medical finished goods, net	209,328	475,285
Component parts and other materials	178,355	57,652
Total	\$2,310,330	\$3,379,209

As of June 30, 2018, and December 31, 2017, inventory was recorded net of allowance for slow moving inventory of approximately \$510,000 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 June 30, 2018 and December 31, 2017 was \$861,782 and \$697,192 respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

#### **NOTE 7 – CONSOLIDATION OF VARIABLE INTEREST ENTITY**

Milestone Education is a 50% owned subsidiary of Milestone Scientific which began operations in 2013 to provide training and education to dentists throughout the world. As of June 30, 2018, and 2017, approximately 73% 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.

## **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 June 30, 2018, and December 31, 2017, Milestone Scientific's investment in Milestone China was \$0. As of June 30, 2018, and December 31, 2017, Milestone Scientific's share of cumulative losses of Milestone China were \$3,701,498 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 June 30, 2018 and December 31, 2017, deferred profit was \$636,126 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 \$78,591 and \$115,374, for the three and six months ended June 30, 2018, respectively, and \$15,460 and (\$28,941) for the three and six months ended June 30, 2017, respectively, inclusive of the 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 June 30, 2018, Milestone Scientific had deferred revenues and deferred costs associated with sales to Milestone China and its agents was approximately \$2.8 million and \$1.8 million. 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 no related party revenue from Milestone China and its agents for three and six months ended June 30, 2018. Milestone Scientific recognized \$356,400 and \$1.7 million of related party revenue for the three and six months ended June 30, 2017. See Note 14 for related party transactions.

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

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

	June 30, 2018	December 31, 2017
Assets:		
Current assets	\$13,700,622	\$13,127,422
Non-current assets	3,258,274	3,213,520
Total assets:	\$16,958,896	\$16,340,942
Liabilities:		
Current liabilities	\$20,633,618	\$18,468,937
Stockholders' deficit	(3,674,722 )	(2,127,995 )
Total liabilities and stockholders' deficit	\$16,958,896	\$16,340,942

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net sales	\$1,328,079	\$322,226	\$2,085,034	\$1,165,552
Cost of goods sold	650,840	422,789	1,098,452	889,204
Gross Profit	677,239	(100,563)	986,582	276,348
Other Expenses	(1,119,440)	(643,570)	(2,371,652)	(1,601,666)
Net Losses	\$(442,201 )	\$(744,133)	\$(1,385,070)	\$(1,325,318)

**NOTE 9 — PATENTS**

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

	2018			2017		
	Cost	Accumulated Amortization	Net	Cost	Accumulated Amortization	Net
Patents-foundation intellectual property	\$1,377,863	\$(817,235)	\$560,628	\$1,377,863	\$(787,821)	\$590,042
Epidural-APAD acquired patents	2,639,646	(879,882)	1,759,764	2,639,647	(439,941)	2,199,706
Total	\$4,017,509	\$(1,697,117)	\$2,320,392	\$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.

Amortization expense was \$231,990 and \$17,682 for the three months ended June 30, 2018 and 2017, respectively. Amortization expense was \$469,356 and \$35,364 for the six months ended June 30, 2018 and 2017, respectively. The annual amortization expense expected to be recorded for existing intangibles assets for the next five years from the balance sheet date of June 30, 2018 are approximately: \$920,000, \$919,000, \$39,000, \$39,000 and \$29,000, respectively.

**NOTE 10 — STOCKHOLDERS' EQUITY****Shares to be Issued**

As of June 30, 2018, and December 31, 2017, there were 1,912,503 and 1,401,247 shares of common stock, respectively, whose issuance has been deferred under the terms of an employment agreements with the Chief Executive Officer, Chief Financial Officer and other employees of Milestone Scientific. Such shares will be issued to each such person upon termination of their employment. The number of shares was fixed at the date of grant and were fully vested upon grant date.

**Shares Reserved for Future Issuance**

As of June 30, 2018, and December 31, 2017 there were 5,431,171 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 June 30, 2018 and December 31, 2017, there were 1,912,503 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 June 30, 2018, and December 31, 2017, no recognition was given to the utilization of the remaining net operating loss carryforwards in each of these periods.

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

Accounting for uncertainties in income taxes prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, disclosure and transition. At June 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 June 30		Six months ended June 30	
	2018	2017	2018	2017
Net Sales:				
Dental	\$2,388,898	\$2,523,750	\$4,158,003	\$6,212,738
Medical	39,600	-	76,100	-
Total	\$2,428,498	\$2,523,750	\$4,234,103	\$6,212,738
Operating Income (Loss):				
Dental	\$723,084	\$697,618	\$1,080,249	\$1,973,250
Medical	(846,164 )	(604,131 )	(1,554,546 )	(1,228,457 )
Corporate	(1,301,607)	(1,645,922)	(2,952,043 )	(2,823,167 )
Total	\$(1,424,687)	\$(1,552,435)	\$(3,426,340 )	\$(2,078,374 )
Depreciation and Amortization:				
Dental	\$4,103	\$4,458	\$8,244	\$8,926
Medical	2,478	6,561	19,355	15,921
Corporate	238,546	20,826	482,519	41,540
Total	\$245,127	\$31,845	\$510,118	\$66,387
Income (Loss) before taxes and equity in earnings of affiliates:				
Dental	\$725,007	\$699,737	\$1,084,829	\$1,975,836
Medical	(846,737 )	(649,726 )	(1,555,691 )	(1,274,522 )
Corporate	(1,302,787)	(1,601,316)	(2,954,345 )	(2,779,009 )
Total	\$(1,424,517)	\$(1,551,305)	\$(3,425,207 )	\$(2,077,695 )
Total Assets:			June 30, 2018	December 31, 2017
Dental			\$9,746,910	\$10,255,144
Medical			361,949	655,513
Corporate			3,320,630	4,718,130
			\$13,429,489	\$15,628,787



The following table presents information about our operations by geographic area as June 30, 2018 and 2017. Net sales by geographic area are based on the respective locations of our subsidiaries

	Three months ended		Six months ended June	
	June 30,		30,	
	2018	2017	2018	2017
Domestic-US & Canada				
Devices	\$11,505	\$219,648	\$132,553	\$405,293
Handpieces	1,158,975	1,182,985	1,927,506	2,693,471
Other	22,377	21,509	51,228	40,449
Total Domestic US & Canada	\$1,192,857	\$1,424,142	\$2,111,287	\$3,139,213
International ROW				
Devices	\$367,450	\$353,805	\$652,518	\$712,475
Handpieces	839,194	362,437	1,418,021	945,786
Other	28,997	26,966	52,277	57,064
Total International-ROW	\$1,235,641	\$743,208	\$2,122,816	\$1,715,325
International-China				
Devices	\$-	\$-	\$-	\$1,000,000
Handpieces	-	356,400	-	356,400
Other	-	-	-	1,800
Total International	\$-	\$356,400	\$-	\$1,358,200
Sales by region				
Domestic-US & Canada	\$1,192,857	\$1,424,142	\$2,111,287	\$3,139,213
International -ROW	1,235,641	743,208	2,122,816	1,715,325
International -China	-	356,400	-	1,358,200
Total Product Sales	\$2,428,498	\$2,523,750	\$4,234,103	\$6,212,738

### 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 June 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, whether because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business and results of operations.

For the three months ended June 30, 2018, an aggregate of approximately 44% of Milestone Scientific's net product sales were to one customer/distributor. For the six months ended June 30, 2018, an aggregate of approximately 43% of Milestone Scientific's net product sales were to one customer/distributor. For the three months ended June 30, 2017, an aggregate of approximately 69% of Milestone Scientific's net product sales were to two customer/distributors (one of which, Milestone China, is a related party), 55%, and 14%, respectively. For the six months ended June 30, 2017, an aggregate of approximately 75% of Milestone Scientific's net product sales were to two customer/distributors (one of which, Milestone China, is a related party), 53%, and 22%, respectively.

Accounts receivable for the major customer/distributors, (one of which, Milestone China, is a related party), amounted to an aggregate of approximately \$3,926,759, or 84% of Milestone Scientific's accounts receivable as of June 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 an aggregate of approximately \$2,555,476, or 78% of Milestone Scientific's accounts receivable, as of December 31, 2017.



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

### **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 \$222,408 and \$573,688 for the three and six months ended June 30, 2018, respectively. Purchases from this manufacturer were \$584,792 and \$1,037,144 for the three and six months ended June 30, 2017, respectively. As of June 30, 2018, and December 31, 2017, Milestone Scientific owed this manufacturer \$1,096,861 and \$985,678, respectively, which is included in accounts payable, related party on the condensed consolidated balance sheet.

During the three months ended June 30, 2018 Milestone Scientific through its wholly owned subsidiary, Wand Dental, entered into an agreement with United Systems, a related party. The agreement was a Royalty Agreement for handpieces sold to Milestone China by United Systems. United Systems will pay Wand Dental a royalty equal to the net profit that Wand Dental would have received if the handpieces were sold directly to Milestone China or its Agent. As of June 30, 2018, Wand Dental has deferred royalty income of \$342,540 which 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. As of June 30, 2018, \$342,540 related to this transaction is included in accounts receivable, related party and deferred revenue, related party from Milestone China disclosed below.

A second agreement represents a Distribution agreement between Wand Dental and United Systems. United Systems purchased 1000 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 had approximately \$750,000 of related party sales of devices to Milestone China under the agreement with United Systems for three and six months ended June 30, 2018. As of June 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 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 instruments 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 June 30, 2018, Milestone Scientific had accounts receivable and deferred revenues of \$2.8 million and deferred costs of \$1.8 million associated with sales to Milestone China and its agents. As of December 31, 2017, Milestone Scientific had deferred revenues and accounts receivable of approximately \$1.7 million and deferred costs of approximately \$1.1 million associated with sales to Milestone China and its agents. Milestone Scientific recognized no related party revenue from Milestone China and its agents for three and six months ended June 30, 2018. Milestone Scientific recognized \$356,400 and \$1.7 million of related party revenue for the three and six months ended June 30, 2017.

### **Other**

In August 2016, K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into a three-year agreement with Milestone Scientific to provide financial and business strategic services. Expenses recognized on this agreement were \$25,000 and \$50,000 for the three and six months ended June 30, 2018 and 2017, respectively.

In January 2017, Milestone Scientific entered into a twelve-month agreement with Innovest S.p.A. to provide consulting services. This agreement will renew for successive twelve-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were \$20,000 and \$40,000 for the three and six months ended June 30, 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 2017, Milestone Scientific entered into a purchase commitment for the delivery of 2,000 instruments beginning in the 4th quarter of 2017. At June 30, 2018, Milestone Scientific's purchase commitment for this purchase order was \$28,147. In January 2018, Wand Dental entered into a new purchase commitment for the delivery of 2,000 devices beginning in the third quarter of 2018, Milestone Scientific's purchase commitment for this purchase order was \$1,397,440. An advance of \$861,782 and \$697,192 was recorded at June 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, \$113,889 was paid through June 2018. The remainder of the settlement will be paid over the next five-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. The Director of Clinical Affairs was granted, pursuant to the agreement, an option to purchase, at fair market value on the date of the grant, 8,333 shares of common stock upon the issuance of each additional patent relating to these technologies. If products produced by third parties use any of these technologies (under license from us) then the Director of Clinical Affairs will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license.

The Director of Clinical Affairs' royalty fee was \$116,956 and \$202,481 for three and six months ended June 30, 2018, respectively. The Director of Clinical Affairs' royalty fee was \$123,764 and \$305,672 for three and six months ended June 30, 2017, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$107,751 for three and six months ended June 30, 2018, respectively, and \$68,751 and

\$137,502 for three and six months ended June 30, 2017, respectively. As of June 30, 2018, and December 31, 2017 Milestone Scientific owes the Director Clinical Affairs for royalties of approximately \$255,000 and \$123,000, respectively which is included in accounts payable, related party.

In January 2017, Milestone Scientific entered into a twelve-month agreement with Innovest S.p.A. to provide consulting services. This agreement will renew for successive twelve-month terms unless terminated by Innovest S.p.A or Milestone Scientific. Expenses recognized on this agreement were \$20,000 and \$40,000 for the three and six months ended June 30, 2018 and 2017, respectively.

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

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

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

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

### **Distribution and Marketing Arrangements**

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

### **Dental Market**

In the spring of 2009, Milestone Scientific signed a distribution and marketing agreement with China National Medicines Corporation, dba Sinopharm. In early October 2012, the State Food and Drug Administration (“CFDA”) of the People’s Republic of China approved the *Wand STA* System. However, the CFDA’s approval of the Wand STA handpieces was not received until May 2014 and the distribution of these handpieces in China began in the fourth quarter of 2014. The distribution and marketing agreement with Sinopharm 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 were converted to a non-exclusive agreement as of December 31, 2016.

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein. In June 2016, that agreement was replaced by a new agreement with Henry Schein providing for an exclusive distribution arrangement for our dental products in the United States and Canada by a newly formed marketing and sales group at Henry Schein. Under this arrangement, we have a semi-dedicated independent sales force visiting dentists. Henry Schein's exclusive products sales specialist team, which is comprised of 25 sales representatives and supported by over 1,000 field service representatives, will exclusively market and distribute the *Wand STA System* and handpieces, together with a select group of other devices in the United States and Canada. Our agreement with Henry Schein has minimum purchase orders to maintain exclusivity in the third through tenth years. We believe that this exclusive arrangement will be more effective than previous arrangements relying on Wand Dental's appearances at dental shows and catalog sales.

### **Medical Market**

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

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 June 30, 2018 and 2017, respectively:

Three months ended June 30, 2018			2017		
Dental	Medical	Total	Dental	Medical	Total

Domestic US / Canada:

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

Device	\$11,505	\$-	\$11,505	\$219,648	\$	-	\$219,648
Handpieces	1,158,975	-	1,158,975	1,182,985	-	-	1,182,985
Other	22,377	-	22,377	21,509	-	-	21,509
Total Domestic US / Canada	1,192,857	-	1,192,857	1,424,142	-	-	1,424,142
International Rest of the World:							
Device	329,450	38,000	367,450	353,805	-	-	353,805
Handpieces	839,194	-	839,194	362,437	-	-	362,437
Other	27,397	1,600	28,997	26,966	-	-	26,966
Total International Rest of the World	1,196,041	39,600	1,235,641	743,208	-	-	743,208
International China:							
Device	-	-	-	-	-	-	-
Handpieces	-	-	-	356,400	-	-	356,400
Other	-	-	-	-	-	-	-
Total International China	-	-	-	356,400	-	-	356,400
Total Product Sales	\$2,388,898	\$39,600	\$2,428,498	\$2,523,750	\$	-	\$2,523,750



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

	Six months ended June 30,			2017		
	2018		Total	Dental	Medical	Total
	Dental	Medical	Total	Dental	Medical	Total
Domestic US / Canada:						
Device	\$132,553	\$-	\$132,553	\$405,293	\$ -	\$405,293
Handpieces	1,927,506	-	1,927,506	2,693,471	-	2,693,471
Other	51,228	-	51,228	40,449	-	40,449
Total Domestic US / Canada	2,111,287	-	2,111,287	3,139,213	-	3,139,213
International Rest of the World:						
Device	576,418	70,500	646,918	712,475	-	712,475
Handpieces	1,418,021	-	1,418,021	945,786	-	945,786
Other	52,277	5,600	57,877	57,064	-	57,064
Total International Rest of the World	2,046,716	76,100	2,122,816	1,715,325	-	1,715,325
International China:						
Device	-	-	-	1,000,000	-	1,000,000
Handpieces	-	-	-	356,400	-	356,400
Other	-	-	-	1,800	-	1,800
Total International China	-	-	-	1,358,200	-	1,358,200
Total Product Sales	\$4,158,003	\$76,100	\$4,234,103	\$6,212,738	\$ -	\$6,212,738

Milestone Scientific plans to support increased sales and marketing activity through our current distributors and through newly appointed distributors of the Wand STA devices and handpieces in the international market. In the United States and Canada, Milestone Scientific will continue the utilization of independent hygienists for training individual practitioners and group practices domestically, refined and directed advertising to dental professionals, continue to develop Key Opinion Leaders (KOL) and support and broaden our global distribution network. Additionally, with the recent FDA marketing clearance for the *CompuFlo* Epidural System, Milestone Scientific is initiating marketing and sales efforts in the 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 June 30, 2018 compared to 2017 as a percentage of revenues. The trends suggested by this table may not be indicative of future operating results:

	For three months ended June 30,			
	2018		2017	
Operating results:				
Product sales, net	\$2,428,498	100 %	\$2,523,750	100 %
Cost of products sold	1,021,573	42 %	873,586	35 %
Gross Profit	1,406,925	58 %	1,650,164	65 %
Operating expenses:				
Selling, general, and administrative	2,821,837	116 %	3,082,534	122 %
Research & development	9,775	0 %	120,065	5 %
Operating Loss	(1,424,687)	-59 %	(1,552,435)	-62 %
Other Income, net	74,686	3 %	11,926	0 %
Net Loss	(1,350,001)	-56 %	(1,540,509)	-61 %
Net loss profit attributable to noncontrolling interest	6,994	0 %	61,684	2 %
Net loss attributable to Milestone Scientific Inc.	\$(1,343,007)	-55 %	\$(1,478,825)	-59 %

The following table sets forth for the consolidated results of operations for the six months ended June 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:

	For six months ended June 30,			
	2018		2017	
Operating results:				
Product sales, net	\$4,234,103	100 %	\$6,212,738	100 %
Cost of products sold	1,584,250	37 %	2,275,871	37 %
Gross Profit	2,649,853	63 %	3,936,867	63 %
Operating expenses:				
Selling, general, and administrative	5,840,601	138 %	5,790,161	93 %
Research & development	235,592	6 %	225,080	4 %
Operating Loss	(3,426,340)	-79 %	(2,078,374)	-33 %
Other Income, (expenses), net	100,969	2 %	(40,127 )	-1 %
Net Loss	(3,325,371)	-78 %	(2,118,501)	-34 %
Net loss profit attributable to noncontrolling interest	108,657	3 %	134,808	2 %
Net loss attributable to Milestone Scientific Inc.	\$(3,216,714)	-76 %	\$(1,983,693)	-32 %

	For six months ended June 30,	
	2018	2017
Cash flow:		
Net cash used in operating activities	\$(1,516,771)	\$(952,386)

Net cash used in investing activities      \$(4,531 ) \$(42,548 )  
 Net cash provided by financing activities   \$(250,000 ) \$338,336

**Three Months ended June 30, 2018 compared to Three Months ended June 30, 2017**

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

	2018	2017	Increase (Decrease)	\$	%
Dental	\$2,388,898	\$2,523,750	\$(134,852 )		-5.34 %
Medical	39,600	-	39,600		-100.00%
Total	\$2,428,498	\$2,523,750	\$(95,252 )		-3.77 %

Consolidated revenue for the three months ended June 30, 2018 and 2017 were approximately \$2.4 million and \$2.5 million, respectively. Dental revenue for the three months ended June 30, 2018 and 2017 were approximately \$2.4 million and \$2.5 million, respectively. Domestic dental revenue decreased approximately \$231,000 during the three months ended June 2018, compared to 2017. The decrease in domestic revenue is related to Henry Schein selling through the inventory purchased in the fourth quarter of 2017 to avoid a price increase effective in the first quarter of 2018.

International dental revenue increased approximately \$453,000 for the three months ended June 2018 compared to 2017. The increase in international dental revenue is due to a sale of instruments and handpieces on a government grant in Mexico for approximately \$382,000. China revenue decreased for three months ended June 30, 2018 by approximately \$356,000. 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 three months ended June 30, 2018 and 2017 were as follows:**

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$1,613,059	\$1,650,164	\$(37,105)	-2.25 %
Medical	(206,134)	-	(206,134)	100 %
Total	\$1,406,925	\$1,650,164	\$(243,239)	-14.74 %

Consolidated gross profit for the three months ended June 30, 2018 and 2017 were approximately 58% and 65%, respectively. The decrease in gross profit percentage for the three months ended June 30, 2018 is due to an increase allowance for slow moving inventory of approximately \$290,000 during the three months ended June 30, 2018.

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

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$957,464	\$1,089,777	\$(132,313)	-12.14 %
Medical	630,254	539,065	91,189	16.92 %
Corporate	1,234,119	1,453,699	(219,580)	-15.10 %
Total	\$2,821,837	\$3,082,541	\$(260,704)	-8.46 %

Consolidated selling, general and administrative expenses for the three months ended June 30, 2018 and 2017 were approximately \$2.8 million and \$3.1 million, respectively. The decrease of \$261,000 is primarily related to a decrease in professional fees, travel expense, and employee related expenses of approximately \$420,000, offset by an increase in amortization of the patents acquired in the APAD purchase in 2017 of approximately \$213,000.

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

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$-	\$-	\$-	0.00 %
Medical	9,775	65,065	(55,290 )	-84.98 %
Corporate	-	55,000	(55,000 )	-100.00 %
Total	\$9,775	\$120,065	\$(110,290 )	-91.86 %

Consolidated research and development expenses for the three months ended June 30, 2018 and 2017 were approximately \$10,000 and \$120,000, respectively. The decrease is due a delay in the development of the cosmetic injection device during the second quarter of 2018.

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

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$723,084	\$540,061	\$183,023	33.89 %
Medical	(846,164 )	(604,130 )	(242,034 )	40.06 %
Corporate	(1,301,607)	(1,488,366)	186,759	-12.55 %
Total	\$(1,424,687)	\$(1,552,435)	\$127,748	-8.23 %

The loss from operations for the three months ended June 30, 2018 and 2017 was approximately \$1.4 million and \$1.6 million, respectively, a decrease of approximately \$128,000. The dental segment of the business is controlling expenses for a mature market. The medical segment is increasing cost as personnel is expanded in the USA to increase our domestic Epidural instrument business

**Six Months ended June 30, 2018 compared to Six Months ended June 30, 2017****Net sales for six months ended June 30, 2018 and 2017 were as follows:**

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$4,158,003	\$6,212,738	\$(2,054,735)	-33.07 %
Medical	76,100	-	76,100	100.00 %
Total	\$4,234,103	\$6,212,738	\$(1,978,635)	-33.07 %

Consolidated revenue for the six months ended June 30, 2018 and 2017 were approximately \$4.2 million and \$6.2 million, respectively. Dental revenue for the six months ended June 30, 2018 and 2017 were approximately \$4.2 million and \$6.2 million, respectively. Domestic dental revenue decreased approximately \$2.1 million during the six months ended June 2018, compared to 2017. The decrease in domestic revenue of approximately \$ 1 million is related to Henry Schein working through the inventory purchased in the fourth quarter of 2017 to avoid a price increase effective in the first quarter of 2018. International dental revenue increased approximately \$331,000 for the six months ended June 2018 compared to 2017. The increase in international dental revenue is due to a sale of instruments and handpieces on a government grant in Mexico for approximately \$382,000. China revenue decrease for six months ended June 30, 2018 by approximately \$1.3 million. Milestone China is working through inventory purchases from 2017 and making modifications to their business strategy to better serve the China dental market.

**Gross Profit (loss) for six months ended June 30, 2018 and 2017 were as follows:**

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$2,831,085	\$3,936,867	\$(1,105,782)	-28.09 %
Medical	(181,232 )	-	(181,232 )	-100 %
Total	\$2,649,853	\$3,936,867	\$(1,287,014)	-32.69 %

Consolidated gross profit for the six months ended June 30, 2018 and 2017 were approximately 63%, respectively. Although the gross margin percentage remained at 63%, gross profit dollars in 2018 decreased to approximately \$2.6 million from approximately \$3.9 million in 2017, or by approximately \$1.3 million over the same period year over year. The gross profit percentage for the six months ended June 30, 2018 would have been approximately 68.6% without the allowance for slow moving inventory. This \$1.9 million in gross profit would have resulted in a gross profit of 68.6%. This increase in gross margin is due to no sales from our lower margin distributor during six months ended June 30, 2018.

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

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$1,818,325	\$2,097,848	\$(279,523)	-13.32%
Medical	1,308,306	1,128,548	179,758	15.93%
Corporate	2,713,970	2,563,765	150,205	5.86%
Total	\$5,840,601	\$5,790,161	\$50,440	0.87%

Consolidated selling, general and administrative expenses for the six months ended June 30, 2018 and 2017 were approximately \$5.8 million respectively. The increase of \$50,000 is primarily related to an increase in amortization of the patents acquired in the APAD purchase in 2017 of approximately \$443,000, offset by a decrease in professional fees, travel expense, and employee related expenses of approximately \$393,000.

**Research and Development for six months ended June 30, 2018 and 2017 were as follows:**

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$-	\$3,000	\$ (3,000 )	100.00 %
Medical	65,008	99,909	(34,901 )	-34.93 %
Corporate	170,584	122,171	48,413	39.63 %
Total	\$235,592	\$225,080	\$ 10,512	4.67 %

Consolidated research and development expenses for the six months ended June 30, 2018 and 2017 were approximately \$235,000 and \$225,000, respectively. The decrease is due a delay in the development of the cosmetic injection device during the second quarter of 2018.

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

	2018	2017	Increase (Decrease)	%
			\$	
Dental	\$1,080,249	\$1,973,249	\$(893,000 )	-45.26 %
Medical	(1,554,546)	(1,228,457)	326,089	-26.54 %
Corporate	(2,952,043)	(2,823,166)	(128,877 )	4.56 %
Total	\$(3,426,340)	\$(2,078,374)	\$(1,347,966)	64.86 %

The loss from operations for the six months ended June 30, 2018 and 2017 was approximately \$3.4 million and 2.1, respectively, an increase of approximately \$1.3 million. This increase is primarily attributable to the reduction in net sales of \$1.3 million, and increase in selling, general and administrative of \$50,000 as explained above.

**Liquidity and Capital Resources**

At June 30, 2018, Milestone Scientific had cash and cash equivalents of approximately \$0.9 million, total current assets of approximately \$11 million and working capital of approximately \$2.8 million. We believe that our cash on hand, collection of accounts receivable and the anticipated revenues from the dental business will be sufficient to fund our business operations for at least the next 12 months from the filing date of this Form 10-Q. However, should the Company's sales performance, selling expenditures for the U.S. Epidural medical device launch, issues collecting the China affiliate receivable and the new product development programs deviate from Managements' plan, the Company



may 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 USA. 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 \$1 million in current assets from December 31, 2017 to June 30, 2018. This decrease in current assets was primarily due to a reduction in cash, notes receivable, and inventory of approximately \$3.3 million. This was offset by increases in accounts receivable and advances on contracts of an aggregate of approximately \$2.2 million.

In this Quarterly Report our consolidated balance sheets included an increase in current liabilities of approximately \$1.4 million from approximately \$6.7 million to approximately \$8.1 million. This increase is primarily due to a decrease in accrued expenses and deferred profit related party of approximately \$466,000 offset by an increase in accounts payable, accounts payable related party, deferred revenue related party of approximately \$1.8 million.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Milestone Scientific is a “smaller reporting company” as defined by Regulation S-K and, as such, is not required to provide the information required by this item.

### **Item 4. Controls and Procedures**

Milestone Scientific’s Interim Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the design and operation of Milestone Scientific’s disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based upon that evaluation, Milestone Scientific’s Interim Chief Executive Officer and Chief Financial Officer have concluded that the disclosure controls and procedures as of June 30, 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 May 2018, the Company issued 165,000 shares of its Common Stock to a financial advisor in connection with the extension of the Company's Engagement Letter with the financial advisor. The 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**

Milestone Scientific is not involved in any material litigation.

**Item 4. Mine Safety Disclosure**

Not applicable.

**Item 5. Other Information**

None

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

Exhibit No Description

- 31.1 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: August 14, 2018