

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, 2020

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.)

425 Eagle Rock Avenue Suite 403, Roseland, NJ 07068

(Address of principal executive offices)

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

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

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

Name of each exchange on which registered
NYSE American

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

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

Title of each class
Common Stock

Trading Symbol(s)
MLSS

Name of Exchange on which registered
NYSE American

As of November 16, 2020, the registrant has a total of 63,693,469 shares of Common Stock, \$0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

MILESTONE SCIENTIFIC INC.
Form 10-Q
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FORWARD-LOOKING STATEMENTS

When used in this Quarterly Report on Form 10-Q, the words “may”, “will”, “should”, “expect”, “believe”, “anticipate”, “continue”, “estimate”, “project”, “intend” and similar expressions are intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) regarding events, conditions and financial trends that may affect Milestone Scientific’s future plans of operations, business strategy, results of operations and financial condition. Milestone Scientific wishes to ensure that such statements are accompanied by meaningful cautionary statements pursuant to the safe harbor established in the Private Securities Litigation Reform Act of 1995. The forward-looking statements included herein are based on current expectations that involve numerous risks and uncertainties. Milestone Scientific’s plans and objectives are based, in part, on assumptions involving the continued expansion of its business. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of Milestone Scientific. Although Milestone Scientific believes that its assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate. Considering the significant uncertainties inherent in the forward-looking statements included herein, our history of operating losses that are expected to continue during the ongoing COVID-19 pandemic, the early stage operations of and relative lack of acceptance of our medical products, relying exclusively on two third parties to manufacture our products, changes in our informal manufacturing arrangements made by the manufacturers of our products and disruptions at the manufacturing facilities of our manufacturers exposes us to risks that may harm our business, restrict our operations or require us to relinquish proprietary rights, if physicians do not accept or use our CompuFlo® Epidural Computer Controlled Anesthesia System our ability to generate revenue from sales will be materially impaired, exposure to the risks inherent in international sales and operations, including China, and developments by competitors may render our products or technologies obsolete or non-competitive, the inclusion of such information should not be regarded as a representation by Milestone Scientific or any other person that the objectives and plans of Milestone Scientific will be achieved. Prospective investors are cautioned that any forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties and the actual results may differ materially from those included within the forward-looking statements as a result of various factors. Such forward-looking statements should, therefore, be considered in light of various important factors, including those set forth herein and others set forth from time to time in Milestone Scientific’s reports, including without limitation, Milestone Scientific’s Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission (the “SEC”). Milestone Scientific disclaims any intent or obligation to update such forward-looking statements.

Milestone Scientific is the owner of the following registered U.S. trademarks: CompuDent®; CompuMed®; CompuFlo®; DPS Dynamic Pressure Sensing technology®; Milestone Scientific ®; the Milestone logo ®; SafetyWand®; STA Single Tooth Anesthesia Device®; and The Wand ®.

Part I- Financial Information
Item 1. Financial Statements

MILESTONE SCIENTIFIC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,448,903	\$ 1,516,272
Accounts receivable, net	962,983	1,710,665
Prepaid expenses and other current assets	527,059	519,063
Inventories, net	2,229,760	1,620,509
Advances on contracts	723,084	710,662
Total current assets	18,891,789	6,077,171
Furniture, fixtures and equipment, net	31,311	44,976
Patents, net	342,501	382,260
Right of use assets	655,870	15,977
Other assets	24,150	35,905
Total assets	<u>\$ 19,945,621</u>	<u>\$ 6,556,289</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 666,094	1,379,425
Accounts payable, related party	393,090	1,358,752
Accrued expenses and other payables	1,147,698	775,055
Accrued expenses, related party	593,625	1,057,958
Current portion of finance leases	7,903	3,904
Current operating lease right-of-use liabilities	68,934	12,072
Note payable	276,180	-
Deferred profit, related party	340,476	340,476
Total current liabilities	3,494,000	4,927,642
Finance lease liabilities, non-current	30,624	-
Operating lease right-of-use liabilities	576,407	-
Total liabilities	<u>\$ 4,101,031</u>	<u>\$ 4,927,642</u>
Commitments and contingencies		
Stockholders' equity		
Common stock, par value \$.001; authorized 75,000,000 shares; 63,605,119 shares issued and 63,571,786 shares outstanding as of September 30, 2020; 49,410,176 shares issued and 49,376,843 shares outstanding as of December 31, 2019;	63,605	49,410
Additional paid in capital	116,577,241	96,082,324
Accumulated deficit	(99,806,352)	(93,524,297)
Treasury stock, at cost, 33,333 shares	(911,516)	(911,516)
Total Milestone Scientific Inc. stockholders' equity	15,922,978	1,695,921
Noncontrolling interest	(78,388)	(67,274)
Total stockholders' equity	15,844,590	1,628,647
Total liabilities and stockholders' equity	<u>\$ 19,945,621</u>	<u>\$ 6,556,289</u>

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

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

	For the three months ended September 30, 2020	For the three months ended September 30, 2019	For the Nine months ended September 30, 2020	For the Nine months ended September 30, 2019
Product sales, net	\$ 1,246,110	\$ 1,899,821	\$ 3,225,170	\$ 6,073,580
Cost of products sold	<u>409,621</u>	<u>523,672</u>	<u>1,024,947</u>	<u>1,894,550</u>
Gross profit	836,489	1,376,149	2,200,223	4,179,030
Selling, general and administrative expenses	2,291,779	2,314,943	8,221,359	6,941,964
Research and development expenses	<u>21,438</u>	<u>7,940</u>	<u>237,089</u>	<u>109,815</u>
Total operating expenses	2,313,217	2,322,883	8,458,448	7,051,779
Loss from operations	(1,476,728)	(946,734)	(6,258,225)	(2,872,749)
Interest expense	(569)	(2,449)	(8,727)	(6,067)
Change in fair value of derivative liability	<u>-</u>	<u>(1,899,484)</u>	<u>-</u>	<u>(1,846,761)</u>
Loss before provision for income taxes and net of equity investments	(1,477,297)	(2,848,667)	(6,266,952)	(4,725,577)
Provision for income taxes	<u>(24,717)</u>	<u>(1,250)</u>	<u>(26,217)</u>	<u>(19,877)</u>
Loss before equity in net earnings (losses) of equity investments	(1,502,014)	(2,849,917)	(6,293,169)	(4,745,454)
Earnings from China Joint Venture	<u>-</u>	<u>-</u>	<u>-</u>	<u>49,099</u>
Net loss	(1,502,014)	(2,849,917)	(6,293,169)	(4,696,355)
Net loss attributable to noncontrolling interests	<u>11,025</u>	<u>12,941</u>	<u>35,501</u>	<u>35,343</u>
Net loss attributable to Milestone Scientific Inc.	<u>\$ (1,490,989)</u>	<u>\$ (2,836,976)</u>	<u>\$ (6,257,668)</u>	<u>\$ (4,661,012)</u>
Net loss per share applicable to common stockholders—				
Basic	(0.02)	(0.06)	(0.11)	(0.11)
Diluted	(0.02)	(0.06)	(0.11)	(0.11)
Weighted average shares outstanding and to be issued—				
Basic	65,817,132	47,721,732	56,478,151	43,311,984
Diluted	65,817,132	47,721,732	56,478,151	43,311,984

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

MILESTONE SCIENTIFIC INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019
(UNAUDITED)

	Preferred Stock Shares	Preferred Stock	Common Stock Share	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Treasury Stock	Total
Balance, January 1, 2020	-	-	49,410,176	\$ 49,410	\$ 96,082,324	\$ (93,524,297)	\$ (67,274)	\$ (911,516)	\$ 1,628,647
Stock based compensation	-	-	-	-	30,715	-	-	-	30,715
Common stock issued to employee for compensation	-	-	22,633	23	14,989	-	-	-	15,012
Common stock to be issued for payment of consulting services	-	-	-	-	25,000	-	-	-	25,000
Common stock to be issued to employees for bonuses	-	-	-	-	171,046	-	-	-	171,046
Common stock issued for warrants	-	-	460,725	460	229,902	-	-	-	230,362
Net loss	-	-	-	-	-	(1,600,215)	(12,738)	-	(1,612,953)
Balance, March 31, 2020	-	-	49,893,534	\$ 49,893	\$ 96,553,976	\$ (95,124,512)	\$ (80,012)	\$ (911,516)	\$ 487,829
Stock based compensation	-	-	-	-	23,946	-	-	-	23,946
Common stock issued to employee for compensation	-	-	11,450	11	14,989	-	-	-	15,000
Common stock issued for payment of consulting services	-	-	278,581	279	381,520	-	-	-	381,799
Common stock issued to board of directors for services	-	-	39,233	39	53,967	-	-	-	54,006
Common stock issued to employees for bonuses	-	-	202,617	203	(203)	-	-	-	-
Common stock to be issued to employees for bonuses	-	-	-	-	462,504	-	-	-	462,504
Common stock issued in public offering April 6,2020	-	-	5,420,000	5,420	4,621,022	-	-	-	4,626,442
Common stock issued in public offering-June 30, 2020	-	-	6,770,000	6,770	13,410,074	-	-	-	13,416,844
Acquired controlling interest in Milestone Advanced Cosmetic Systems	-	-	-	-	-	(24,387)	24,387	-	-
Common stock issued for warrants	-	-	620,750	621	718,029	-	-	-	718,650
Net loss	-	-	-	-	-	(3,166,464)	(11,738)	-	(3,178,202)
Balance, June 30, 2020	-	-	63,236,165	\$ 63,236	\$ 116,239,824	\$ (98,315,363)	\$ (67,363)	\$ (911,516)	\$ 17,008,818
Stock based compensation	-	-	-	-	18,392	-	-	-	18,392
Common stock issued to employee for compensation	-	-	7,692	8	14,992	-	-	-	15,000
Common stock issued for payment of consulting services	-	-	112,140	113	227,928	-	-	-	228,041
Common stock issued to board of directors for services	-	-	16,350	16	29,984	-	-	-	30,000
Common stock issued to employees for bonuses	-	-	180,272	180	9,422	-	-	-	9,602
Common stock issued for warrants	-	-	52,500	52	36,699	-	-	-	36,751
Net loss	-	-	-	-	-	(1,490,989)	(11,025)	-	(1,502,014)
Balance, September 30, 2020	-	-	63,605,119	\$ 63,605	\$ 116,577,241	\$ (99,806,352)	\$ (78,388)	\$ (911,516)	\$ 15,844,590

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

	Preferred Stock Shares	Preferred Stock	Common Stock Share	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Treasury Stock	Total
Balance, January 1, 2019	7,000	\$ 7	36,329,600	\$ 36,330	\$ 88,414,718	\$ (85,999,929)	\$ (11,402)	\$ (911,516)	\$ 1,528,208
Stock based compensation	-	-	-	-	56,988	-	-	-	56,988
Common stock to be issued to employees for bonuses	-	-	175,715	175	61,325	-	-	-	61,500
Common stock to be issued for payment of consulting services	-	-	118,115	118	39,882	-	-	-	40,000
Common stock to be issued to employee for compensation	-	-	22,727	23	7,477	-	-	-	7,500
Common stock to be issued to board of directors for services rendered	-	-	20,588	21	6,979	-	-	-	7,000
Common stock issued in public offering	-	-	6,282,400	6,281	1,968,265	-	-	-	1,974,546
Common stock issued in private offering	-	-	714,286	714	249,286	-	-	-	250,000
Reclassification of warrants and Shares to be issued to derivative liability (Note 9)	-	-	-	-	(406,045)	-	-	-	(406,045)
Net loss	-	-	-	-	-	(782,752)	(10,443)	-	(793,195)
Balance, March 31, 2019	7,000	\$ 7	43,663,431	\$ 43,662	\$ 90,398,875	\$ (86,782,681)	\$ (21,845)	\$ (911,516)	\$ 2,726,502
Stock based compensation	-	-	-	-	44,712	-	-	-	44,712
Common stock issued for payment of consulting services	-	-	265,140	265	139,735	-	-	-	140,000
Common stock to be issued to employee for compensation	-	-	41,667	42	14,958	-	-	-	15,000
Common stock to be issued to board of directors for services rendered	-	-	82,442	82	29,918	-	-	-	30,000
Conversion of Preferred Shares to Common Stock (Mandatory)	(7,000)	(7)	5,982,906	5,983	(5,976)	-	-	-	-
Reclassification of warrants and Shares to be issued to derivative liability (Note 9)	-	-	(2,903,366)	(2,902)	(1,062,637)	-	-	-	(1,065,539)
Net loss	-	-	-	-	-	(1,041,284)	(11,959)	-	(1,053,243)
Balance, June 30, 2019	-	\$ -	47,132,220	\$ 47,132	\$ 89,559,585	\$ (87,823,965)	\$ (33,804)	\$ (911,516)	\$ 837,432
Stock based compensation	-	-	-	-	45,147	-	-	-	45,147
Common stock to issued for payment of consulting services	-	-	316,824	317	122,683	-	-	-	123,000
Common stock to issued for payment of consulting services	-	-	202,325	202	113,298	-	-	-	113,500
Common stock to be issued to employees for bonuses	-	-	170,454	170	149,830	-	-	-	150,000
Common stock to be issued to employee for compensation	-	-	18,072	18	14,982	-	-	-	15,000
Common stock to be issued to board of directors for services rendered	-	-	44,408	44	29,956	-	-	-	30,000
Common stock issued for warrants exercised	-	-	57,750	58	28,817	-	-	-	28,875
Shares issued previously classified as derivative liability (Note 9)	-	-	692,281	693	410,026	-	-	-	410,719
Reclassification of warrants and Shares to be issued to derivative liability (Note 9)	-	-	(435,260)	(435)	(308,065)	-	-	-	(308,500)
Net loss	-	-	-	-	-	(2,836,976)	(12,941)	-	(2,849,917)
Balance, September 30, 2019	-	-	48,199,074	\$ 48,199	\$ 90,166,259	\$ (90,660,941)	\$ (46,745)	\$ (911,516)	\$ (1,404,744)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

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

	For the Nine months ended September 30, 2020	For the Nine months ended September 30, 2019
Cash flows from operating activities:		
Net loss	\$ (6,293,169)	\$ (4,696,355)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	35,103	37,159
Amortization of patents	39,759	39,760
Stock compensation	76,611	146,847
Employees paid in stock	768,463	315,425
Expense paid in stock	644,865	292,915
Non-cash operating lease expense	30,175	-
Earnings on China joint venture	-	(49,100)
Change in fair value of derivative liability	-	1,846,761
Changes in operating assets and liabilities:		
Decrease in accounts receivable	747,682	739,195
Decrease in accounts receivable, related party	-	100,000
Decrease in other assets	11,755	(9,027)
(Increase) decrease in inventories	(609,251)	303,989
(Increase) decrease in advances on contracts	(12,422)	20,289
Decrease (Increase) in prepaid expenses and other current assets	(7,996)	(90,362)
(Decrease) in accounts payable	(713,331)	(465,670)
(Decrease) in accounts payable, related party	(965,662)	(109,989)
Decrease in deferred cost, related party	-	50,000
Increase (decrease) in accrued expenses	431,917	(50,428)
(Decrease) increase in accrued expenses, related party	(530,659)	402,905
(Decrease) in deferred revenue, related party	-	(100,000)
Net cash used in operating activities	<u>(6,346,160)</u>	<u>(1,275,686)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(21,438)	(9,916)
Net cash used in investing activities	<u>\$ (21,438)</u>	<u>\$ (9,916)</u>
Cash flows from financing activities:		
Proceeds from exercise of warrants	985,763	28,875
Payments finance lease obligations	(4,998)	-
Net proceeds from note payable	276,180	-
Net proceeds from Public Placement Offering	18,043,284	1,974,547
Net proceeds from Private Placement Offering	-	250,000
Net cash provided by financing activities	<u>\$ 19,300,229</u>	<u>\$ 2,253,422</u>
Net increase in cash and cash equivalents	12,932,631	967,820
Cash and cash equivalents at beginning of period	<u>1,516,272</u>	<u>743,429</u>
Cash and cash equivalents at end of period	<u>\$ 14,448,903</u>	<u>\$ 1,711,249</u>
Supplemental non-cash disclosure of cash flow information:		
Shares issued to board of directors	-	67,000
Shares issued to employees for compensation	-	37,500
Shares issued to consultants in lieu of cash payments	-	416,500
Shares issued to employee for bonuses	-	211,500
Credit from United Systems for defective handpieces	-	(151,562)
Initial recognition of operating lease-right of use assets	(706,071)	(166,292)
Initial recognition of operating lease right to used liabilities	706,071	166,292

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements

MILESTONE SCIENTIFIC INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 1 — ORGANIZATION AND BUSINESS

All references in this report to “Milestone Scientific, Inc.,” “us,” “our,” “we,” the “Company” or “Milestone” refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., Milestone Advanced Cosmetic Inc. and Milestone Medical Inc. and affiliate, Milestone Education LLC, 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*®; *CathCheck*™, the *Milestone logo*®; *Safety Wand*®; *STA Single Tooth Anesthesia System*®; and *The Wand*®.

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific is a medical 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. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery device, using *The Wand*®, a single use disposable handpiece. The device is marketed in the dental market under the trademark *CompuDent*®, and *STA Single Tooth Anesthesia System*® and in the medical market under the trademark *CompuMed*®. *CompuDent*® is suitable, for all dental procedures that require local anesthetic. *CompuMed*® is suitable upon regulatory approval, as required, 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 60 other countries.

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (FDA) for both intra-articular and epidural injections with the *CompuFlo*® Computer Controlled Anesthesia System. In June 2017, the FDA approved the *CompuFlo*® Epidural Computer Controlled Anesthesia System for epidural injections. Milestone Scientific is in the process of 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. To date there have been eleven medical devices sold in the United States and limited amounts sold internationally, although certain medical devices have obtained CE mark approval and can be marketed and sold in most European countries.

In December 2016, the Company 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. The Company provided an additional data submission to the FDA in April 2017, in support of a resubmission 510(k) application for the device. The 510(k) original application filed with FDA lapsed in January 2019. Following consultation with the FDA Office of Device Evaluation, we intended to file a new 510(k) application for the device during 2020. As of September 30, 2020, the Company has suspended the pursuit of an intra-articular 510(k) application due to the COVID-19 Pandemic. The company will revisit this project in 2021.

On April 21, 2020, Milestone Scientific announced that it had validated and integrated the new *CathCheck*™ feature into the *CompuFlo*® Epidural System. Using *CathCheck*™, physicians and nurses can monitor the placement of a catheter to determine the presence or absence of a pulsatile waveform (heartbeat) providing new information that can be used to determine if the catheter is in place or has become dislodged from the epidural space.

On October 13, 2020, Milestone Medical announced a Group Purchasing Agreement with Premier, a leading healthcare improvement company, utilizing an alliance of approximately 4,100 U.S. hospitals and 200,000 other providers to transform healthcare. The Agreement, which was effective November 1, 2020, allows Premier members, at their discretion, to utilize pricing and terms pre-negotiated by Premier for the *CompuFlo*® Epidural System and *CathCheck*™. The Agreement expires on February 28, 2022.

NOTE 2- LIQUIDITY AND UNCERTAINTIES

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.

In the second quarter of 2020 the Company completed two capital raises. In April and June of 2020, the Company completed Common Stock Offerings generating net proceeds of approximately \$4.6 million and \$13.4 million, respectively (see Note 9). As of September 30, 2020, cash on hand was approximately \$14.4 million, an increase of \$13 million from December 31, 2019. With the combination of these two Common Stock Offerings, the Company has sufficient liquidity to support operations beyond a year after the condensed consolidated financial statements issue date.

The coronavirus (COVID-19) that was reported to have surfaced in Wuhan, China in December 2019 and that has now spread to other countries throughout the world has adversely impact our operations and those of our third-party partners. As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of COVID-19, revenues for the three and the nine months ended September 30, 2020 was adversely affected.

Although there has been a slow pick up in dental instrument and disposable sell through to dentists beginning in the third quarter, it is too early to determine what the continuing effect COVID-19 may have on our fourth quarter revenue. In addition, it is uncertain as to what the effect will be on the anticipated commercialization of our CompuFlo Epidural and CathCheck system as a medical device. The extent to which the coronavirus impacts our operations, our third-party partners, the dental offices and hospital operations and demand depends on future developments which are still highly uncertain. Such future developments could have a material adverse effect on our financial results and our ability to conduct business as expected.

NOTE 3 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1. Principles of Consolidation

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

2. Basis of Presentation

The unaudited condensed consolidated financial statements of Milestone Scientific have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information with the instructions for Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present such interim results. Interim results are not necessarily indicative of the results of operations which may be expected for a full year or any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2019, included in Milestone Scientific's Annual Report on Form 10-K.

3. Reclassifications

Certain reclassification has been made to the 2019 financial statements to conform to the unaudited condensed consolidated 2020 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

4. Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the allowance for doubtful accounts, inventory valuation, and cash flow assumptions regarding evaluations for impairment of long-lived assets and going concern considerations, and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

5. Revenue Recognition

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 customer arrangements 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 transfer of control, except for specific contracts and arrangements that provide for customer right to return provisions, is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

Sales Returns

The Company records allowances for product returns as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the customers' return rights and the Company's historical experience with returns and the amount of product in the distribution channel not consumed by end users and subject to return. The Company relies on historical return rates to estimate returns. In the future, if any of these factors and/or the history of product returns change, adjustments to the allowance for product returns may be required.

Financing and Payment

Our payment terms differ by geography and customer, but payment is generally required within 90 days from the date of shipment or delivery.

Disaggregation of Revenue

We operate in two operating segments: dental and medical. Therefore, results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. See Note 11 for revenues by geographical market, and product category for the three and nine months ended September 30, 2020 and 2019.

6. Variable Interest Entities

A variable interest entity ("VIE") is an entity that either (i) has insufficient equity to permit the entity to finance its activities without additional subordinated financial support or (ii) has equity investors who lack the characteristics of a controlling financial interest. A VIE is consolidated by its primary beneficiary. The primary beneficiary has both the power to direct the activities that most significantly impact the entity's economic performance and the obligation to absorb losses or the right to receive benefits from the entity that could potentially be significant to the VIE.

Because Milestone Scientific has a variable interest in Milestone China it considered the guidance in ASC 810, "Consolidation" as it relates to determining whether Milestone China is a VIE and, if so, identifying the primary beneficiary. Milestone Scientific would be considered the primary beneficiary of the VIE if it has both of the following characteristics:

- Power Criterion: The power to direct the activities that most significantly impact the entity's economic performance; and
- Losses/Benefits Criterion: The obligation to absorb losses that could potentially be significant or the right to receive benefits that could potentially be significant to the VIE.

Milestone Scientific does not have the ability to control the activities that most significantly impact Milestone China's economics and, therefore, the power criterion has not been met. Management placed the most weight on the relationship and significance of activities of Milestone China to the CEO and a group of significant shareholders, including the Milestone China CEO, 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. See Note 6.

7. Cash and Cash Equivalents

Milestone Scientific considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company maintains its cash and cash equivalents in bank deposit and other interest-bearing accounts, the balances of which, at times, may exceed federally insured limits.

8. Accounts Receivable

Milestone Scientific sells a significant amount of its product on credit terms to its major distributors. Milestone Scientific estimates losses from the inability of its customers to make payments on amounts billed. Most credit sales are due within 90 days from invoicing. There have not been any significant credit losses incurred to date. As of September 30, 2020, and December 31, 2019, accounts receivable was recorded, net of allowance for doubtful accounts of \$10,000.

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, defective, and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence, and product expiration requirements. The valuation allowance creates a new cost basis for the inventory, and it is not subsequently marked up through a reduction in the valuation allowance based on any changes in the underlying facts and circumstances. When the valuation allowance is initially recorded, the increase to the allowance is recognized as an increase in cost of sales. The valuation allowance is only reduced if or when the underlying inventory is sold or destroyed, at which time cost of sales recognized would include the previous adjusted cost basis.

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 long-term assets on the Condensed Consolidated Balance Sheets. Under this method of accounting, Milestone Scientific's share of the net earnings or losses of the investee is presented below the income tax line on the unaudited 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. Furniture, Fixture and Equipment

Equipment is recorded at cost, less accumulated depreciation. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets, which range from two to seven years. The costs of maintenance and repairs are charged to operations as incurred.

12. Intangible Assets – Patents and Developed Technology

Patents are recorded at cost to prepare and file the applicable documents with the US Patent Office, or internationally with the applicable governmental office in the respective country. The costs related to these patents are being amortized using the straight-line method over the estimated useful life of the patent. Patents and other developed technology acquired from another business entity will be amortized based on the estimated useful life of the patent. These patents and developed technology are recorded at the acquisition cost.

13. Impairment of Long-Lived Assets

Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company's impairment review process is based upon an estimate of future undiscounted cash flow. Factors the Company considers that could trigger an impairment review include the following:

- significant under performance relative to expected historical or projected future operating results,
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business
- significant negative industry or economic trends; and
- significant technological changes, which would render the technology obsolete

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs.

14. Note Payable

On April 27, 2020, the Company, was granted a loan (the "Loan") from Savoy Bank. in the aggregate amount of approximately \$276,000, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the CARES Act, which was enacted March 27, 2020.

The Loan, which was in the form of a Note dated April 27, 2020, matures on April 27, 2022, and bears interest at a rate of 1.00% per annum, payable monthly commencing on November 26, 2020. The Note may be prepaid by the Borrower at any time prior to maturity with no prepayment penalties. Funds from the Loan may only be used for payroll costs, costs used to continue group health care benefits, mortgage payments, rent, utilities, and interest on other debt obligations incurred before February 15, 2020. The Company intends to use the entire Loan amount for qualifying expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act.

15. Research and Development

Research and development costs, which consist principally of new product development costs payable to third parties, are expense as incurred. Advance payments for the research are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

16. Income Taxes

Milestone Scientific accounts for income taxes pursuant to the asset and liability method which requires deferred income tax assets and liabilities to be computed for temporary differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

On September 30, 2020 and December 31, 2019, we had no uncertain tax positions that required recognition in the condensed consolidated financial statements. Milestone Scientific's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the condensed consolidated statements of operations. No interest and penalties are present for periods open. Tax returns for the 2016, 2017, and 2018 years are subject to audit by federal and state jurisdictions.

17. 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 and warrants were issued during the period.

Since Milestone Scientific had net losses in the three and nine months ended September 30, 2020 and 2019, 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 7,477,171 and 5,004,415 on September 30, 2020 and 2019, respectively.

18. Fair Value of Financial Instruments

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

- Level 1 inputs which are defined as quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity can access at the measurement date.
- Level 2 inputs which are defined as inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.
- Level 3 inputs are defined as unobservable inputs for the assets or liabilities.

Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of an input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels. As of September 30, 2020 the Company does not have any assets or liabilities that were measured at fair value on a recurring basis. The carrying amounts reported in the accompanying unaudited condensed consolidated financial statements for current assets and current liabilities approximate the fair value because of the immediate or short-term maturities of the financial instruments.

19. Derivative Liability

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks; however, the Company had certain financial instruments that qualified as derivatives and were classified as liabilities on the balance sheet during the year ended December 31, 2019. The Company evaluates all its financial instruments to determine if those instruments or any potential embedded components of those instruments qualify as derivatives that need to be separately accounted for in accordance with FASB ASC 815, "Derivatives and Hedging". Derivatives satisfying certain criteria are recorded at fair value at issuance and marked-to-market at each balance sheet date with the change in the fair value recorded as income or expense. In addition, upon the occurrence of an event that requires a derivative liability to be reclassified to equity, the derivative liability is revalued to fair value at that date. See Note 9, Outstanding Equity Instruments in Excess of Authorized Shares.

20. Stock-Based Compensation

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

21. Leases

At the inception of an arrangement, we determine whether an arrangement is, or contains, a lease. An arrangement is, or contains, a lease if the arrangement conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Leases with a term greater than one year are generally recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable. We have elected not to recognize on the balance sheet leases with terms of 12 months or less. We typically only include the initial lease term in our assessment of a lease arrangement. Options to extend a lease are not included in our assessment unless there is reasonable certainty that we will renew.

Finance and operating lease right-of-use assets represent the Company's right to use an underlying asset over the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. These assets and obligations are recognized at the lease commencement date based on the present value of lease payments, net of incentives, over the lease term. The interest rate implicit in our leases is typically not readily determinable. As a result, we utilize our incremental borrowing rate, which reflects the fixed rate at which we could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

We evaluate the classification of our leases as either finance leases or operating leases. Leases that are economically similar to the purchase of assets are generally classified as finance leases; otherwise, the leases are classified as operating leases. Lease cost for our operating leases is recognized on a straight-line basis over the lease term. Included in lease cost are any variable lease payments incurred in the period that are not included in the initial lease liability and lease payments incurred in the period for any leases with an initial term of 12 months or less.

22. Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (“FASB”) issued a new standard ASU No. 2016-13, “Financial Instruments – Credit Losses” (Topic 326), and subsequently amended. The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all smaller reporting entities for fiscal years and interim periods, beginning after December 15, 2022. The adoption of this standard is not expected to have a material effect on financial statement presentation.

In August 2018, FASB issued ASU 2018-13, “Fair Value Measurement: Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (Topic 820), which changes the fair value measurement disclosure requirements of ASC 820. This ASU removes certain disclosure requirements regarding the amounts and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy and the policy for timing of transfers between the levels. This ASU also adds disclosure requirements regarding unrealized gains and losses included in Other Comprehensive Income for recurring Level 3 fair value measurements and the range and weighted average of unobservable inputs used in Level 3 fair value measurements. ASU 2018-13 is effective for all entities with fiscal years beginning after December 15, 2019, including interim periods therein. The adoption of this standard did not have a material effect on financial statement presentation.

In August 2018, FASB issued ASU 2018-15, “Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40):Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract”, which provides guidance for the accounting treatment for the software arrangements used by companies. ASU 2018-15 is effective for all entities with fiscal years beginning after December 15, 2019, including interim periods therein. The adoption of this standard did not have a material effect on financial statement presentation.

In December 2019, FASB issued ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which clarifies for the accounting treatment for the accounting tax aspects relating, in part, to the intraperiod allocations and foreign subsidiaries. ASU 2019-12 is effective for all entities with fiscal years beginning after December 15, 2020. The adoption of this standard is not expected to have a material effect on financial statement presentation.

In January 2020, FASB issued ASU 2020-01, “Investments—Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815), which, generally, provides guidance for investments in entities accounted for under the equity method of accounting. ASU 2020-01 is effective for all entities with fiscal years beginning after December 15, 2021, including interim periods therein. We are currently evaluating the impact of adopting this guidance on our consolidated balance sheets, results of operations, and financial condition.

In August 2020, FASB issued ASU 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity; which, generally, provides guidance for accounting regarding derivatives relating to entities common stock and earnings per share. ASU 2020-06 is effective for all entities with fiscal years beginning after December 15, 2021, including interim periods therein. The adoption of this standard is not expected to have a material effect on financial statement presentation

NOTE 4 — INVENTORIES

Inventories consist of the following:

	September 30, 2020	December 31, 2019
Dental finished goods, net	\$ 1,705,519	\$ 1,306,763
Medical finished goods, net	169,549	213,861
Component parts and other materials	354,692	99,885
Total inventories	<u>\$ 2,229,760</u>	<u>\$ 1,620,509</u>

On September 30, 2020, there is a reserve for slow moving medical finished goods of approximately \$450,000 and damaged or slow moving dental finished goods of approximately \$7,000. The reserve for the medical finished goods was primarily related to the delay in regulatory approval and commercialization of the intra-articular medical instrument. As of December 31, 2019, there is a reserve for slow moving medical finished goods of approximately \$450,000 and damaged or slow moving dental finished goods of approximately \$318,000. Approximately \$311,000 of the dental finished inventory reserved at December 31, 2019 was destroyed during the nine months ended September 30, 2020.

NOTE 5 — ADVANCES ON CONTRACTS

The advances on contracts represent funding of future STA inventory purchases, epidural instruments, and epidural replacements parts. The balance of the advances as of September 30, 2020 and December 31, 2019 is approximately \$723,000 and \$710,000, respectively. The advance is classified as current based on the estimated annual usage of the underlying inventory.

NOTE 6 – INVESTMENT IN AND TRANSACTIONS WITH EQUITY INVESTEEES

Milestone China Ltd.

Ownership

In June 2014, Milestone Scientific invested \$1 million in Milestone China Ltd. (“Milestone China”), by contributing dental instruments to Milestone China for a forty (40%) ownership interest. Milestone China owns approximately 75% of Milestone Beijing Medical Equipment Company, Ltd (“Milestone Beijing”). Milestone Beijing has primary responsibility for the sales, marketing, and distribution of the Company’s dental products in China. Milestone Scientific recorded their investment in Milestone China under the equity method of accounting.

In first quarter 2020, Milestone China and certain marketing affiliates entered into a plan to merge (the Transaction) into an affiliated manufacturing company, Anhui Maishida Medical Technology, Co. Ltd. (Anhui). Anhui will be the surviving entity after the merger and will have complete responsibility for sales, marketing, and distribution for the Company’s dental products in China. However, as of the filing date of this Quarterly Report, due to the COVID-19 Pandemic, the regulatory documentation for the planned merger has been placed in suspense since applicable government offices are still closed in China and Hong Kong. After completion of the Transaction, Milestone Scientific is expected to have an approximate 28.4% direct ownership in Anhui. Milestone China and certain marketing affiliates are expected to be dissolved upon completion of the merger and upon the required regulatory filings in China and Hong Kong.

Related Party Transactions

Milestone China is Milestone Scientific’s exclusive distributor in China. During 2017 and prior to the payment default during 2018, Milestone Scientific agreed to sell inventory to Milestone China and its agent. During 2018, Milestone Scientific entered into a payment arrangement with Milestone China to satisfy past due receivables from Milestone China and its agents which amounted to \$2.8 million at the time of the payment arrangement. Milestone Scientific collected \$950,000 under this arrangement, until Milestone China defaulted on the payment arrangements. Milestone Scientific halted shipments to Milestone China and the Company has adjusted the accounts receivable related party and the deferred revenue related party based on the expected payment realization and recorded a charge for deferred cost associated with these transactions of \$1.25 million during the fourth quarter of 2018.

For the three and nine months ended September 30, 2020 Milestone Scientific did not ship nor recognize any deferred revenue or net revenue for Milestone China and its agents. For the three and nine months ended September 30, 2019 Milestone Scientific did not ship nor recognize any deferred revenues, but did recognize revenue of zero, and \$100,000 for Milestone China and its agents, respectively, that was previously deferred as a result of additional cash collected.

United System Agreement

In April of 2020, the Company entered into an agreement with United Systems, Inc., related party (see Note 13) regarding certain handpieces supplied to Milestone China in 2018, that were billed and shipped to Milestone China by United Systems, as well as STA instruments billed to United Systems and delivered to Milestone China, and not paid by Milestone China. United Systems sold their entire accounts receivable due from Milestone China for the above described handpieces and STA instruments for \$370,260 to Milestone Scientific. Milestone Scientific paid United Systems the sale price as follows; \$100,000 in cash paid in April 2020, \$170,260 in shares of the Company’s Common Stock (priced as of the close of business on April 23, 2020, \$1.59) issued in June 2020, and \$100,000 in cash paid in July 2020. The Company is entitled to the cash collections, if and when received, on the accounts receivable due to United Systems prior to this agreement up to approximately \$1.4 million.

The Company has recorded a charge to the unaudited condensed consolidated statement of operations for \$370,260 during the nine months ended September 30, 2020.

Milestone Advanced Cosmetic Systems Inc. Transaction

In May 2020, Milestone Scientific finalized an agreement for the purchase of Milestone China’s 50% interest in Advanced Cosmetic Systems Inc., for the forgiveness of \$900,000 in accounts receivable owed by Milestone China to Milestone Scientific (and previously fully reserved for), resulting in a noncash transaction. Milestone China will have the option to repurchase the 50% interest in Advanced Cosmetic Systems within one year from the sale date for \$900,000 in cash. As a result of the purchase Milestone Scientific will own 100% of Advanced Cosmetic Systems Inc. at the expiration of the option period.

Gross Profit Deferral

Due to timing differences of when the inventory sold to Milestone China is recognized and when Milestone China sells the acquired inventory to third parties, an elimination of the profit is required as of the balance sheet date. In accordance with ASC 323 Equity Method and Joint Ventures, Milestone Scientific has deferred 40% of the gross profit associated with recognized revenue from sales to Milestone China until that product is sold to third parties.

At September 30, 2020 and December 31, 2019, the deferred profit was \$340,476, which is included in deferred profit, related party in the condensed consolidated balance sheets. For the three and nine months ended September 30, 2020 and 2019 Milestone Scientific recorded earnings on equity investment of \$0 and \$0 and \$0 and \$49,099 respectively, for product sold by Milestone China to third parties.

Equity Method Disclosures

As a result of the COVID-19 Pandemic, as previously noted, Milestone China, Milestone Beijing and Anhui have not legally finalized the Transaction. Further, Milestone China and Milestone Beijing have not completed the financial accounting and reporting as of and for the three and nine months ended September 30, 2020. Consequently, the summarized financial information (unaudited) for Milestone China, Milestone Beijing are not available and therefore not included herein.

Milestone Scientific, in previous years, reduced its investment in Milestone China to zero and had accumulated losses over the investment balance of approximately \$4.3 million as of December 31, 2019, which have been suspended. Milestone Scientific believes that its equity method portion of Milestone China’s expected losses for the three- and nine-months ending September 30, 2020 do not have a significant impact on and are not material to the consolidated financial statements of the Company.

NOTE 7 — PATENTS

	September 30, 2020		December 31, 2019	
	Cost	Accumulated Amortization	Cost	Accumulated Amortization
Patents-foundation intellectual property	\$ 1,377,863	\$ (1,035,362)	\$ 1,377,863	\$ (995,603)
Total	<u>\$ 1,377,863</u>	<u>\$ (1,035,362)</u>	<u>\$ 1,377,863</u>	<u>\$ (995,603)</u>
		Net		Net
		\$ 342,501		\$ 382,260
		<u>\$ 342,501</u>		<u>\$ 382,260</u>

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. Amortization expense was approximately \$13,000 and \$40,000 for the three and nine months ended September 30, 2020, respectively. Amortization expense was approximately \$13,000 and \$40,000 for the three and nine months ended September 30, 2019, respectively.

NOTE 8 — NOTE PAYABLE

On April 27, 2020, the Company, was granted a loan (the “Loan”) from Savoy Bank in the aggregate amount of approximately \$276,000, pursuant to the Paycheck Protection Program (the “PPP”) under Division A, Title I of the CARES Act, which was enacted March 27, 2020. The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loans and accrued interest are forgivable after seven weeks as long as the borrower uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The amount of loan forgiveness will be reduced if the borrower terminates employees or reduces salaries during the eight-week period.

The Loan matures on April 27, 2022 and bears interest at a rate of 1.00% per annum, payable monthly commencing on November 26, 2020. The Note payable principal is due April 27, 2022 in a balloon payment if the loan is not forgiven. The Note may be prepaid by the Borrower at any time prior to maturity with no prepayment penalties. Funds from the Loan may only be used for payroll costs, costs used to continue group health care benefits, mortgage payments, rent, utilities, and interest on other debt obligations originating before February 15, 2020. The Company intends to use the entire Loan amount for qualifying expenses. While the Company currently believes that its use of the loan proceeds will meet the conditions for forgiveness of the loan, we cannot be assured that certain actions taken that could cause the Company to be ineligible for forgiveness of the loan, in whole or in part.

NOTE 9— STOCKHOLDERS’ EQUITY

PUBLIC OFFERING AND PRIVATE PLACEMENT

In February 2019, Milestone Scientific consummated a public offering and a private placement of Common Stock. The public offering generated gross proceeds of approximately \$2.0 million for the issuance of 5,715,000 shares of common stock and warrants to purchase 1,428,750 shares of common stock. The warrants have a term of 5 years and are exercisable at \$0.50 per share. Subsequent, to the public offering the underwriter exercised its over-allotment option and paid approximately \$198,000 for 567,400 additional shares of common stock and 141,850 warrants.

Also, in February 2019, the Company generated gross proceeds from a private placement of approximately \$250,000 for 714,286 shares of common stock and warrants to purchase 178,571 shares of common stock from Bp4 S.p.A., a principal stockholder of Milestone Scientific that exercised its right to participate on a pro-rata basis on the recent public offering. Bp4’s CEO is a director of Milestone Scientific and at the time also Chief Executive Officer and Director of Wand Dental, a wholly owned subsidiary of Milestone Scientific. The warrants have a term of 5 years and are exercisable at \$0.50 per share.

In the second quarter of 2020, the Company completed two public offerings. In April 2020, a Common Stock offering generating gross proceeds of approximately \$5.1 million (5,420,000 common shares and 2,710,000 warrants). The combined price of the shares and warrants was \$0.95 per share. The warrants are exercisable at a price of \$1.20 per share and have an expiration of three (3) years from the issue date. In June 2020, the Company completed a second Common Stock offering generating gross proceeds of approximately \$14.6 million (6,770,000 common shares and 3,749,000 warrants). The combined price of the shares and warrants was \$2.15 per share. The warrants are exercisable at \$2.60 and expire three (3) years from the issue date.

WARRANTS

The following table summarizes information about shares issuable under warrants outstanding as of September 30, 2020 :

	Warrant shares outstanding	Weighted Average exercise price	Weighted Average remaining life	Intrinsic value
Outstanding at January 1, 2020	1,074,171	\$ 0.50	\$ 4.10	956,012
Issued	6,459,000	2.01	3.00	-
Exercised	(1,133,975)	0.87	-	-
Expired or cancelled	-	-	-	-
Outstanding and exercisable at September 30, 2020	<u>6,399,196</u>	<u>\$ 1.95</u>	<u>\$ 2.73</u>	<u>880,449</u>

The following table summarizes information about shares issuable under warrants outstanding as of September 30, 2019

	Warrant shares outstanding	Weighted Average exercise price	Weighted Average remaining life	Intrinsic value
Outstanding at January 1, 2019	1,592,775	\$ 2.55	\$ 0.21	-
Issued	1,749,171	0.50	4.35	560,199
Exercised	(57,750)	0.50	-	-
Expired or cancelled	-	-	-	-
Outstanding and exercisable at September 30, 2019	<u>3,284,196</u>	<u>\$ 1.49</u>	<u>\$ 2.30</u>	<u>560,199</u>

PREFERRED STOCK

In May 2014, Milestone completed a private placement, which raised gross proceeds of \$10 million, from the sale of \$3 million of Milestone Scientific common stock (two million shares at \$1.50 per share) and \$7 million of our Series A Convertible Preferred Stock ("Preferred Stock") (7,000 shares at \$1,000 per share). These shares were convertible, at the option of the holder, into the number of shares of common stock equal to the stated value divided by \$2.545, subject to anti-dilution adjustments, at any time before May 14, 2019.

These shares were mandatory convertible on May 14, 2019, into the number of shares of common stock equal to the stated value divided by \$2.54 per share or \$1.50 per share if the common stock does not trade at \$3.15 for period of time, as defined by the agreements, both subject to anti-dilution adjustment.

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

SHARES TO BE ISSUED

As of September 30, 2020 and 2019, there were 2,202,229 and 2,294,734 shares to be issued whose issuance has been deferred to the Chief Executive Officer, Chief Financial Officer, and other employees of Milestone Scientific, respectively.

As of September 30, 2020, and 2019, there were 149,498 and 351,612 shares, respectively, to be issued to non-employees, that will be issued for services rendered. The number of shares was fixed at the date of grant and were fully vested upon grant date.

The following table summarizes information about shares to be issued on September 30, 2020 and 2019, respectively.

	September 30, 2020	September 30, 2019
Shares-to-be-issued, outstanding January 1, 2020 and 2019, respectively	2,375,762	2,470,566
Granted in current period	363,956	1,392,460
Issued in current period	<u>(387,991)</u>	<u>(1,216,680)</u>
Shares-to be issued outstanding September 30, 2020 and 2019, respectively	<u>2,351,727</u>	<u>2,646,346</u>

OUTSTANDING EQUITY INSTRUMENTS IN EXCESS OF AUTHORIZED SHARES

As a result of the shares and warrants issued in the public and private offerings as well as other issuance of common stock during 2019, the Company did not have a sufficient number of authorized shares of common stock to cover the exercise and issue of all outstanding equity instruments. Therefore, as of September 30, 2019, the warrants issued in the public and private placement were classified as liabilities. As long as the warrants remained liability-classified, they were continued to be re-measured each reporting period, with any increase or decrease in value recorded as a loss or gain in the condensed consolidated statement of operations.

The initial fair value of the warrants was determined using a Black-Scholes option pricing model. The following assumptions were used to value the warrants at the reclassification date in 2019:

	2016 Warrants	2019 Warrants
Fair Value of Common Stock	\$.36- \$.83	\$ 0.33
Expected Term (years)	.25-.5 years	4.9 years
Volatility	86%-100%	83%
Dividend yield	0%	0%
Exercise Price	\$ 2.55	\$ 0.50
Risk-free interest rate	1.88%-2.09%	2.30%
Weighted average fair value of warrants granted	\$ -	\$ 0.19
Number of shares underlying warrants granted	1,512,067	1,749,171

On the date of issuance and reclassification the fair value of the warrants was approximately \$376,000.

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

	2016 Warrants	2019 Warrants
Fair Value of Common Stock	\$ 0.83	\$ 0.08
Expected Term (years)	.02 years	4.4 years
Volatility	86%	86%
Dividend yield	0%	0%
Exercise Price	\$ 2.55	\$ 0.50
Risk-free interest rate	1.88%	1.55%
Weighted average fair value of warrants granted	\$ -	61.00%
Number of shares underlying warrants granted	\$ 1,512,067	\$ 1,691,421

For the three and nine months ended September 30, 2019 the loss on the liability classified warrants was approximately \$680,542 and \$674,792, respectively.

Additionally, approximately 2.6 million of shares to be issued are classified as liabilities until there are sufficient number of authorized shares of common stock to cover the issuance of such shares. These shares were valued at the trading price of a share of the Company's common stock (\$0.83 as of September 30, 2019) and they will continue to be re-measured each reporting period, with any increase or decrease in value recorded as a loss or gain in the condensed consolidated statement of operations. For the three and nine months ended September 30, 2019 the loss on the liability classified shares to be issued was approximately \$1.2 million, respectively.

On December 17, 2019, the Company's shareholders approved an increase to the authorized share limit to 75,000,000. On December 17, 2019, the Company reclassified all derivative liabilities related to the insufficient number of authorized shares to stockholders' equity. As such, there were no derivative liabilities during the nine months ended September 30, 2020.

NOTE 10 — INCOME TAXES

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

NOTE 11 — SEGMENT AND GEOGRAPHIC DATA

We conduct our business through two reportable segments: Dental and Medical. These segments offer different products and services to different customer base. The Company provides general corporate services to its segments; however, these services are not considered when making operating decisions and assessing segment performance. These services are reported under "Corporate Services" below and these include costs associated with executive management, investor relations, patents, trademarks, licensing agreements, new instruments developments, financing activities and public company compliance.

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

	Three months ended September 30,2020	Three months ended September 30, 2019	Nine months ended September 30,2020	Nine months ended September 30, 2019
Net Sales:				
Dental	\$ 1,240,110	\$ 1,884,321	\$ 3,209,370	\$ 6,042,580
Medical	6,000	15,500	15,800	31,000
Total net sales	\$ 1,246,110	\$ 1,899,821	\$ 3,225,170	\$ 6,073,580
Operating Income (Loss):				
Dental	\$ 191,235	\$ 644,650	\$ (32,624)	\$ 1,766,087
Medical	(812,840)	(554,843)	(2,297,080)	(1,711,184)
Corporate	(855,123)	(1,036,541)	(3,928,521)	(2,927,652)
Total operating loss	\$ (1,476,728)	\$ (946,734)	\$ (6,258,225)	\$ (2,872,749)
Depreciation and Amortization				
Dental	\$ 402	\$ 3,950	\$ 9,202	\$ 11,875
Medical	674	2,424	5,006	7,424
Corporate	15,429	19,044	60,653	57,620
Total depreciation and amortization	\$ 16,505	\$ 25,418	\$ 74,861	\$ 76,919
Income (loss) before taxes and equity in earnings of affiliates:				
Dental	\$ 190,472	\$ 645,442	\$ (35,376)	\$ 1,765,475
Medical	(813,935)	(556,969)	(2,300,243)	(1,713,362)
Corporate	(853,834)	(2,937,140)	(3,931,333)	(4,777,690)
Total loss before taxes and equity in earnings of affiliate	\$ (1,477,297)	\$ (2,848,667)	\$ (6,266,952)	\$ (4,725,577)
Total Assets:			September 30, 2020	December 31, 2019
Dental			\$ 5,391,842	\$ 5,008,324
Medical			977,160	590,727
Corporate			13,576,619	957,238
Total assets			\$ 19,945,621	\$ 6,556,289

The following table presents information about our operations by geographic area for three months ended September 30, 2020 and 2019. Net sales by geographic area are based on the respective locations of our subsidiaries:

	Three months ended September 30, 2020			Three months ended September 30, 2019		
	Dental	Medical	Total	Dental	Medical	Total
Domestic-US						
Devices	\$ 34,657	\$ -	\$ 34,657	\$ 199,926	\$ -	\$ 199,926
Handpieces	356,566	-	356,566	679,621	-	679,621
Other	16,906	-	16,906	17,343	-	17,343
Total Domestic US	\$ 408,129	\$ -	\$ 408,129	\$ 896,890	\$ -	\$ 896,890
international						
Devices	\$ 220,694	\$ -	\$ 220,694	\$ 412,819	\$ -	\$ 412,819
Handpieces	602,000	6,000	608,000	564,265	15,500	579,765
Other	9,287	-	9,287	10,347	-	10,347
Total International	\$ 831,981	\$ 6,000	\$ 837,981	\$ 987,431	\$ 15,500	\$ 1,002,931
International-China						
Devices	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Handpieces	-	-	-	-	-	-
Other	-	-	-	-	-	-
Total International	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total Product Sales	\$ 1,240,110	\$ 6,000	\$ 1,246,110	\$ 1,884,321	\$ 15,500	\$ 1,899,821

The following table presents information about our operations by geographic area for the nine months ended September 30, 2020 and 2019. Net sales by geographic area are based on the respective locations of our subsidiaries:

	Nine months ended September 30, 2020			Nine months ended September 30, 2019		
	Dental	Medical	Total	Dental	Medical	Total
Domestic-US & Canada						
Devices	\$ 35,181	\$ -	\$ 35,181	\$ 398,729	\$ 10,800	\$ 409,529
Handpieces	992,057	2,000	994,057	2,250,542	300	2,250,842
Other	37,895	-	37,895	61,408	-	61,408
Total Domestic US & Canada	\$ 1,065,133	\$ 2,000	\$ 1,067,133	\$ 2,710,679	\$ 11,100	\$ 2,721,779
International ROW						
Devices	\$ 494,998	\$ 7,600	\$ 502,598	\$ 1,100,488	\$ 8,000	\$ 1,108,488
Handpieces	1,618,524	6,200	1,624,724	2,028,750	11,500	2,040,250
Other	30,715	-	30,715	102,663	400	103,063
Total International-ROW	\$ 2,144,237	\$ 13,800	\$ 2,158,037	\$ 3,231,901	\$ 19,900	\$ 3,251,801
International-China						
Devices	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Handpieces	-	-	-	100,000	-	100,000
Other	-	-	-	-	-	-
Total International	\$ -	\$ -	\$ -	\$ 100,000	\$ -	\$ 100,000
Total Product Sales	\$ 3,209,370	\$ 15,800	\$ 3,225,170	\$ 6,042,580	\$ 31,000	\$ 6,073,580

NOTE 12 -- CONCENTRATIONS

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, epidural, and intra-articular 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 on September 30, 2020 and December 31, 2019. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business, and results of operations.

For the three and nine months ended September 30, 2020, approximately 40% and 45% of the Company's net product sales were from the Company's exclusive domestic dental distributor, respectively. For the three and nine months ended September 30, 2019 net product sales were 54% and 51%, respectively, to the Company's exclusive domestic dental distributor. Accounts receivable for two customers/distributors amounted to approximately \$720,000 or 74%, or 60% and 14% of Milestone Scientific's gross accounts receivable as of September 30, 2020, one of which was the Company's exclusive domestic dental distributor. Accounts receivable for the Company's exclusive domestic dental distributor amounted to approximately 77%, of Milestone Scientific's gross accounts receivable as of December 31, 2019. The Company's exclusive domestic dental distributor exclusivity for the domestic dental market is subject to annual purchase requirements and other requirements, as defined in the agreement.

The COVID-19 pandemic affected the Company's operations in the second quarter and third quarter and may continue to do so indefinitely thereafter. The Company is continuously monitoring its own operations and intends to take appropriate actions to mitigate the risks arising from the COVID-19 pandemic to the best of its abilities, but there can be no assurances that the Company will be successful in doing so. To the extent the Company is able to obtain information about and maintain communications with its customers, suppliers, vendors, and other business partners, the Company will seek to minimize disruptions to its supply chain and distribution channels, but many circumstances will be beyond the Company's control. Governmental action may further cause the Company to temporarily close its facilities and/or regional quarantines may result in labor shortages and work stoppages. All of these factors may have far reaching direct and indirect impacts on the Company's business, operations, and financial results and condition. The ultimate extent of the effects of the COVID-19 pandemic on the Company is highly uncertain and will depend on future developments which cannot be predicted.

NOTE 13 -- RELATED PARTY TRANSACTIONS

United Systems

Milestone Scientific has a manufacturing agreement with United Systems (whose controlling shareholder, Tom Cheng, is a significant stockholder of Milestone Scientific), the principal manufacturers of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were approximately \$373,000 and \$549,000 for the three months ended September 30, 2020 and 2019, respectively. Purchases from this manufacturer were approximately \$1,200,000 and \$1,100,000 for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020 and December 31, 2019, Milestone Scientific owed this manufacturer approximately \$365,000 and \$943,000, respectively, which is included in accounts payable, related party on the condensed consolidated balance sheets. In February 2019, Milestone Scientific Board of Directors granted United Systems 285,714 shares of stock at \$0.35 or \$100,000 for consulting services. These shares were issued July 2019.

On April 29, 2020, the Board of Directors approved the purchase of United Systems accounts receivable (\$370,260) See Note 6.

Milestone China

As of September 30, 2020, Milestone Scientific owned a 40% interest in Milestone China. See Note 6.

Other

As of September 30, 2020, and December 31, 2019, Milestone Scientific had deferred compensation for the previous Chief Executive Officer of Wand Dental of approximately of and \$308,000 and \$380,000, respectively which is included accrued expenses related party.

In August 2016, K. Tucker Andersen, a significant stockholder of Milestone Scientific, entered into an 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, 2020, and 2019, 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 both the three and nine months ended September 30, 2020, and 2019, respectively. This agreement was terminated September 30, 2020.

The Director of Clinical Affairs' royalty fee was approximately \$61,000 and \$92,000 for the three months ended September 30, 2020 and 2019, respectively. The Director of Clinical Affairs' royalty fee was approximately \$158,000 and \$292,000 for the nine months ended September 30, 2020 and 2019, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$117,000 for the three and nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020 and December 31, 2019, Milestone Scientific owed the Director Clinical Affairs for royalties of approximately \$80,000 and \$390,000, respectively, which is included in accounts payable, related party and accrued expense, related party.

NOTE 14 — COMMITMENTS

(1) Contract Manufacturing Agreement

Milestone Scientific has informal arrangements with third-party manufacturers of the STA, epidural, and intra-articular devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. As of September 30, 2020, the purchase order commitment for dental instruments was \$515,284 and advances of \$350,311 are reported in inventory advances.

In August 2019, the company entered a new purchase commitment for the delivery of 100 Epidural instruments beginning in 2020. As of September 30, 2020, we have an open purchase order of \$299,000 for 100 Epidural instruments and have advanced \$161,000 against this purchase commitment. In July 2020, the company entered a new purchase commitment for the delivery of 110 cases of Epidural and Cathcheck disposable kits beginning in November 2020. As of September 30, 2020, we have an open purchase order of \$30,395 for 110 cases of Epidural and Cathcheck disposable kits and have advanced \$21,195 against this purchase commitment.

(2) Leases

Operating Leases

In June 2015, the Company amended its original office lease for its headquarters in Livingston, New Jersey. Under the amendment, the Company leased an additional 774 square feet of rentable area of the building and extended the term of the lease through January 31, 2020 at a monthly cost of \$12,522. The Company had an option to further extend the term of the lease, however, this option was not included in the determination of the lease's right-of-use asset or lease liability. Per the terms of the lease agreement, the Company does not have a residual value guarantee. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts. These costs are considered to be variable lease payments and are not included in the determination of the lease's right-of-use asset or lease liability.

In August 2019, the Company made the decision to not renew the its existing office lease for its corporate headquarters located in Livingston, New Jersey and instead signed a new seven (7) year lease in a new facility located in Roseland, New Jersey (the "Roseland Facility"), which commenced of January 8, 2020. Under the Roseland Facility lease, rent payments commence on April 1, 2020 and the monthly lease payments escalate annually on January 1 of each year, and range from \$9,275 to \$10,898 per month over the lease term. The Company is also required to pay a fixed electric charge equal to \$2.00 per square foot which is paid in equal monthly installments over the lease term or \$11,130 annually. These fixed monthly payments have been included in the measurement of the operating lease liability and related operating lease right-of-use asset as the Company has elected the practical expedient to not separate lease and non-lease components for all leases. The Company is also required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts, which are accounted for as variable lease expenses.

As of September 30, 2020, total operating lease right-of-use assets were \$655,870 and total operating lease liabilities were \$645,341, of which \$68,934 and \$576,407 were classified as current and non-current, respectively. As of December 31, 2019, total operating right-of-use assets were \$15,977 and total operating lease liabilities (current) were \$15,977. During the nine months ended September 30, 2020, the Company also entered into a five-year lease for copiers which resulted in the recognition of property and equipment and total finance lease liabilities of \$43,242. As of September 30, 2020, total finance lease liabilities were \$38,527, of which \$7,903 and \$30,624 were classified as current and non-current, respectively.

Cash flow information related to the Company's right-of-use assets and related lease liabilities were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2020	2019	2020	2019
Lease cost				
Cash paid for operating lease liabilities	30,820	39,555	78,904	118,664
Cash paid for finance lease liabilities	2,658	-	7,622	-
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	-	-	663,009	-
Property and equipment obtained in exchange for new finance lease liabilities	-	-	43,242	-
(1) For the nine months ended September 30, 2019, the balance includes operating leases existing as of the adoption of ASC 842 on January 1, 2019.				
Weighted-average remaining lease term - operating leases (years)	-	-	6.5	0.4
Weighted-average remaining lease term- finance leases (years)	-	-	4.3	-

(3) Other Commitments

The technology underlying the *Safety Wand*® and *CompuFlo*®, and an improvement to the controls for *CompuDent*® were developed by the Director of Clinical Affairs and assigned to Milestone Scientific. Milestone Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs will receive additional payments of 2.5% of the total sales of products using certain of these technologies, and 5% of the total sales of products using certain other of the technologies until the expiration of the last patent covering these technologies. If products produced by third parties use any of these technologies (under license from us) then the Director of Clinical Affairs will receive the corresponding percentage of the consideration received by Milestone Scientific for such sale or license. See note 13 Other.

NOTE 15— SUBSEQUENT EVENTS

Since the quarter ended September 30, 2020, the Company issued 8,000 shares of common stock for warrants exercised at \$1.20 for proceeds of \$9,600.

The Company engaged Gian Domenico Trombetta, former CEO of Wand Dental Inc. as a consultant to Leonard Osser, Interim – Chief Executive Officer of Milestone Scientific for a period of twelve months (beginning October 1, 2020 and ending September 30, 2021). Gian Domenico Trombetta will provide historical International Business, Dental Segment information and business contacts to Mr. Osser and provide consulting services for new International Business and Dental Segment concepts during this twelve month consulting period. Under this agreement, Mr. Trombetta is to receive \$60,000 payable in Milestone Scientific shares.

ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussions of the financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements contained in this report and in connection with management's discussion and analysis and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission, or SEC on March 30, 2020. 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

Our common stock was listed on the NYSE American on June 1, 2015 and trades under the symbol "MLSS". We have developed a proprietary, computer-controlled anesthetic delivery instrument, using The Wand, a single use disposable handpiece. The instrument is marketed in dental sector under the trademark *CompuDent*®, and STA Single Tooth Anesthesia System and in medical sector under the trademark *CompuMed*. *CompuDent* is suitable for all dental procedures that require local anesthetic. *CompuMed* is suitable for many medical procedures regularly performed in plastic surgery, hair restoration surgery, podiatry, colorectal surgery, dermatology, orthopedics, and several other disciplines. The dental instruments are sold in the United States, U.S. territories, Canada, and in over 58 other countries abroad. In June 2017, the FDA approved our 510(k) applications for marketing clearance in the United States of our *CompuFlo* Epidural Computer Controlled Anesthesia System. We are in the process of meeting with medical facilities and device distributors within the United States and Europe. There have been five medical instruments sold in the United States in 2018 and limited amounts sold internationally as of the reporting date. Certain of our medical instruments have obtained European CE mark approval and can be marketed and sold in most European countries.

Milestone Scientific remains focused on advancing efforts to achieve the following four 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 devices, Milestone Scientific is transitioning from a research and development organization to a commercially focused medical device company;
- Expanding our global footprint of our *CompuFlo* Epidural and *CathCheck* System by utilizing a Direct Field Sales Force and partnering with distribution companies worldwide; and
- Continuing the development of our proprietary cosmetic injection device for delivery of botulinum toxin (such as *Botox*® and *Dysport*®)

Wand/STA Dental Market

Since its market introduction in early 2007, the Wand/STA Instrument and prior C-CLAD devices have been used to deliver over 80 million safe, effective, and comfortable injections. The instrument has also been favorably evaluated in numerous peer-reviewed, published clinical studies and associated articles. Moreover, there appears to be a growing consensus among users that the STA Instrument is proving to be a valuable and beneficial instrument that is positively impacting the practice of dentistry worldwide.

Beginning January 1, 2016, Milestone Scientific entered into a non-exclusive distribution agreement with Henry Schein, Inc. ("Henry Schein"). In June 2016, that agreement was replaced with an exclusive distribution arrangement for our dental products for the United States and Canada with Henry Schein. Under this arrangement we have a semi-dedicated independent sales force visiting dentists. The Company's exclusive agreement is subject to annual purchase requirements and other requirements, as defined in the agreement.

To date, Henry Schein has endeavored to accomplish the goals set forth in the exclusive distribution agreement for *The Wand* STA instrument and handpieces, including training of its exclusive products sales specialists. Specifically, up to 25 exclusive product sales specialists have now been fully trained as experts in the features, advantages and benefits of *The Wand*/STA instrument and handpieces and all are currently in the field selling the instrument.

Henry Schein increased the number of exclusive product specialist in 2019 and trained an additional customer service representative to support dentists across North America through its exclusive product sales customer call center. During the Covid-19 Pandemic, Henry Schein has lost one of its exclusive product specialist. Henry Schein is in the process of recruiting additional specialist in the fourth quarter of 2020.

On the global front, we have granted exclusive marketing and distribution rights for the Wand/STA Instrument to select dental suppliers in various international regions in Asia, Africa, South America, and Europe. They include FM Produkty Dla Stomatologii in Poland and Unident AB in the Scandinavian countries of Denmark, Sweden, Norway, and Iceland.

In October 2012, the State Food and Drug Administration (CFDA) of the People's Republic of China approved our Wand/STA *Single Tooth Anesthesia System* (STA System). In May 2014, the CFDA also approved the Wand STA handpieces for sale in China.

Medical Market

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

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

In January 2019, the Company announced the results of a four hundred patient clinical trial by researchers from the University of Miami, University of Texas, and Northwestern University, and two prominent California-based pain clinics. Published-Ahead-of-Print in *Anesthesia & Analgesia* (the official Journal of the International Anesthesia Research Society), the randomized, controlled study compared the effectiveness of the CompuFlo Epidural System in labor and delivery and chronic pain management, where loss of resistance and fluoroscopy are the current standards of care. The CompuFlo Epidural System was found to be ninety-nine percent successful in objectively identifying the epidural space even in challenging patients with a higher body mass index.

In February 2019, the Company announced a new 120-patient clinical study published in *Anesthesiology Research & Practice* that verifies the CompuFlo Epidural System consistently differentiates false loss of resistance from true loss of resistance during epidural placement. In all cases where the CompuFlo Epidural System's pressure measurements were used to objectively identify the epidural space, the block was performed successfully with no complications.

In February 2019, the Company announced Ospedale "Pugliese Ciaccio" di Catanzaro is the first hospital in Italy to use the CompuFlo Epidural System for all epidurals in labor and delivery. For a local hospital performing a limited number of epidurals, the CompuFlo Epidural System offers a real-time, objective tool for accurate epidural space identification to help reduce failure rates and accidental dural punctures that can require further treatment and interventions.

In April, 2019 the Company entered the medical education market with the introduction of the *CompuFlo*® Epidural Trainer (CompuFlo Trainer), an instructional instrument that uses pressure sensing technology to improve epidural placement success. The Company has signed an agreement to distribute the CompuFlo Trainer with American 3B Scientific, a leading supplier of didactic material for medical education.

In June 2019 the Company announced the results of two research abstracts featuring the CompuFlo Epidural device at Euroanesthesia 2019, Europe's largest annual event showcasing the latest knowledge in the field of anesthesia. The abstracts were presented during scientific poster sessions highlighting how CompuFlo's objective detection of tissue pressure makes challenging procedures with difficult patients more efficient and accelerates clinical competency for trainees.

In October 2019, the Company announced the first international multicenter study to compare the incidence of accidental dural puncture using the CompuFlo Epidural System versus the continuous loss of resistance (LOR) technique. The study collected records between 2015 and 2019 of epidural administration on labor and delivery patients using the CompuFlo Epidural System from four institutions, one in the U.S., one in Chile, and two from Italy. Among the four sites, there were 812 patients who received epidural analgesia with CompuFlo, and none had accidental dural puncture regardless of the composition of the epidural performer types.

The Company also announced that Professor Rovnat Babazade, MD, University of Texas Medical Branch at Galveston, Department of Anesthesiology, presented a poster at the ANESTHESIOLOGY® 2019 Annual Meeting in Orlando, Florida, entitled, "International Multicenter Study of Accidental Dural Puncture Rate; Comparison of the CompuFlo with Traditional Method". ANESTHESIOLOGY 2019, hosted by the American Society of Anesthesiologists (ASA), unites more than 14,000 clinicians, thought leaders and professionals from around the world.

In November 2019, the Company and 3B Scientific, the world's leading supplier of didactic material for medical education, signed a global agreement expanding distribution of the CompuFlo Trainer. The expanded agreement allows 3B Scientific to capitalize on momentum from strong interest in the CompuFlo Trainer at its unveiling at Euroanesthesia 2019 and the Association of Women's Health, Obstetric and Neonatal Nurses meeting, and gives more anesthesia instructors the ultimate solution to accelerate the epidural procedure's learning curve and trainee success.

On April 21, 2020, Milestone Scientific, announced that it has validated and integrated the new CathCheck™ feature into the CompuFlo® Epidural System. Using CathCheck™, physicians and nurses can monitor the placement of a catheter to determine the presence or absence of a pulsatile waveform (heartbeat) providing new information that can be used to determine if the catheter is in place or has become dislodged from the epidural space. This can be performed within seconds by measuring the pulsatile waveform within the epidural space.

On October 13, 2020, Milestone Scientific announced a Group Purchasing Agreement with Premier a leading healthcare improvement company, utilizing an alliance of approximately 4,100 U.S. hospitals and 200,000 other providers to transform healthcare. The Agreement, which became effective November 1, 2020, allows Premier members, at their discretion, to take advantage of special pricing and terms pre-negotiated by Premier for the CompuFlo® Epidural System and CathCheck™. This agreement expires on February 28, 2022.

Covid-19 Pandemic

While the COVID-19 pandemic did not materially adversely affect the Company's financial results and business operations in the Company's first fiscal quarter ended March 31, 2020, economic and health conditions in the United States and across most of the globe have changed rapidly since the end of the first quarter. In the short-term, demand for the Company's products decreased, notably in our dental and medical divisions. Such decrease demand may or may not continue and/or demand may or may not increase from historical levels depending on the duration and severity of the COVID-19 pandemic, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that have been imposed to date, and numerous other uncertainties. Such events may result in business and manufacturing disruption, inventory shortages, delivery delays, and reduced sales and operations, any of which could materially affect our business, financial condition, and results of operations.

The Company's employees are being affected by the COVID-19 pandemic. The majority of our office and management personnel are working remotely. The health of the Company's workforce is of primary concern and the Company may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus. Further, our management team is focused on mitigating the adverse effects of the COVID-19 pandemic, which has required and will continue to require a large investment of time and resources across the entire Company, thereby diverting their attention from other priorities that existed prior to the outbreak of the pandemic. If these conditions worsen, or last for an extended period of time, the Company's ability to manage its business may be impaired, and operational risks, cybersecurity risks and other risks facing the Company prior to the pandemic may be elevated.

The COVID-19 pandemic is affecting the Company's customers, suppliers, vendors, and other business partners, but the Company is not able to predict the ultimate consequences that will result therefrom.

The COVID-19 pandemic did affect the Company's operations in the second and third quarters and may continue to do so indefinitely thereafter. All of these factors may have far reaching impacts on the Company's business, operations, and financial results and conditions, directly and indirectly, including without limitation impacts on the health of the Company's management and employees, manufacturing, distribution, marketing and sales operations, customer and consumer behaviors, and on the overall economy. The scope and nature of these impacts, most of which are beyond the Company's control, continue to evolve and the outcomes are uncertain.

Due to the above circumstances and as described generally in this Form 10-Q, the Company's results of operations for the three- and nine month period ended September 30, 2020 are not necessarily indicative of the results to be expected for the full fiscal year.

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

	Three months ended September 30,		Nine months ended September 30	
	2020	2019	2020	2019
Domestic-US				
Devices	\$ 34,657	\$ 199,926	\$ 35,181	\$ 409,529
Handpieces	356,566	679,621	994,057	2,250,842
Other	16,906	17,343	37,895	61,408
Total Domestic US	\$ 408,129	\$ 896,890	\$ 1,067,133	\$ 2,721,779
International ROW				
Devices	\$ 220,694	\$ 412,819	\$ 502,598	\$ 1,108,488
Handpieces	608,000	579,765	1,624,724	2,040,250
Other	9,287	10,347	30,715	103,063
Total International-ROW	\$ 837,981	\$ 1,002,931	\$ 2,158,037	\$ 3,251,801
International-China				
Devices	\$ -	\$ -	\$ -	\$ -
Handpieces	-	-	-	100,000
Other	-	-	-	-
Total International	\$ -	\$ -	\$ -	\$ 100,000
Total Product Sales	\$ 1,246,110	\$ 1,899,821	\$ 3,225,170	\$ 6,073,580

Current Product Platform

See Note 1 Organization and Business.

Results of Operations

The following table sets forth the consolidated results of operations for the three months ended September 30, 2020 and 2019, respectively. The trends suggested by this table may not be indicative of future operating results:

	Three months ended September 30,	
	2020	2019
Operating results:		
Product sales, net	\$ 1,246,110	\$ 1,899,821
Cost of products sold	409,621	523,672
Gross profit	836,489	1,376,149
Operating expenses:		
Selling, general and administrative expenses	2,291,779	2,314,943
Research and development expenses	21,438	7,940
Loss from operations	(1,476,728)	(946,734)
Other income, and loss on earning net	(25,286)	(1,903,183)
Net loss	(1,502,014)	(2,849,917)
Net loss attributable to noncontrolling interests	11,025	12,941
Net loss attributable to Milestone Scientific Inc.	\$ (1,490,989)	\$ (2,836,976)

The following table sets forth the consolidated results of operations for the nine months ended September 30, 2020 and 2019, respectively. The trends suggested by this table may not be indicative of future operating results:

	Nine months ended September 30,	
	2020	2019
Operating results:		
Product sales, net	\$ 3,225,170	\$ 6,073,580
Cost of products sold	<u>1,024,947</u>	<u>1,894,550</u>
Gross profit	2,200,223	4,179,030
Operating expenses:		
Selling, general and administrative expenses	8,221,359	6,941,964
Research and development expenses	<u>237,089</u>	<u>109,815</u>
Loss from operations	(6,258,225)	(2,872,749)
Other income, and loss on earning net	<u>(34,944)</u>	<u>(1,823,606)</u>
Net loss	(6,293,169)	(4,696,355)
Net loss attributable to noncontrolling interests	35,501	35,343
Net loss attributable to Milestone Scientific Inc.	<u>\$ (6,257,668)</u>	<u>\$ (4,661,012)</u>
Cash flow:		
	September 30, 2020	September 30, 2019
Net cash used in operating activities	\$ (6,346,160)	\$ (1,275,686)
Net cash used in investing activities	\$ (21,438)	\$ (9,916)
Net cash provided by financing activities	\$ 19,300,229	\$ 2,253,422

Three months ended September 30, 2020 compared three months ended September 30, 2019

Net sales for 2020 and 2019 were as follows:

	2020	2019	Increase	Decrease	%
Dental	\$ 1,240,110	\$ 1,884,321	\$ (644,211)		-34.19%
Medical	<u>6,000</u>	<u>15,500</u>	<u>(9,500)</u>		-61.29%
Total sales, net	<u>\$ 1,246,110</u>	<u>\$ 1,899,821</u>	<u>\$ (653,711)</u>		<u>-34.41%</u>

Consolidated revenue for the three months ended, September 30, 2020 and 2019 were approximately \$1.2 million and \$1.9 million, respectively. Dental revenue for the three months ended September 30, 2020 and 2019 were approximately \$1.2 and \$1.9 million, respectively. Dental revenues decreased by approximately \$644,000 which is related to COVID-19 pandemic affecting the Company's customers, suppliers, vendors, and other business partners. In the short-term, demand for the Company's products decreased, notably in our dental divisions. Such decreased demand may or may not continue and/or demand may or may not increase from historical levels depending on the duration and severity of the COVID-19 pandemic, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that have been imposed to date, and numerous other uncertainties.

As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of COVID-19, our revenue for the third quarter was materially and adversely affected. At this point in time, it is too early to determine an estimate of what the fourth quarter impact will be, or the effect COVID-19 may have on our fourth quarter revenue. In addition, it is too early to determine what the effect will be on the anticipated commercialization of our CompuFlo Epidural system as a medical device for the remainder of 2020, and the first quarter of 2021.

Gross Profit for 2020 and 2019 were as follows:

	2020	2019	Increase Decrease	%
Dental	\$ 833,254	\$ 1,372,758	\$ (539,504)	-39.30%
Medical	3,235	3,391	(156)	-4.60%
Total gross profit	\$ 836,489	\$ 1,376,149	\$ (539,660)	-39.22%

Consolidated gross profit for the three months ended September 30, 2020 and 2019 approximately 67% and 72%, respectively.

Selling, general and administrative expenses for 2020 and 2019 were as follows:

	2020	2019	Increase Decrease	%
Dental	\$ 643,794	\$ 728,108	\$ (84,314)	-11.58%
Medical	792,866	550,294	242,572	44.08%
Corporate	855,119	1,036,541	(181,422)	-17.50%
Total selling, general and administrative expenses	\$ 2,291,779	\$ 2,314,943	\$ (23,164)	-1.00%

Consolidated selling, general and administrative expenses for the three months ended September 30, 2020 and 2019, were approximately \$2.2 million and \$2.3 million, respectively. The decrease of approximately \$16,000 is categorized in several areas. Employee salaries, and benefits expenses increased approximately \$154,000 during the three months ended September 30, 2020, as the Company hired additional employees to work on the commercialization of the *CompuFlo*® Epidural System. During the three months ended September 30, 2020 D&O insurance increased approximately \$54,000 due to the increase of premiums. Due to Covid-19 Pandemic, the Company's travel expenses, trade shows, professional fees, quality control, and general expenses decreased approximately \$275,000 while marketing and consulting expense increased approximately \$43,000 for three months ended September 30, 2020.

Research and Development for 2020 and 2019 were as follows:

	2020	2019	Increase Decrease	%
Dental	\$ -	\$ -	\$ -	0.00%
Medical	21,438	7,940	13,498	170.00%
Corporate	-	-	-	0.00%
Total research and development	\$ 21,438	\$ 7,940	\$ 13,498	170.00%

Consolidated research and development expenses for the three months ended, 2020 and 2019, were approximately \$21,000 and \$7,900, respectively. The increase is associated with the Company developing software upgrades and enhancement for the *CompuFlo*® Epidural System and handpieces.

Profit (Loss) from Operations for 2020 and 2019 were as follows:

	2020	2019	Increase Decrease	%
Dental				
Medical	\$ 191,235	\$ 644,650	\$ (453,415)	-70.34%
Corporate	(812,840)	(554,843)	(257,997)	46.50%
Total loss from operations	(855,123)	(1,036,541)	181,418	-17.50%
	\$ (1,476,728)	\$ (946,734)	\$ (529,994)	55.98%

The loss from operations was approximately \$1.5 million and \$1 million for the three months ending September 30, 2020 and 2019, respectively. The increase is the result of decreased dental revenue, due to reduced hours and closings of dental and medical offices throughout the country and the rest of the world due to the continuing spread of COVID-19. We anticipate that our revenue for the fourth quarter, and possibly the first quarter of 2021, will be materially and adversely affected.

Nine months ended September 30, 2020 compared to nine months ended September 30, 2019

Net sales for 2020 and 2019 were as follows:

	2020	2019	Increase Decrease	%
Dental	\$ 3,209,370	\$ 6,042,580	\$ (2,833,210)	-46.89%
Medical	15,800	31,000	(15,200)	-49.03%
Total sales, net	\$ 3,225,170	\$ 6,073,580	\$ (2,848,410)	-46.90%

Consolidated revenue for the nine months ended September 30, 2020 and 2019 were approximately \$3.2 million and \$6.1 million, respectively. Dental revenue for the nine months ended September 30, 2020 and 2019 were approximately \$3.2 million and \$6.0 million, respectively. Dental revenues decreased by approximately \$2.8 million, which is mostly related to COVID-19 pandemic affecting the Company's customers and other business partners. In the short-term, demand for the Company's products has decreased, notably in our dental and medical divisions. Such decreased demand may or may not continue and/or demand may increase from historical levels depending on the duration and severity of the COVID-19 pandemic, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that have been imposed to date, and numerous other uncertainties. Such events may result in business and manufacturing disruption, inventory shortages, delivery delays, and reduced sales and operations, any of which could materially affect our business, financial condition, and results of operations.

As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of COVID-19, our revenue for the third quarter was materially and adversely affected. At this point in time, it is too early to determine an estimate of what the fourth quarter impact will be, or the effect COVID-19 may have on our first quarter of 2021. In addition, it is too early to determine what the effect will be on the anticipated commercialization of our CompuFlo Epidural system as a medical device in the fourth quarter of 2020 and the first quarter 2021.

Gross Profit for 2020 and 2019 were as follows:

	2020	2019	Increase Decrease	%
Dental	\$ 2,191,934	\$ 4,168,927	\$ (1,976,993)	-47.42%
Medical	8,289	10,103	(1,814)	-17.96%
Total gross profit	\$ 2,200,223	\$ 4,179,030	\$ (1,978,807)	-47.35%

Consolidated gross profit for the nine months ended September 30, 2020 and 2019 approximately 68% and 69%, respectively.

Selling, general and administrative expenses for 2020 and 2019 were as follows:

	2020	2019	Increase Decrease	%
Dental	\$ 2,226,303	\$ 2,402,840	\$ (176,537)	-7.35%
Medical	2,066,535	1,611,472	455,063	28.24%
Corporate	3,928,521	2,927,652	1,000,869	34.19%
Total selling, general and administrative expenses	\$ 8,221,359	\$ 6,941,964	\$ 1,279,395	18.43%

Consolidated selling, general and administrative expenses for the nine months ended September 30, 2020 and 2019, were approximately \$8.2 million and 6.9 million, respectively. The increase of approximately \$1.3 million is categorized in several areas. Employee salaries, and benefits expenses increased approximately \$1 million during the nine months ended September 30, 2020, the Company hired additional employees to work on the commercialization of the CompuFlo® Epidural System and recorded additional bonuses in 2020. During the nine months ended September 30, 2020 D&O insurance increase approximately \$117,000 due to the increase of premiums. The company expenses approximately \$370,000 of bad debt related to a settlement with United Systems, See Note 6. Due to Covid-19 Pandemic, the Company's travel expenses, trade shows and general expenses decreased approximately \$424,000. Office expense increased approximately \$143,000 associated with the relocation of the Company's office and other related costs.

Research and Development for 2020 and 2019 were as follows:

	2020	2019	Increase	Decrease	%
Dental	\$ -	\$ -	\$ -		0.00%
Medical	237,089	109,815	127,274		115.90%
Corporate	-	-	-		0.00%
Total research and development	\$ 237,089	\$ 109,815	\$ 127,274		115.90%

Consolidated research and development expenses for the nine months ended, September 30, 2020 and 2019, were approximately \$237,000 and \$109,000, respectively. The increase is associated with the Company developing software upgrades and enhancement for the CompuFlo® Epidural System and disposables.

Profit (Loss) from Operations for 2020 and 2019 were as follows:

	2020	2019	Increase	Decrease	%
Dental					
Medical	\$ (32,624)	\$ 1,766,087	\$ (1,798,711)		-101.85%
Corporate	(2,297,080)	(1,711,184)	(585,896)		34.24%
Total loss from operations	(3,928,521)	(2,927,652)	(1,000,869)		34.19%
	\$ (6,258,225)	\$ (2,872,749)	\$ (3,385,476)		117.85%

The loss from operations was approximately \$6.3 million and \$2.9 million for the nine months ending September 30, 2020 and 2019, respectively an increase of approximately \$3.4 million. This increase is the result of a decrease in revenues due to the reduced hours and closings of dental and medical offices throughout the country and the rest of the world due to the continuing spread of COVID-19. We anticipate that our revenue for the fourth quarter, and possibly the first quarter of 2021, will be materially and adversely affected.

Liquidity and Capital Resources

On September 30, 2020, Milestone Scientific had cash and cash equivalents of approximately \$14.4 million and working capital of approximately \$15.4 million versus working capital of \$1.2 million on December 31, 2019. For the nine months ended September 30, 2020, we had negative cash flows from operating activities of approximately \$6.3 million compared to \$1.3 million for the nine months ended September 30, 2019.

In the second quarter of 2020 the Company completed two capital raises. In April 2020, the Company completed a Common Stock Offering generating gross proceeds of approximately \$5.1 million (5,420,000 common shares and 2,710,000 warrants). The combined price of the shares and warrants was \$0.95 per share. The warrants are exercisable at a price of \$1.20 per share and have an expiration of three years from the issue date. In June 2020, the Company completed a second Common Stock Offering generating gross proceeds of approximately \$14.6 million (6,770,000 common shares and 3,749,000 warrants). The combined price of shares and warrants of was \$2.15 per share. The warrants are exercisable at a of \$2.60 and expire three years from the issue date. See Note 9. With the combination of these two Common Stock Offerings, the Company has sufficient liquidity to support operations for at least a year after the condensed consolidated financial statements issue date.

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, as well as considering other strategic plans or transactions. However, the COVID-19 pandemic is expected to have a continued adverse effect on the Company's operations and cash flows for at least in the next two quarters and possibly longer depending on the length and severity in of the pandemic in important dental markets.

Now that the CompuFlo Epidural System has obtained FDA clearance in the United States (June 2017), the development costs were reduced in 2020, but the selling costs are expected to continue to increase. The FDA clearance has provided the Company with the opportunity to establish distribution in the U.S. The Company intends to restart the 510K application process for the intra-articular device, subject to available allocated internal resources.

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, 2020 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

The COVID-19 pandemic is adversely affecting the Company’s business currently. Additional factors could exacerbate such negative consequences and/or cause other materially adverse effects.

The COVID-19 pandemic did materially adversely affect the Company’s financial results and business operations in the Company’s third fiscal quarter ended September 30, 2020, while economic and health conditions in the United States and across most of the globe have continued to change rapidly since the end of the third quarter. In the short-term, demand for the Company’s dental products is showing an increase in sell through activity to dental offices. However the change in demand may or may not continue and/or demand may or may not increase from historical levels depending on the duration and severity of the COVID-19 pandemic, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that have been imposed to date, and numerous other uncertainties. Such events may result in business and manufacturing disruption, inventory shortages, delivery delays, and reduced sales and operations, any of which could materially affect our business, financial condition, and results of operations.

The ability of the Company’s employees to work may be significantly impacted by the coronavirus.

The Company’s employees are being affected by the COVID-19 pandemic. The majority of our office and management personnel are working remotely. The health of the Company’s workforce is of primary concern and the Company may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus. Further, our management team is focused on mitigating the adverse effects of the COVID-19 pandemic, which has required and will continue to require a large investment of time and resources across the entire Company, thereby diverting their attention from other priorities that existed prior to the outbreak of the pandemic. If these conditions worsen, or last for an extended period of time, the Company’s ability to manage its business may be impaired, and operational risks, cybersecurity risks and other risks facing the Company even prior to the pandemic may be elevated.

The COVID-19 pandemic is affecting the Company’s customers, suppliers, vendors, and other business partners, but the Company is not able to assess the full extent of the current impact nor predict the ultimate consequences that will result therefrom.

The full effects of the COVID-19 pandemic are highly uncertain and cannot be predicted.

The COVID-19 pandemic affected the Company's operations in the third quarter and year to date 2020, and may continue to do so indefinitely thereafter. All of these factors may have far reaching impacts on the Company's business, operations, and financial results and conditions, directly and indirectly, including without limitation impacts on the health of the Company's management and employees, manufacturing, distribution, marketing and sales operations, customer and consumer behaviors, and on the overall economy. The scope and nature of these impacts, most of which are beyond the Company's control, continue to evolve and the outcomes are uncertain.

Due to the above circumstances and as described generally in this Form 10-Q, the Company's results of operations for the three month and nine-month period ended September 30, 2020 are not necessarily indicative of the results to be expected for the full fiscal year. Management cannot predict the full impact of the COVID-19 pandemic on the Company's sales channels, supply chain, manufacturing, and distribution nor to economic conditions generally, including the effects on consumer spending. The ultimate extent of the effects of the COVID-19 pandemic on the Company is highly uncertain and will depend on future developments, and such effects could exist for an extended period of time even after the pandemic might end.

Item 2. Unregistered Sales of Equity Securities and use of proceeds

During the quarter ended September 30, 2020, the Company issued 112,140 shares of common stock in payment of \$227,928 of consulting expenses incurred by the Company.

These securities were issued in reliance upon the exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"). These securities may not be offered or sold in the United States absent registration under or exemption from the Act and any applicable state securities laws.

Item 3. Default upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None

Item 6. Exhibits and Financial Statement Schedules

Exhibit No	Description
31.1	<u>Rule 13a-14(a) Certification-Chief Executive Officer*</u>
31.2	<u>Rule 13a-14(a) Certification-Chief Financial Officer*</u>
32.1	<u>Section 1350 Certifications-Chief Executive Officer**</u>
32.2	<u>Section 1350 Certifications-Chief Financial Officer**</u>
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*

* Filed herewith.

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

SIGNATURES

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

MILESTONE SCIENTIFIC INC.

/s/ Leonard Osser

Leonard Osser
Interim Chief Executive Officer
(Principal Executive Officer)

/s/ Joseph D'Agostino

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

Date: November 16, 2020

Rule 13a-14(a)/15d-14(a) Certification

I, Leonard Osser, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Milestone Scientific Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2020

/s/ Leonard Osser

Leonard Osser
Interim Chief Executive Officer
(Principal Executive Officer)

Rule 13a-14(a)/15d-14(a) Certification

I, Joseph D'Agostino, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Milestone Scientific Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, considering the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under the supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under the supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report the conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on the most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2020

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

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Milestone Scientific Inc. ("Milestone") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard Osser, Interim Chief Executive Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone.

Date November 16, 2020

/s/ Leonard Osser

Leonard Osser
Interim Chief Executive Officer
(Principal Executive Officer)

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of Milestone Scientific Inc. ("Milestone") on Form 10-Q for the period ending September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph D'Agostino Chief Operating Officer and Chief Financial Officer of Milestone, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of Milestone.

Date November 16, 2020

/s/ Joseph D'Agostino

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

A signed original of this certification has been provided to Milestone and will be retained by Milestone and furnished to the Securities and Exchange Commission or its staff upon request.