

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, 2021

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

For the transition period from _____ to _____

Commission file number 001-14053

Milestone Scientific Inc.

(Exact name of registrant as specified in its charter)

Delaware

State or other jurisdiction of Incorporation or organization

13-3545623

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

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:

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of Exchange on which registered</u>
Common Stock	MLSS	NYSE American

As of November 12, 2021, the registrant has a total of 67,845,930 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 and continued disruptions to our and our customers’ supply chains, 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, 2020 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)

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,490,745	\$ 14,223,917
Accounts receivable, net	968,107	1,080,656
Prepaid expenses and other current assets	514,417	415,915
Inventories, net	1,676,532	2,420,179
Advances on contracts	<u>1,509,530</u>	<u>414,202</u>
Total current assets	19,159,331	18,554,869
Furniture, fixtures and equipment, net	27,139	30,729
Intangibles, net	295,189	329,249
Right of use assets	571,678	632,453
Other assets	24,150	24,150
Total assets	<u>\$ 20,077,487</u>	<u>\$ 19,571,450</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 743,879	\$ 482,972
Accounts payable, related party	420,251	385,138
Accrued expenses and other payables	1,335,755	824,454
Accrued expenses, related party	535,481	586,734
Current portion of finance leases liabilities	8,351	7,796
Current portion of operating lease right-of-use liabilities	78,476	72,031
Deferred profit, related party	407,050	242,589
Note payable	-	276,180
Total current liabilities	<u>3,529,243</u>	<u>2,877,894</u>
Finance lease liabilities	22,273	28,607
Operating lease liabilities	497,932	557,981
Total liabilities	<u>\$ 4,049,448</u>	<u>\$ 3,464,482</u>
Commitments and contingencies		
Stockholders' equity		
Common stock, par value \$.001; authorized 100,000,000 shares; 67,610,864 shares issued and 67,577,531 shares outstanding as of September 30, 2021; 64,171,435 shares issued and 64,138,102 shares outstanding as of December 31, 2020;	67,610	64,171
Additional paid in capital	123,590,412	117,934,696
Accumulated deficit	(106,582,501)	(100,885,957)
Treasury stock, at cost, 33,333 shares	<u>(911,516)</u>	<u>(911,516)</u>
Total Milestone Scientific Inc. stockholders' equity	16,164,005	16,201,394
Noncontrolling interest	<u>(135,966)</u>	<u>(94,426)</u>
Total stockholders' equity	16,028,039	16,106,968
Total liabilities and stockholders' equity	<u>\$ 20,077,487</u>	<u>\$ 19,571,450</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,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Product sales, net	\$ 2,108,233	\$ 1,246,110	\$ 7,458,678	\$ 3,225,170
Cost of products sold	747,997	409,621	2,926,794	1,024,947
Gross profit	1,360,236	836,489	4,531,884	2,200,223
Selling, general and administrative expenses	2,968,625	2,275,274	9,729,594	8,146,498
Research and development expenses	356,179	21,438	588,043	237,089
Depreciation and amortization expense	16,353	16,505	52,113	74,861
Total operating expenses	3,341,157	2,313,217	10,369,750	8,458,448
Loss from operations	(1,980,921)	(1,476,728)	(5,837,866)	(6,258,225)
Interest expense	(4,608)	(569)	(11,604)	(8,727)
Gain on debt extinguishment-PPP	-	-	276,180	-
Loss before provision for income taxes and net of equity investments	(1,985,529)	(1,477,297)	(5,573,290)	(6,266,952)
Provision for income taxes	-	(24,717)	(333)	(26,217)
Loss before equity in net earnings (losses) of equity investments	(1,985,529)	(1,502,014)	(5,573,623)	(6,293,169)
Loss from China Joint Venture	(69,905)	-	(164,461)	-
Net loss	(2,055,434)	(1,502,014)	(5,738,084)	(6,293,169)
Net loss attributable to noncontrolling interests	(12,227)	(11,025)	(41,540)	(35,501)
Net loss attributable to Milestone Scientific Inc.	\$ (2,043,207)	\$ (1,490,989)	\$ (5,696,544)	\$ (6,257,668)
Net loss per share applicable to common stockholders—				
Basic	(0.03)	(0.02)	(0.08)	(0.11)
Diluted	(0.03)	(0.02)	(0.08)	(0.11)
Weighted average shares outstanding and to be issued—				
Basic	69,573,795	65,817,132	68,609,143	56,478,151
Diluted	69,573,795	65,817,132	68,609,143	56,478,151

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 THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020
(UNAUDITED)

	<u>Common Stock Share</u>	<u>Common Stock Amount</u>	<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Noncontrolling Interest</u>	<u>Treasury Stock</u>	<u>Total</u>
Balance, January 1, 2021	64,171,435	\$ 64,171	\$ 117,934,696	\$ (100,885,957)	\$ (94,426)	\$ (911,516)	\$ 16,106,968
Stock based compensation	-	-	113,507	-	-	-	113,507
Common stock issued to employee for compensation expensed in prior periods	7,075	7	-	-	-	-	7
Common stock to be issued for payment of consulting services expensed in prior periods	40,010	40	-	-	-	-	40
Common stock issued to board of directors for services expensed in prior periods	18,879	18	-	-	-	-	18
Common stock issued to employee for stock options exercised	435,558	436	689,754	-	-	-	690,190
Common stock to be issued to employees for bonuses	-	-	100,000	-	-	-	100,000
Common stock issued for warrants exercised	1,918,925	1,919	3,010,297	-	-	-	3,012,216
Net loss	-	-	-	(972,869)	(12,988)	-	(985,857)
Balance, March 31, 2021	<u>66,591,882</u>	<u>\$ 66,591</u>	<u>\$ 121,848,254</u>	<u>\$ (101,858,826)</u>	<u>\$ (107,414)</u>	<u>\$ (911,516)</u>	<u>\$ 19,037,089</u>
Stock based compensation	-	-	193,824	-	-	-	193,824
Common stock issued to employee for compensation	4,202	4	14,996	-	-	-	15,000
Common stock to be issued for payment of consulting services	96,018	94	262,589	-	-	-	262,683
Common stock issued to board of directors for services	277,767	280	617,887	-	-	-	618,167
Common stock issued for warrants exercised in prior periods	86,000	86	138,114	-	-	-	138,200
Net loss	-	-	-	(2,680,468)	(16,325)	-	(2,696,793)
Balance, June 30, 2021	<u>67,055,869</u>	<u>\$ 67,055</u>	<u>\$ 123,075,664</u>	<u>\$ (104,539,294)</u>	<u>\$ (123,739)</u>	<u>\$ (911,516)</u>	<u>\$ 17,568,170</u>
Stock based compensation	-	-	191,946	-	-	-	191,946
Common stock issued to employee for compensation	6,122	6	14,994	-	-	-	15,000
Common stock to be issued for payment of consulting services	96,694	97	227,748	-	-	-	227,845
Common stock issued to employee for stock options exercised	49,689	50	80,462	-	-	-	80,512
Common stock issued to employee for bonus expensed in prior periods	402,490	402	(402)	-	-	-	-
Net loss	-	-	-	(2,043,207)	(12,227)	-	(2,055,434)
Balance, September 30, 2021	<u>67,610,864</u>	<u>\$ 67,610</u>	<u>\$ 123,590,412</u>	<u>\$ (106,582,501)</u>	<u>\$ (135,966)</u>	<u>\$ (911,516)</u>	<u>\$ 16,028,039</u>

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 THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2020
(UNAUDITED)

	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

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

	For the Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:	\$ (5,738,084)	\$ (6,293,169)
Net loss		
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	23,076	35,103
Amortization of patents	34,060	39,759
Stock compensation	499,276	76,611
Employees paid in stock	748,658	768,463
Expense paid in stock	490,614	644,865
Loss on China joint venture	164,461	-
Non-cash operating lease expense	7,172	30,175
Gain on debt extinguishment-PPP	(276,180)	-
Changes in operating assets and liabilities:		
Decrease in accounts receivable	112,549	747,682
Decrease in other assets	-	11,755
Decrease (Increase) inventories	743,647	(609,251)
Increase in advances on contracts	(1,095,328)	(12,422)
Increase in prepaid expenses and other current assets	(98,501)	(7,996)
Increase (Decrease) in accounts payable	260,905	(713,331)
Increase (decrease) in accounts payable, related party	35,113	(965,662)
Increase in accrued expenses	510,790	431,917
Decrease in accrued expenses, related party	(51,253)	(530,659)
Net cash used in operating activities	\$ (3,629,025)	\$ (6,346,160)
Cash flows from investing activities:		
Purchase of property and equipment	(19,486)	(21,438)
Net cash used in investing activities	\$ (19,486)	\$ (21,438)
Cash flows from financing activities:		
Proceeds from exercise of warrants	3,150,416	985,763
Payments finance lease obligations	(5,779)	(4,998)
Net proceeds from employee options exercised	770,702	-
Net proceeds from note payable	-	276,180
Net proceeds from Public Placement Offering	-	18,043,284
Net cash provided by financing activities	\$ 3,915,339	\$ 19,300,229
Net increase in cash and cash equivalents	266,828	12,932,631
Cash and cash equivalents at beginning of period	14,223,917	1,516,272
Cash and cash equivalents at end of period	\$ 14,490,745	\$ 14,448,903
Supplemental non-cash disclosure of cash flow information:		
Initial recognition of operating lease-right of use assets	-	(706,071)
Initial recognition of operating lease right to used liabilities	-	706,071

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,” “us,” “our,” “we,” the “Company” or “Milestone” refer to Milestone Scientific Inc., and its consolidated subsidiaries, Wand Dental, Inc., Milestone Advanced Cosmetic Systems, Inc., and Milestone Medical, Inc. (all described below), unless the context otherwise indicates. Milestone Scientific is the owner of the following registered U.S. trademarks: *CompuDent*®; *CompuMed*®; *CompuFlo*®; *DPS Dynamic Pressure Sensing technology*®; *Milestone Scientific* ®; *the Milestone logo* ®; *SafetyWand*®; *STA Single Tooth Anesthesia System*®; and *The Wand*®.

Milestone Scientific was incorporated in the State of Delaware in August 1989. Milestone Scientific has developed a proprietary, computer-controlled anesthetic delivery device, using *The Wand*®, a single use disposable handpiece. The device is marketed in dentistry under the trademark *CompuDent*®, and *STA Single Tooth Anesthesia System*® and is suitable for all dental procedures that require local anesthetic. The dental devices are sold in the United States, Canada and in approximately 60 other countries. Certain medical devices have obtained CE mark approval and can be marketed and sold in most European countries. In June 2017, Milestone Scientific received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) on the *CompuFlo*® Epidural Computer Controlled Anesthesia System.

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 intended to file a new 510(k) application for the device in 2019, however, due to financing constraints, a new 510(k) application was not filed in 2019 or 2020. The Company has decided not to proceed with securing the FDA approval for the intra-articular instrument at this time. Milestone Medical’s immediate focus is on marketing its epidural device throughout the United States, Europe and other countries.

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 unaudited condensed consolidated financial statements are issued. As of September 30, 2021, the Company had an accumulated deficit of \$106,582,501 and has incurred a net loss of approximately \$2 million and \$5.7 million for the three and nine month periods ending September 30, 2021, respectively.

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, 2021, cash on hand was approximately \$14.5 million, an increase of \$0.3 million from December 31, 2020. Management believes the Company has sufficient liquidity to support operations beyond a year after the unaudited condensed consolidated financial statements issue date.

The coronavirus (COVID-19) adversely impacted our operations and those of our distributors. 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 nine months ended September 30, 2020, were adversely affected. Business interruptions, including any interruptions resulting from COVID-19, could significantly disrupt our operations and could have a material adverse impact on our business during the remainder of 2021 and into 2022.

In addition to our employees, we rely on (i) distributors, agents, and third-party logistics providers in connection with product sales and distribution and (ii) raw material and component suppliers in the U.S., Europe, and China. If we, or any of these entities encounter any disruptions to our or their respective operations or facilities, or if we or any of these third-party partners were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute, pandemic or other public health crises, or other unforeseen disruption, then we or they may be prevented or delayed from effectively operating our or their business, respectively.

In addition, it is uncertain as to what effect the continuing spread of COVID-19 (such as the Delta variant) will have on the commercialization efforts of our CompuFlo Epidural and CathCheck systems. 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), 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 condensed consolidated 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 consolidated financial statements and notes thereto for the year ended December 31, 2020, included in Milestone Scientific's Annual Report on Form 10-K.

3. Reclassifications

Certain reclassifications have been made to the 2020 unaudited condensed consolidated financial statements to conform to the 2021 unaudited condensed consolidated 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, 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 evaluate 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 standalone selling prices; and 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, "Revenue from Contracts with Customers".

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 that includes 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 free-on-board (FOB) shipping, revenue is recognized upon delivery to the carrier. 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 customers' 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, 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 dental and medical basis for purposes of segment reporting, consistent with internal management reporting. See Note 11 for revenues by geographical market, and product category for the nine months ended September 30, 2021

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.

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. Therefore, 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. As of September 30, 2021 and December 31, 2020 Milestone Scientific has approximately \$14.3 million and \$13.1 million, respectively, of investments with short term maturities classified as a cash equivalent. At times, such investment, may be more than the Federal Deposit Insurance Corporation insurance limit.

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, 2021, and December 31, 2020, accounts receivable was recorded, net of allowance for doubtful accounts of \$79,973 and \$10,000, respectively.

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. As of September 30, 2021 and December 31, 2020, inventory was recorded net of a valuation allowance for slow moving and defective inventory of approximately \$450,000, and \$453,000, respectively. See Note 4.

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 within long-term assets in the unaudited 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 in 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. See Note 6.

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 expense, as incurred.

12. Intangible Assets – Patents and Developed Technology

Patents and other developed technology created “in-house” 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 or person are 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 received 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. During the quarter ended June 30, 2021, the Company received forgiveness for the Loan.

15. Research and Development

Research and development costs, which consist principally of new product development costs payable to third parties, are expensed as incurred. Advance payments received 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. See Note 10.

On September 30, 2021 and December 31, 2020, we had no uncertain tax positions that required recognition in the unaudited 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 2017, 2018, 2019, and 2020 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 nine months ended September 30, 2021 and 2020, 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, warrants restricted stock totaled 7,674,239 and 7,477,171 on September 30, 2021 and 2020, 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, 2021 and December 31, 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. Stock-Based Compensation

Milestone Scientific accounts for stock-based compensation under ASC 718, "Compensation - Stock Compensation" ("ASC 718"). ASC 718 requires all share-based payments to employees, including grants of employee stock options and restricted stock units, to be recognized in the Condensed Consolidated Statements of Operations over the vesting period based on the grant-date fair values.

20. 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. See Note 14.

22. Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In December 2019, FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes", which clarifies the accounting treatment for the accounting tax aspects relating, in part, to the intra-period 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 as of January 1, 2021, did not have a material effect on the Company's unaudited condensed consolidated financial statement presentation.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued a new standard ASU No. 2016-13, "Financial Instruments – Credit Losses" (Topic 326). 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 Company is analyzing the impact of the adoption of this standard.

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. ASU2020-01 is effective for all entities with fiscal years beginning after December 15, 2021, including interim periods therein. The Company is analyzing the impact of the adoption of this standard; however, the adoption is not expected to have a material effect on the Company’s unaudited condensed consolidated financial statement presentation.

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 Company is analyzing the impact of the adoption of this standard; however, the adoption of this standard is not expected to have a material effect on the Company’s unaudited condensed consolidated financial statement.

In May 2021, FASB issued ASU 2021-04, Earnings Per Share (topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718) and Derivatives and Hedging – Contracts in an Entity’s Own Equity (Subtopic 815-40) – Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, which provides guidance of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU are effective January 1, 2022, including interim periods. Early adoption is permitted. The Company will apply the amendments prospectively to modifications or exchanges occurring on or after January 1, 2022. The Company will evaluate the impact of ASU 2021-04 on any future changes to the terms and conditions of its warrants.

NOTE 4 — INVENTORIES

Inventories consist of the following:

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Dental finished goods, net	\$ 526,308	\$ 1,888,141
Medical finished goods, net	1,057,476	200,327
Component parts and other materials	92,748	331,711
Total inventories	<u>\$ 1,676,532</u>	<u>\$ 2,420,179</u>

On September 30, 2021, there are allowances for slow moving medical finished goods of approximately \$450,000. As of December 31, 2020, there are allowances for slow moving medical finished goods of approximately \$450,000 and damaged slow moving dental finished goods of approximately \$3,000.

NOTE 5 — ADVANCES ON CONTRACTS

The advances on contracts represent funding of future STA inventory purchases, epidural instruments, and epidural replacement parts. The balance of the advances as of September 30, 2021 and December 31, 2020 is \$1,509,530 and \$414,202, respectively.

NOTE 6 — INVESTMENT IN AND TRANSACTIONS WITH EQUITY INVESTEES

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 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 its investment in Milestone China under the equity method of accounting.

In the first quarter of 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), with Anhui to be the surviving entity after the merger and to 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 because applicable government offices are still closed in China and Hong Kong. According to documentation provided to Milestone Scientific with respect to the Transaction, Milestone Scientific is expected to have an approximate 28.4% direct ownership interest in Anhui. However, this transaction has not been completed, and the participation of Milestone Scientific and the final terms may change.

Milestone Scientific, in previous years, reduced its investment in Milestone China to zero and had accumulated losses over its investment of approximately \$5.9 million at December 31, 2020.

For the three and nine months ended September 30, 2021, Milestone Scientific shipped instruments and handpieces to Milestone China and its agents and recognized revenue approximately of \$360,000 and \$1.4 million, respectively. The Company did not recognize any revenue related to Milestone China for the three and nine months ended September 30, 2020. As of September 30, 2021, the Company has approximately \$253,000 of deposits from Milestone China for future shipment of goods included in accrued expenses, related party on the accompanying condensed consolidated balance. Due to the current geo-economic situation and US-China relations, Milestone Scientific recorded an allowance against accounts receivable, related party and sales allowance of \$269,973 for the quarter ended September 30, 2021. This reserve will be reviewed quarterly and adjusted based on updated facts and circumstances.

Related Party Transactions

Milestone China Distribution Agreement

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.

United Systems, Inc. Agreement

In April of 2020, the Company entered into an agreement with United Systems, Inc., a related party (see Note 3), 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 its 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 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.

Advanced Cosmetics Systems Agreement

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. As a result of the purchase, Milestone Scientific now owns 100% of Advanced Cosmetic Systems Inc. Milestone China had the option to repurchase the 50% interest in Advanced Cosmetic Systems within one year from the sale date for \$900,000 in cash. On May 18, 2021, Milestone China's repurchase option expired. Milestone Advanced Cosmetic Systems Inc. has been dissolved.

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 recorded profit is required as of the balance sheet date. In accordance with ASC 323 Equity Method and Joint Ventures, Milestone Scientific has deferred its ownership percentage of the gross profit associated with recognized revenue from sales to Milestone China until that product is sold to third parties.

At September 30, 2021 and December 31, 2020, the deferred profit was approximately \$407,000 and \$243,000, respectively, which is included in deferred profit, related party in the condensed consolidated balance sheets. For three and nine months ended September 30, 2021, Milestone Scientific recorded loss on equity investment of approximately \$70,000 and \$164,000 respectively in relation to gross profit on product sold to Milestone China. For three and nine months ended September 30, 2020, Milestone Scientific did not record any loss on equity investment in relation to gross profit on product sold to Milestone China.

NOTE 7 — PATENTS

	September 30, 2021		
	Cost	Accumulated Amortization	Net
Patents-foundation intellectual property	\$ 1,377,863	\$ (1,082,674)	\$ 295,189
Total	\$ 1,377,863	\$ (1,082,674)	\$ 295,189

	December 31, 2020		
	Cost	Accumulated Amortization	Net
Patents-foundation intellectual property	\$ 1,377,863	\$ (1,048,614)	\$ 329,249
Total	\$ 1,377,863	\$ (1,048,614)	\$ 329,249

Patents are amortized utilizing the straight-line method over estimated useful lives ranging from 3 to 20 years. Amortization expense was approximately \$11,000 and \$34,000 for the three and nine months ended September 30, 2021, respectively, and was approximately \$13,000 and \$40,000 for the three and nine months ended September 30, 2020, 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 specified period.

The Loan matured on April 27, 2022, and bore interest at a rate of 1.00% per annum, payable monthly commencing on November 26, 2020. The Note was due April 27, 2022, in a balloon payment if the loan was not forgiven. The Note may be prepaid by the Borrower at any time prior to maturity without 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.

During the quarter ending June 30, 2021, the Company received forgiveness for the PPP Loan which is included in the condensed consolidated income statements as Gain on debt extinguishment-PPP.

NOTE 9 — STOCKHOLDERS' EQUITY

Public Offering and Private Placement

In the second quarter of 2020, the Company completed two public offerings. In April 2020, a Common Stock offering generated 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 the shares and warrants was \$2.15 per share. The warrants are exercisable at \$2.60 and expire three years from the issue date.

Warrants

The following table summarizes information about shares issuable under warrants outstanding as of September 30, 2021 :

	<u>Warrant shares outstanding</u>	<u>Weighted Average exercise price</u>	<u>Weighted Average remaining life</u>	<u>Intrinsic value</u>
Outstanding at January 1, 2021	6,369,396	\$ 1.97	\$ 2.48	\$ 2,784,117
Issued	-			
Exercised	(2,004,926)	1.57	-	-
Expired or cancelled	-	-	-	-
Outstanding and exercisable at September 30, 2021	<u>4,364,470</u>	<u>\$ 2.15</u>	<u>\$ 1.76</u>	<u>\$ 1,088,192</u>

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

	<u>Warrant shares outstanding</u>	<u>Weighted Average exercise price</u>	<u>Weighted Average remaining life</u>	<u>Intrinsic value</u>
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>

Shares to Be Issued

As of September 30, 2021 and 2020, there were 1,861,639 and 2,202,229 shares, respectively, the issuance of which has been deferred to certain executives and employees of Milestone Scientific.

As of September 30, 2021 and 2020, there were 144,024 and 149,498 shares, respectively, to be issued to non-employees, that will be issued for services rendered. In each case, 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, 2021 and 2020, respectively:

	<u>September 30, 2021</u>	<u>September 30, 2020</u>
Shares-to-be-issued, outstanding January 1, 2021 and 2020, respectively	2,428,329	2,375,762
Granted in current period	33,238	363,956
Issued in current period	(455,906)	(387,991)
Shares-to be issued outstanding September 30, 2021 and 2020, respectively	<u>2,005,661</u>	<u>2,351,727</u>

Stock Option Plans

In June 2011, the stockholders of Milestone Scientific approved the 2011 Stock Option Plan (the "2011 Plan") which originally provided for stock options to our employees, directors and consultants to purchase, and restricted common stock, restricted stock units, and other awards for, up to 2,000,000 shares of common stock and was later amended in 2016 to increase the maximum number of shares reserved for grant to 4,000,000. Generally, options become exercisable over a three-year period from the grant date and expire five years after the date of grant. As of September 30, 2021 and December 31, 2020, the Company had 2,471,659, and 424,425, respectively, remaining options available for grants under the 2011 Plan.

The Milestone Scientific Inc. 2020 Equity Compensation Plan, as amended and restated (the "2020 Plan"), provides for awards of restricted common, stock restricted stock units, options to purchase and other awards, up to a maximum 4,000,000 shares of common stock and expires in June 2031. Options may be granted to employees, directors, and consultants of Milestone Scientific for the purchase of shares of common stock at a price not less than the fair market value of common stock on the date of grant. In general, options become exercisable over a three-year period from the grant date and expire five years after the date of grant.

On April 8, 2021, as part of its Succession Plan going into effect on April 23, 2021, the Company announced that Leonard Osser, the Interim Chief Executive Officer, would be accepting the role of Vice Chairman of the Board of Directors. As part of accepting this role, he would be granted options to purchase 2,000,000 shares of common stock, exercisable at the fair market value of the common stock on the date of grant, vesting over the five-year period after he steps down as Interim Chief Executive Officer of the Company or ten years from the date of grant, whichever shall end first. The options were issued pursuant to the 2020 Plan.

Milestone Scientific recognizes compensation expense over the requisite service period and in the case of performance-based options over the period of the expected performance. For the nine months ended September 30, 2021 and 2020, Milestone Scientific recognized approximately \$451,000 and \$68,000 of total employee compensation cost, respectively. As of September 30, 2021 there was approximately \$3.3 million of total unrecognized compensation cost related to non-vested options. Milestone Scientific expects to recognize these costs over a weighted average period of 4.1 years.

A summary of option activity for employees under the plans and changes during the nine months ended September 30, 2021 and 2020 is presented below:

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Options outstanding January 1, 2021	1,953,443	1.88	3.09	476,964
Granted	2,032,175	2.48	9.48	-
Exercised during 2021	(485,247)	1.59	-	-
Forfeited or expired	(351,759)	1.99	-	-
Options outstanding September 30, 2021	3,148,612	2.30	7.14	35,776
Exercisable, September 30, 2021	604,817	1.95	1.90	35,776

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Options outstanding January 1, 2020	1,212,442	1.61	2.00	-
Granted	80,000	-	-	-
Exercised during 2020	-	-	-	-
Forfeited or expired	(289,464)	3.89	-	-
Options outstanding September 30, 2020	1,002,978	1.56	1.59	114,570
Exercisable, September 30, 2020	828,370	1.55	1.38	88,983

The Company used the following assumptions to calculate the fair value of the stock option grants using the Black-Scholes option pricing model on the measurement date during the nine month period ended September 30, 2021 risk free interest rate of 0.19%-1.15%, Volatility of 69.1%-94% (which is based on the Company's historical volatility over the expected term), expected term of 3-6.5 years, 0% dividend rate and closing price of the stock of \$2.46-\$3.79.

A summary of option activity for non-employees under the plans and changes during the nine months ended September 30, 2021 and 2020 is presented below:

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Options outstanding January 1, 2021	74,997	1.41	3.18	54,748
Granted	16,666	3.94	4.48	
Exercised during 2021	(8,333)	2.34	2.34	-
Options outstanding September 30, 2021	83,330	1.83	3.09	38,082
Exercisable, September 30, 2021	55,553	1.09	2.19	32,860

	Number of Options	Weighted Averaged Exercise Price \$	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Options Value \$
Options outstanding January 1, 2020	49,998	1.43	2.94	19,333
Granted	24,999	1.70	3.00	-
Exercised during 2020	-	-	-	-
Options outstanding September 30, 2020	74,997	1.52	2.86	19,333
Exercisable, September 30, 2020	52,776	1.57	2.24	14,666

The fair value of the non-employee options was estimated on the date of grant using the Black Scholes option-pricing model at the date of grant. For the nine months ended September 30, 2021, Milestone Scientific recognized approximately \$20,000 expense related to non-employee options. For the nine months ended September 30, 2020, Milestone Scientific recognized approximately \$9,000 and expense related to non-employee options.

The Company used the following assumptions to calculate the fair value of the stock option grants using the Black-Scholes option pricing model on the measurement date during the nine months ended September 30, 2021, risk free interest rate of 0.3 %, Volatility of 97.69% to 98.09%, expected term of 2.9 years, 0% dividend rate and closing price of the stock of \$3.57 to \$4.30.

The information below summarizes the restricted stock activity for the nine months ended September 30, 2021:

Restricted Stock Awards	Shares	Weighted Average Grant-Date Fair Value per Award
Non-vested as December 31, 2020	-	\$ -
Granted	89,285	2.52
Vested	-	-
Cancelled	(11,458)	-
Non-vested as September 30, 2021	77,827	\$ 2.52

For the three and nine months ended September 30, 2021, stock compensation expense for restricted stock was \$16,667 and \$37,500, respectively.

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 bases. 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:

	<u>Three months ended September 30, 2021</u>	<u>Three months ended September 30, 2020</u>	<u>Nine months ended September 30, 2021</u>	<u>Nine months ended September 30, 2020</u>
Net Sales:				
Dental	\$ 2,076,233	\$ 1,240,110	\$ 7,334,628	\$ 3,209,370
Medical	32,000	6,000	124,050	15,800
Total net sales	<u>\$ 2,108,233</u>	<u>\$ 1,246,110</u>	<u>\$ 7,458,678</u>	<u>\$ 3,225,170</u>
	<u>Three months ended September 30, 2021</u>	<u>Three months ended September 30, 2020</u>	<u>Nine months ended September 30, 2021</u>	<u>Nine months ended September 30, 2020</u>
Operating Income (Loss):				
Dental	\$ 193,252	\$ 191,235	\$ 1,844,083	\$ (32,624)
Medical	(937,876)	(812,840)	(2,968,596)	(2,297,080)
Corporate	(1,236,297)	(855,123)	(4,713,353)	(3,928,521)
Total operating loss	<u>\$ (1,980,921)</u>	<u>\$ (1,476,728)</u>	<u>\$ (5,837,866)</u>	<u>\$ (6,258,225)</u>
	<u>Three months ended September 30, 2021</u>	<u>Three months ended September 30, 2020</u>	<u>Nine months ended September 30, 2021</u>	<u>Nine months ended September 30, 2020</u>
Depreciation and Amortization				
Dental	\$ 892	\$ 402	\$ 3,458	\$ 9,202
Medical	1,241	674	6,257	5,006
Corporate	14,220	15,429	42,398	60,653
Total depreciation and amortization	<u>\$ 16,353</u>	<u>\$ 16,505</u>	<u>\$ 52,113</u>	<u>\$ 74,861</u>
	<u>Three months ended September 30, 2021</u>	<u>Three months ended September 30, 2020</u>	<u>Nine months ended September 30, 2021</u>	<u>Nine months ended September 30, 2020</u>
Income (loss) before taxes and equity in earnings of affiliates:				
Dental	\$ 191,864	\$ 190,472	\$ 1,915,148	\$ (35,376)
Medical	(939,202)	(813,935)	(2,972,462)	(2,300,243)
Corporate	(1,238,191)	(853,834)	(4,515,976)	(3,931,333)
Total loss before taxes and equity in earnings of affiliate	<u>\$ (1,985,529)</u>	<u>\$ (1,477,297)</u>	<u>\$ (5,573,290)</u>	<u>\$ (6,266,952)</u>
Total Assets:			<u>September 30, 2021</u>	<u>December 31, 2020</u>
Dental			\$ 6,047,663	\$ 6,035,645
Medical			1,369,098	923,658
Corporate			12,660,726	12,612,147
Total assets			<u>\$ 20,077,487</u>	<u>\$ 19,571,450</u>

The following table presents information about our operations by geographic area for three months ended September 30, 2021 and 2020. Net sales by geographic area are based on the respective locations of our subsidiaries:

	Three Months Ended September 30, 2021			Three Months Ended September 30, 2020		
	Dental	Medical	Grand Total	Dental	Medical	Grand Total
Domestic: US						
Instruments	\$ 36,480	\$ -	\$ 36,480	\$ 34,657	\$ -	\$ 34,657
Handpieces	721,149	11,500	732,649	356,566	-	356,566
Accessories	21,253	-	21,253	16,906	-	16,906
Total Domestic US	\$ 778,882	\$ 11,500	\$ 790,382	\$ 408,129	\$ -	\$ 408,129
International: Rest of World						
Instruments	\$ 253,063	\$ 4,500	\$ 257,563	\$ 220,694	\$ -	\$ 220,694
Handpieces	674,133	16,000	690,133	602,000	6,000	608,000
Accessories	9,300	-	9,300	9,287	-	9,287
Total International	\$ 936,496	\$ 20,500	\$ 956,996	\$ 831,981	\$ 6,000	\$ 837,981
International: China						
Instruments	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Handpieces	360,855	-	360,855	-	-	-
Accessories	-	-	-	-	-	-
Total International	\$ 360,855	\$ -	\$ 360,855	\$ -	\$ -	\$ -
Total Product Sales	\$ 2,076,233	\$ 32,000	\$ 2,108,233	\$ 1,240,110	\$ 6,000	\$ 1,246,110

The following table presents information about our operations by geographic area for nine months ended September 30, 2021 and 2020. Net sales by geographic area are based on the respective locations of our subsidiaries:

	Nine Months Ended September 30, 2021			Nine Months Ended September 30, 2020		
	Dental	Medical	Grand Total	Dental	Medical	Grand Total
Domestic: US						
Instruments	\$ 391,250	\$ -	\$ 391,250	\$ 35,181	\$ -	\$ 35,181
Handpieces	2,319,049	19,650	2,338,699	992,057	2,000	994,057
Accessories	58,134	-	58,134	37,895	-	37,895
Total Domestic US	\$ 2,768,433	\$ 19,650	\$ 2,788,083	\$ 1,065,133	\$ 2,000	\$ 1,067,133
International: Rest of World						
Instruments	\$ 792,903	\$ 62,500	\$ 855,403	\$ 494,998	\$ 7,600	\$ 502,598
Handpieces	2,337,692	41,900	2,379,592	1,618,524	6,200	1,624,724
Accessories	42,409	-	42,409	30,715	-	30,715
Total International	\$ 3,173,004	\$ 104,400	\$ 3,277,404	\$ 2,144,237	\$ 13,800	\$ 2,158,037
International: China						
Instruments	\$ 228,000	\$ -	\$ 228,000	\$ -	\$ -	\$ -
Handpieces	1,165,191	-	1,165,191	-	-	-
Accessories	-	-	-	-	-	-
Total International	\$ 1,393,191	\$ -	\$ 1,393,191	\$ -	\$ -	\$ -
Total Product Sales	\$ 7,334,628	\$ 124,050	\$ 7,458,678	\$ 3,209,370	\$ 15,800	\$ 3,225,170

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. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Scientific would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, because of termination of such a relationship, would have a material adverse effect on Milestone Scientific's financial condition, business, and results of operations.

For the three months ended September 30, 2021, domestic and international net product sales were approximately 38% and 62%, respectively, of aggregate net product sales, and for the nine months ended September 30, 2021, domestic and international net product sales were approximately 38% and 62%, respectively, of aggregate net product sales. For the three and nine months ended September 30, 2020, domestic and international net product sales were approximately 33% and 67%, respectively, of aggregate net product sales.

Accounts receivable for domestic and international distributors was approximately 32% and 68%, respectively, of Milestone Scientific's gross accounts receivable as of September 30, 2021. Accounts receivable for the major customer/distributors amounted to approximately 69%, of Milestone Scientific's gross accounts receivable as of December 31, 2020.

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 sole manufacturer of its handpieces, pursuant to which it manufactures products under specific purchase orders, but without minimum purchase commitments. Purchases from this manufacturer were approximately \$417,000 and \$373,000 for the three months ended September 30, 2021 and 2020, respectively. Purchases from this manufacturer were approximately \$1.3 million and \$1.2 million for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021 and December 31, 2020, Milestone Scientific owed this manufacturer approximately \$417,000 and \$362,000, respectively, which is included in accounts payable, related party on the condensed consolidated balance sheets as of September 30, 2021 and December 31, 2020, respectively. In June 2021, the Company signed a ten year agreement with United Systems for manufacturing the handpieces. On April 29, 2020, the Board of Directors approved the purchase of United Systems' accounts receivable (\$370,260). See Note 6.

Milestone China

See Note 6.

Other

As of September 30, 2021 and December 31, 2020, Milestone Scientific had deferred compensation for Gian Domenico Trombetta, a director of the Company and the previous Chief Executive Officer of Wand Dental, of approximately \$30,000 and \$275,000, respectively, which is included in accrued expenses related party.

The Company engaged Mr. Trombetta as a consultant for a period of twelve months (beginning October 1, 2020 and ending September 30, 2021), to provide international business dental information and business contacts to the Company and provide consulting services for new international business and dental segment. For the three and nine months ended September 30, 2021 the Company expensed \$15,000 and \$45,000, respectively, for services rendered by Mr. Trombetta.

In January 2017, Milestone Scientific entered into a twelve-month agreement with Innovest S.p.A., a significant stockholder of Milestone Scientific controlled by Mr. Trombetta, to provide consulting services. Expenses recognized on this agreement were \$20,000, and \$60,000 for the three and nine months ended September 30, 2020, respectively. This agreement was terminated on September 30, 2020.

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 each of the three and nine months ended September 30, 2021 and 2020, respectively.

The Director of Clinical Affairs' royalty fee was approximately \$74,000 and \$61,000 for the three months ended September 30, 2021 and 2020, respectively. The Director of Clinical Affairs' royalty fee was approximately \$322,000 and \$158,000 for the nine months ended September 30, 2021 and 2020, respectively. Additionally, Milestone Scientific expensed consulting fees to the Director of Clinical Affairs of \$39,000 and \$117,000 for each of the three and nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and December 31, 2020, Milestone Scientific owed the Director Clinical Affairs for royalties of approximately \$103,000 and \$127,000, respectively, which is included in accounts payable, related party and accrued expense, related party, in the unaudited condensed consolidated balance sheet. See Note 14(3) below for additional information about the royalty agreement.

On March 2, 2021, Milestone Scientific entered into a Royalty Sharing Agreement with Leonard Osser, the Company's then Interim Chief Executive Officer, pursuant to which Mr. Osser sold, transferred and assigned to the Company all of his rights in and to a certain patent application as to which he is a co-inventor with Dr. Hochman, and the Company agreed to pay to Mr. Osser, beginning May 9, 2027, half of the royalty (2.5%) on net sales that would otherwise be payable to Dr. Hochman and his wife under their Technology Sale Agreement with the Company, the Hochman's having agreed with the Company pursuant to an addendum to such Technology Sale Agreement dated February 25, 2021 to reduce from 5% to 2.5% the payments due to them on May 9, 2027 and thereafter, with respect to dental products.

Pursuant to a Succession Agreement dated April 6, 2021 between Mr. Osser and the Company: (i) the Employment Agreement dated as of July 10, 2017 between Mr. Osser and the Company, pursuant to which upon Mr. Osser stepping down as Interim Chief Executive Officer of the Company, the Company agreed to employ him as Managing Director, China Operations of the Company (the "China Operations Agreement"), and (ii) the Consulting Agreement dated as of July 10, 2017 (the "Consulting Agreement") between the Company and U.S. Asian Consulting Group, LLC, a company of which Mr. Osser is a principal, the compensation under the China Operations Agreement was modified to reduce the overall compensation by \$100,000 to \$200,000, split equally between a cash amount and an amount in shares, and the compensation under the Consulting Agreement is increased by \$100,000 to \$200,000, equally split between a cash amount and an amount in shares, which shares were formerly payable under the China Operations Agreement. Compensation under the China Operations Agreement and the Consulting Agreement are payable for 9.5 years from May 19, 2021.

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. In January 2021, the Company entered into a new purchase commitment for the delivery of 2,000 dental instruments beginning in 2021. As of September 30, 2021, the purchase order commitment for dental instruments was approximately \$2.9 million and advances of approximately \$1.5 million are reported in advances on contracts in the unaudited condensed consolidated balance sheet.

As of September 30, 2021, the purchase order commitment for epidural instruments was approximately \$98,902 and advances of approximately \$38,257 are reported in advances on contract in the unaudited condensed consolidated balance sheet.

(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 did not have a residual value guarantee. The Company was 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 were considered to be variable lease payments and were 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 existing office lease for its corporate headquarters located in Livingston, New Jersey and instead signed a new seven year lease in a new facility located in Roseland, New Jersey (the "Roseland Facility"), which commenced on January 8, 2020. Under the Roseland Facility lease, rent payments commenced 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, 2021 total operating lease right-of-use assets were \$571,678 and total operating lease liabilities were \$576,408, of which \$78,476 and \$497,932 were classified as current and non-current, respectively. As of September 30, 2021, total finance lease liabilities were \$30,624, of which \$8,351 and \$22,273 were classified as current and non-current, respectively. As of December 31, 2020, total operating lease right-of-use assets were \$632,453 and total operating lease liabilities were \$630,012, of which \$72,031 and \$557,981 were classified as current and non-current, respectively. As of December 31, 2020, total finance lease liabilities were \$36,403, of which \$7,796 and \$28,607 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,	
	2021	2020	2021	2020
Lease cost				
Cash paid for operating lease liabilities	31,882	30,820	95,645	78,904
Cash paid for finance lease liabilities	2,658	2,685	8,055	76,622
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, 2021, the balance includes operating leases existing as of the adoption of ASC 842 on January 1, 2021				
Weighted-average remaining lease term - operating leases (years)	-	-	5.5	6.5
Weighted-average remaining lease term- finance leases (years)	-	-	3.3	4.3

(3) Other Commitments

The technology underlying the *Safety Wand*® and *CompuFlo*®, and an improvement to the controls for *CompuDent*®, were developed by Dr. Mark Hochman, the Company's Director of Clinical Affairs. Milestone Scientific purchased this technology pursuant to that certain Technology Sale Agreement, dated January 1, 2005, as amended. 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% (or 2.5% effective as of May 9, 2027 – see below) of the total sales of products using certain other of the technologies until the expiration of the last patent covering these technologies (see Note 13).

On March 2, 2021, Milestone Scientific entered into a Royalty Sharing Agreement with Leonard Osser, the Company's then Interim Chief Executive Officer, pursuant to which Mr. Osser sold, transferred and assigned to the Company all of his rights in and to a certain patent application as to which he is a co-inventor with Dr. Hochman, and the Company agreed to pay to Mr. Osser, beginning May 9, 2027, half of the royalty (2.5%) on net sales that would otherwise be payable to Dr. Hochman and his wife under the Technology Sale Agreement referred to above, the Hochman's having agreed with the Company pursuant to an addendum to such Technology Sale Agreement dated February 25, 2021 to reduce from 5% to 2.5% the payments due to them on May 9, 2027 and thereafter, with respect to dental products.

Succession Agreement

Pursuant to a Succession Agreement dated April 6, 2021 between Mr. Osser and the Company: (i) the Employment Agreement dated as of July 10, 2017 between Mr. Osser and the Company, pursuant to which upon Mr. Osser stepping down as Interim Chief Executive Officer of the Company, the Company agreed to employ him as Managing Director, China Operations of the Company (the “China Operations Agreement”), and (ii) the Consulting Agreement dated as of July 10, 2017 (the “Consulting Agreement”) between the Company and U.S. Asian Consulting Group, LLC, a company of which Mr. Osser is a principal, the compensation under the China Operations Agreement was modified to reduce the overall compensation by \$100,000 to \$200,000, split equally between a cash amount and an amount in shares, and the compensation under the Consulting Agreement is increased by \$100,000 to \$200,000, equally split between a cash amount and an amount in shares, which shares were formerly payable under the China Operations Agreement. Compensation under the China Operations Agreement and the Consulting Agreement are payable for 9.5 years from May 19, 2021. As of September 30, 2021, Milestone Scientific owed Leonard Osser approximately \$83,000, which is included in accrued expenses, related party, in the unaudited condensed consolidated balance sheet. See Note 14(3) above for additional information about the royalty agreement.

NOTE 15— SUBSEQUENT EVENTS

On November 9, 2021, Leonard Osser, Managing Director, China Operations exercised 171,429 options awarded in 2016 at a stock price \$1.93.

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, 2020, which was filed with the Securities and Exchange Commission, or SEC, on March 31, 2021. 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 the dental sector under the trademark *CompuDent*®, and STA Single Tooth Anesthesia System and is suitable for all dental procedures that require local anesthetic. The dental instruments are sold in the United States, U.S. territories, Canada, and in over 60 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. To date there have been seventeen medical devices sold in the United States and limited amounts sold internationally. 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 three primary objectives:

- Establishing Milestone's DPS Dynamic Pressure Sensing technology platform as the standard-of-care in painless and precise drug delivery, providing for the first time, objective visual and audible in-tissue pressure feedback, and continuing to expand platform applications;
- Following obtaining successful FDA clearance of our first medical device, 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

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. In December 2020, the exclusive distribution arrangement with Henry Schein was replaced with a non-exclusive distribution arrangement, for distribution in the United States and Canada.

In January 2021, the Company began a process of signing non-exclusive dental distribution arrangements with dental distributors in specific geographical locations in the United States and Canada. To date there are ten new non-exclusive dental distributors engaged in the USA and Canada. The goal is to add not only additional non-exclusive distributors in the USA, but as well as exploring other co-operation opportunities with Dental Service Organization, and entities in specific dental market segments.

The goal of changing our marketing plan from a sole exclusive distributor in the USA and Canada, to a large number of non-exclusive distributors is to increase placement of our Wand/STA instrument and thus the expansion of our dental disposables.

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 countries of Denmark, Sweden, Norway, and Iceland. Additionally, the Company is in the process of evaluating current international distributors and adding new distributors, globally as required based on the economics of the region.

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. During the end of the second quarter 2021, Milestone Scientific invested in sales force expansion, thus building up a stronger direct sales force aiming at increasing the adoption and penetration of its technology. At the beginning of the year Milestone Scientific had three sales managers and by July 31, 2021 had established a direct sales force consisting of eleven full time employees covering the US North and South East region and California. Milestone Scientific continues to partner with distributors for the international markets

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 intended to file a new 510(k) application for the device in 2019. However, due to financing constraints, a new 510(k) application was not filed in 2019. The Company has decided not to proceed with securing FDA approval for the intra-articular instrument at the present time.

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 now 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 Inc., a leading healthcare improvement company. 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

The COVID-19 pandemic materially adversely affected the Company's financial results and business operations. Demand for the Company's products decreased, notably in our dental division, during the last fiscal year and only began to increase during the first quarter of 2021. However, such increased 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 effectiveness of the on-going vaccination process, 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 have been and 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.

We are experiencing supply delays and shortages due to the disruptions the ongoing COVID-19 pandemic is having on the global supply chain, especially with respect to goods from China. The ongoing COVID-19 pandemic has resulted in significant disruption to the operations of certain suppliers in China and the related transportation of their goods to the United States that are parts of our global supply chain. We have been able to make alternative delivery arrangements for limited quantities of goods, at increased cost. While we have not yet experienced material shortages in supply as a result of these disruptions and our alternative delivery arrangements, if they were to be prolonged or expanded in scope, there could be resulting supply shortages which could impact our ability to have manufactured and delivered our products to the United States and, ultimately to our customers. Accordingly, such supply shortages and delivery limitations could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

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. 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, 2021 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,	
	2021	2020	2021	2020
Domestic-US				
Instruments	\$ 36,480	\$ 34,657	\$ 391,250	\$ 35,181
Handpieces	732,649	356,566	2,338,699	994,057
Accessories	21,253	16,906	58,134	37,895
Total Domestic US	\$ 790,382	\$ 408,129	\$ 2,788,083	\$ 1,067,133
International ROW				
Instruments	\$ 257,563	\$ 220,694	\$ 855,403	\$ 502,598
Handpieces	690,133	608,000	2,379,592	1,624,724
Accessories	9,300	9,287	42,409	30,715
Total International-ROW	\$ 956,996	\$ 837,981	\$ 3,277,404	\$ 2,158,037
International-China				
Instruments	\$ -	\$ -	\$ 228,000	\$ -
Handpieces	360,855	-	1,165,191	-
Accessories	-	-	-	-
Total International	\$ 360,855	\$ -	\$ 1,393,191	\$ -
Total Product Sales	\$ 2,108,233	\$ 1,246,110	\$ 7,458,678	\$ 3,225,170

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, 2021 and 2020, respectively. The trends suggested by this table may not be indicative of future operating results:

	Three Months Ended September 30,	
	2021	2020
Operating results:		
Product sales, net	\$ 2,108,233	\$ 1,246,110
Cost of products sold	747,997	409,621
Gross profit	1,360,236	836,489
Operating expenses:		
Selling, general and administrative expenses	2,968,625	2,275,274
Research and development expenses	356,179	21,438
Depreciation and amortization expense	16,353	16,505
Loss from operations	(1,980,921)	(1,476,728)
Other income, and loss on earning net	(74,513)	(25,286)
Gain on debt extinguishment-PPP	-	-
Net loss	(2,055,434)	(1,502,014)
Net loss attributable to noncontrolling interests	(12,227)	(11,025)
Net loss attributable to Milestone Scientific Inc.	\$ (2,043,207)	\$ (1,490,989)

The following table sets forth the consolidated results of operations for the nine months ended September 30, 2021 and 2020, respectively. The trends suggested by this table may not be indicative of future operating results:

	Nine Months Ended September 30,	
	2021	2020
Operating results:		
Product sales, net	\$ 7,458,678	\$ 3,225,170
Cost of products sold	2,926,794	1,024,947
Gross profit	4,531,884	2,200,223
Operating expenses:		
Selling, general and administrative expenses	9,729,594	8,146,498
Research and development expenses	588,043	237,089
Depreciation and amortization expense	52,113	74,861
Loss from operations	(5,837,866)	(6,258,225)
Other income, and loss on earning net	(176,398)	(34,944)
Gain on debt extinguishment-PPP	276,180	-
Net loss	(5,738,084)	(6,293,169)
Net loss attributable to noncontrolling interests	41,540	35,501
Net loss attributable to Milestone Scientific Inc.	\$ (5,696,544)	\$ (6,257,668)
Cash flow:		
Net cash used in operating activities	\$ (3,629,025)	\$ (6,346,160)
Net cash used in investing activities	\$ (19,486)	\$ (21,438)
Net cash provided by financing activities	\$ 3,915,339	\$ 19,300,229

Three months ended September 30, 2021 compared to three months ended September 30, 2020

Net sales for 2021 and 2020 were as follows:

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 2,076,233	\$ 1,240,110	\$ 836,123
Medical	32,000	6,000	26,000
Total sales, net	<u>\$ 2,108,233</u>	<u>\$ 1,246,110</u>	<u>\$ 862,123</u>

Consolidated revenue for the three months ended, September 30, 2021 and 2020 were approximately \$2.1 million and 1.2 million, respectively. Dental revenue increased approximately \$836,000 for the three months ending September 30, 2021 as compared to the three months ended September 30, 2020, due to re-opening of dental offices throughout the country, and the rest of the world, including China. Medical revenue increased approximately \$26,000 for the three months ending September 30, 2021 as compared to the three months ending September 30, 2020 due to the company arranging introductory meetings at hospitals by the direct sales force organization and medical device distributors in European markets. The Company recorded an allowance against revenue and accounts receivable, related party of \$269,973 for the quarter ended September 30, 2021.

Gross Profit for 2021 and 2020 were as follows:

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 1,343,027	\$ 833,254	\$ 509,773
Medical	17,209	3,235	13,974
Total gross profit	<u>\$ 1,360,236</u>	<u>\$ 836,489</u>	<u>\$ 523,747</u>

Consolidated gross profit for the three months ended September 30, 2021 and 2020 were approximately 65% and 67%, respectively.

Selling, general and administrative expenses 2021 and 2020 were as follows:

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 818,577	\$ 643,392	\$ 175,186
Medical	927,971	792,192	\$ 135,779
Corporate	1,222,077	839,690	\$ 382,387
Total selling, general and administrative expenses	<u>\$ 2,968,625</u>	<u>\$ 2,275,274</u>	<u>\$ 693,352</u>

Consolidated selling, general and administrative expenses for the three months ended September 30, 2021 and 2020, were approximately \$2.9 million and 2.2 million respectively. The increase of approximately \$693,000 is categorized in several areas. Employee salaries, and benefits expenses increased approximately \$566,000 during the three months ended September 30, 2021, as the Company hired additional employees to work on the commercialization of the *CompuFlo*® Epidural System. During the three months ended September 30, 2021, quality control regulations, royalties, employee travel and marketing expenses increased approximately \$335,000 due to the re-opening of dental, and medical offices throughout the country, and the rest of the world. The Company's trade shows, professional fees, and general expenses decreased approximately \$209,000 during for three months ended September 30, 2021.

Research and Development for 2021 and 2020 were as follows:

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 330,306	\$ -	\$ 330,306
Medical	25,873	21,438	4,435
Corporate	-	-	-
Total research and development	<u>\$ 356,179</u>	<u>\$ 21,438</u>	<u>\$ 334,741</u>

Consolidated research and development expenses for the three months ended September 30, 2021 and 2020 were approximately \$356,000 and \$21,000, respectively. The increase of approximately \$335,000 is related to the Company exploring possible development of our proprietary STA Single Tooth Anesthesia System.

Profit (Loss) from Operations for 2021 and 2020 were as follows:

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 193,252	\$ 191,235	\$ 2,017
Medical	(937,876)	(812,840)	(125,036)
Corporate	(1,236,297)	(855,123)	(381,174)
Total loss from operations	<u>\$ (1,980,921)</u>	<u>\$ (1,476,728)</u>	<u>\$ (504,193)</u>

The loss from operations was approximately \$2 million and \$1.5 million for the three months ended September 30, 2021 and 2020, respectively. The increase is the result of increased dental revenue, due to re-opening of dental offices throughout the country, the rest of the world, including China, partially offset by an increase in selling, general and administrative expenses as discussed above.

Nine months ended September 30, 2021 compared to nine months ended September 30, 2020

Net sales for 2021 and 2020 were as follows:

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 7,334,628	\$ 3,209,370	\$ 4,125,258
Medical	124,050	15,800	108,250
Total sales, net	<u>\$ 7,458,678</u>	<u>\$ 3,225,170</u>	<u>\$ 4,233,508</u>

Consolidated revenue for the nine months ended September 30, 2021 and 2020 were approximately \$7.4 million and \$3.2 million, respectively. Dental revenue increased approximately \$4.1 million for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020, due to re-opening of dental offices throughout the country, and the rest of the world, including China. Medical revenue increased approximately \$108,000 for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 due to the company arranging introductory meetings at hospitals by the direct sales force organization and medical device distributors in European markets. The Company recorded an allowance against revenue and accounts receivable, related party of \$269,973 for the quarter ended September 30, 2021.

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 4,460,935	\$ 2,191,934	\$ 2,269,001
Medical	70,949	8,289	62,660
Total gross profit	<u>\$ 4,531,884</u>	<u>\$ 2,200,223</u>	<u>\$ 2,331,661</u>

Consolidated gross profit for the nine months ended September 30, 2021 and 2020 was approximately 60% and 68%, respectively. The decreased in the gross profit is due to the lower margin in sales to China.

Selling, general and administrative expenses 2021 and 2020 were as follows:

	<u>2021</u>	<u>2020</u>	<u>Increase (Decrease)</u>
Dental	\$ 2,098,687	\$ 2,217,101	\$ (118,414)
Medical	2,959,927	2,061,529	898,398
Corporate	4,670,980	3,867,868	803,112
Total selling, general and administrative expenses	<u>\$ 9,729,594</u>	<u>\$ 8,146,498</u>	<u>\$ 1,583,096</u>

Consolidated selling, general and administrative expenses for the nine months ended September 30, 2021 and 2020 were approximately \$9.7 million and \$8.1 million, respectively. The increase of approximately \$1.6 million is categorized in several areas. Employee salaries, and benefits expenses increased approximately \$1 million during the nine months ended September 30, 2021, as the Company hired additional employees to work on the commercialization of the *CompuFlo*® Epidural System. During the nine months ended September 30, 2021, the Company expensed board fees of approximately \$643,000 and issued 267,980 shares of restricted stock to the board of directors for services provided over the next year. During the nine months ended September 30, 2021, royalties, quality control, and marketing expenses increased approximately \$542,000 due to the reopening of dental and medical offices throughout the country, and the rest of the world. The Company's trade shows, professional fees, and general expenses decreased approximately \$639,000 for the nine months ended September 30, 2021.

Research and Development for 2021 and 2020 were as follows:

	2021	2020	Increase (Decrease)
Dental	\$ 514,682	\$ -	\$ 514,682
Medical	73,361	237,089	(163,728)
Corporate	-	-	-
Total research and development	\$ 588,043	\$ 237,089	\$ 350,954

Consolidated research and development expenses for the nine months ended September 30, 2021 and 2020 were approximately \$588,000 and \$237,000, respectively. The increase of approximately \$351,000 is related to the Company exploring possible development of our proprietary STA Single Tooth Anesthesia System.

Profit (Loss) from Operations for 2021 and 2020 were as follows:

	2021	2020	Increase (Decrease)
Dental			
Medical	\$ 1,844,083	\$ (32,624)	1,876,707
Corporate	(2,968,596)	(2,297,080)	(671,516)
Total loss from operations	(4,713,353)	(3,928,521)	(784,832)
	\$ (5,837,866)	\$ (6,258,225)	\$ 420,359

The loss from operations was approximately \$5.8 million and \$6.3 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease is the result of increased in dental revenue, due to re-opening of dental offices throughout the country, the rest of the world, including China, partially offset by an increase in selling, general and administrative expenses as discussed above.

Liquidity and Capital Resources

On September 30, 2021, Milestone Scientific had cash and cash equivalents of approximately \$14.5 million and working capital of approximately \$15.7 million versus cash and cash equivalents of approximately \$14.2 million and working capital of \$15.7 million on December 31, 2020. For the nine months ended September 30, 2021 and 2020, we had cash flows used in operating activities of approximately \$3.6 million and \$6.3 million, respectively.

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 price 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 date the unaudited condensed consolidated financial statements are issued.

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 Chief Executive Officer has 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 Chief Executive Officer has concluded that the disclosure controls and procedures as of September 30, 2021 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 Chief Executive Officer, 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 has and may continue to adversely affect the Company's business. 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 fiscal year ended December 31, 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 2020. 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 effectiveness of the ongoing vaccination process, 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.

We are experiencing supply delays and shortages due to the disruptions the ongoing COVID-19 pandemic is having on the global supply chain, especially with respect to goods from China.

We are experiencing supply delays and shortages due to the disruptions the ongoing COVID-19 pandemic is having on the global supply chain, especially with respect to goods from China. The ongoing COVID-19 pandemic has resulted in significant disruption to the operations of certain suppliers in China and the related transportation of their goods to the United States that are parts of our global supply chain. We have been able to make alternative delivery arrangements for limited quantities of goods, at increased cost. While we have not yet experienced material shortages in supply as a result of these disruptions and our alternative delivery arrangements, if they were to be prolonged or expanded in scope, there could be resulting supply shortages which could impact our ability to have manufactured and delivered our products to the United States and, ultimately to our customers. Accordingly, such supply shortages and delivery limitations could have an material adverse effect on our business, financial condition, results of operations, and cash flows.

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 fiscal year ended December 31, 2020 and may continue to do so for an indeterminable period 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, 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 nine-month period ended September 30, 2021 are not necessarily indicative of the results to be expected for the full fiscal year. Management cannot predict the continued 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, 2021, the Company issued 42,947 shares of common stock to Dr. Giorgio Capogna in payment of \$45,948 of consulting services.

During the quarter ended September 30, 2021, the Company issued an aggregate of 18,287 shares of common stock to Dr. Abraham Sheer in an aggregate payment of \$62,337 of consulting services.

During the quarter ended September 30, 2021, the Company issued 3,847 shares of common stock to Dr. Edward Zelnick in payment of \$9,000 of consulting services.

During the quarter ended September 30, 2021, the Company issued 15,000 shares of common stock to RedChip in payment of \$31,200 of investor relations services.

During the quarter ended September 30, 2021, the Company issued 1,594 shares of common stock to Dr. Peter Kranke in payment of \$6,250 of consulting services.

During the quarter end September 30, 2021, the Company issued 12,019 shares of common stock to K. Tucker Andersen in payment of \$25,000 of consulting services.

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	Rule 13a-14(a) Certification-Chief Executive Officer*
32.1	Section 1350 Certifications-Chief Executive Officer**
101.INS	Inline XBRL Instance Document*
101.SCH	Inline XBRL Taxonomy Extension Schema Document*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* 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/ Jan A. Haverhals

Jan Haverhals

Chief Executive Officer

(Principal Executive and Acting Chief Accounting Officer)

Date: November 12, 2021

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

I, Jan A. Haverhals, 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 12, 2021

/s/ Jan A. Haverhals

Jan A. Haverhals
Chief Executive Officer
(Principal Executive and Acting Chief 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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jan A. Haverhals, 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 12, 2021

/s/ Jan A. Haverhals

Jan A. Haverhals

Chief Executive Officer and

(Principal Executive and Acting Chief 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.