

**Condensed Consolidated report of**  
**MILESTONE MEDICAL, INC. and its**  
**SUBSIDIARY**  
**3<sup>rd</sup> quarter (from July 1, 2020 to September 30, 2020)**

***Report include:***

1. General information about Milestone Medical, Inc. (“Issuer”) and Milestone Medical Poland Sp. z.o.o. (the Subsidiary).
2. Condensed Consolidated Financial Statements prepared according to the accounting rules applicable to the Issuer together with information on accounting rules (policy) applied to the preparation of report.
3. Information on the rules applied to the preparation of the report, including information on changes to the applied accounting rules (policies).
4. Brief description of the most important achievements or failures of the Issuer and its Subsidiary during the period of the report as well as a description of the most important factors and events, atypical ones, which affect the achieved results.
5. A description of the status of implementation of activities and investments of the Issuer and its Subsidiary and the timetable of their implementation.
6. If the Issuer and its Subsidiary took initiatives to develop, its activities aimed to implement innovative solutions at the enterprise during the period of the report – information on such activities.
7. Description of the organization of the group indicating consolidated entities.

New Jersey, November 13, 2020

## 1. General information

**Table 1 General Information about the Issuer**

<b>THE ISSUER</b>	<b>MILESTONE MEDICAL INC.</b>
	<b>(earlier: Milestone Scientific Research and Development, Inc.)</b>
<b>Registered office/Office:</b>	425 Eagle Rock Avenue, Roseland, NJ 07068, USA
<b>Telephone number:</b>	011-973-535-2717
<b>Facsimile number:</b>	011-973-535-2829
<b>E-mail:</b>	<a href="mailto:jdagostino@milestonescientific.com">jdagostino@milestonescientific.com</a>
<b>Main website address:</b>	<a href="http://www.medicalmilestone.com">www.medicalmilestone.com</a>

Source: The Issuer

\*Milestone Medical, Inc. moved its office to Roseland, New Jersey in January 2020.

### 1.1. Shareholding structure

In the table below shares issued are outstanding for computing the ownership percentage of shareholders holding at least 5% of votes at the General Meeting of Shareholders, applicable percentages are based on 22,000,000 shares outstanding on the date of this annual report preparation. All percentages are rounded.

**Table 2 Shareholder structure with specification of shareholders holding at least 5% of votes at the General Meeting of Shareholders at the date of the report.**

<b>Name of Shareholder</b>	<b>Number of owned shares/votes</b>	<b>Shareholding/votes at General Meeting of Shareholders [%]</b>
<b>MILESTONE SCIENTIFIC, INC.</b>	21,633,084	98.33%
<b>OTHERS (&lt;5%)</b>	366,916	1.67%
<b>TOTAL</b>	<b>22,000,000</b>	<b>100.00%</b>

Source: The Issuer

The company reported on ESPI report 6/2016 published on September 17, 2016 that Milestone Scientific initiated a share exchanged program pursuant to which one share of common stock of Milestone Scientific, Inc. would be exchanged for every two outstanding shares of Milestone Medical common stock. Through the report date, Milestone Scientific, Inc. acquired 10,689,078 (48.35%) shares of the Issuer's outstanding share from various shareholders. The company reported on ESPI report 8/2017 published on August 8, 2017 that Milestone Scientific increased its shareholding in the Company and reached 98.33% of total number of votes at the Company's Shareholders' Meeting.

## 1.2. Board of Directors

**Table 3 Board of Directors**

<b>NAME OF DIRECTOR</b>	<b>CURRENT AGE</b>	<b>DIRECTOR SINCE</b>	<b>END OF TERM</b>
<b>Zhu Yun</b>	53	Sep-13	Next Annual Meeting of Shareholders
<b>Martin S. Siegel</b>	76	Sep-14	Next Annual Meeting of Shareholders

*\* On November 4, 2020, the Annual General Meeting of Shareholders adopted the resolution on the appointment of two Directors to the Board of Directors for new term of office.*

*Source: The Issuer*

## 1.3. Information on the number of persons employed by the Issuer converted into FTEs

As of September 30, 2020, the Issuer employed four (4) full time employees and four (4) persons allocated from the parent company (Milestone Scientific Inc.) converted into full-time equivalents (“FTEs”). The Company has contracted with one Business Development Consultant for business activities in Europe and the Middle East in 2019 and 2020. Milestone Medical has four fulltime employees as September 30, 2020: A Vice President of USA Sales, and three Medical Device Territory Sales Managers. These four employees will promote direct market support for Milestone Medical and assist on moving the medical business forward.

In September 2020, the parent company (Milestone Scientific Inc.) engaged a new full time Corporate Vice President of Marketing. This new employee will function with all consolidated business sectors, corporate, dental, and medical and will provide his services as required for the Issuer beginning on September 1, 2020.

**2. Condensed Consolidated quarterly financial statements prepared according to the accounting rules applicable to the Issuer and its Subsidiary together with information on accounting rules (policy) applied to the preparation of report**

**Milestone Medical, Inc. and Subsidiary**

**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**As of and for the three and nine months ended September 30, 2020 and 2019 (unaudited)**

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Milestone Medical, Inc. And Subsidiary  
Condensed Consolidated Balance Sheets  
(unaudited)

	September 30, 2020	December 31, 2019
<u>ASSETS</u>		
Cash and cash equivalents	\$ 18,004	\$ 8,773
Accounts receivable	-	2,600
Inventories, net	437,245	215,151
Advances to contractors	372,773	273,149
Prepaid expenses and other current assets	140,162	82,814
Total current assets	968,184	582,487
Equipment, net	8,976	8,240
Total assets	\$ 977,160	\$ 590,727
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Accounts payable	\$ 199,254	\$ 291,956
Accrued expenses and other payables	634,421	251,868
Accrued interest due to Milestone Scientific, Inc.	471,200	402,889
Advances from Milestone Scientific Inc.	13,155,966	10,759,137
Due to Milestone Scientific, Inc.	2,800,000	2,800,000
Total current liabilities	17,260,841	14,505,850
Commitments and contingencies		
Stockholders' deficit		
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at September 30, 2020 and December 31, 2019	2,200	2,200
Additional paid-in capital	6,931,861	6,931,861
Accumulated deficit	(23,217,742)	(20,849,184)
Total stockholders' deficit	(16,283,681)	(13,915,123)
Total liabilities and stockholders' deficit	\$ 977,160	\$ 590,727

See Notes to Condensed Consolidated Financial Statements

Milestone Medical, Inc. And Subsidiary  
Condensed Consolidated Statements of Operations  
(Unaudited)

	Three Months ended September 30, 2020	Three Months ended September 30, 2019	Nine Months ended September 30, 2020	Nine Months ended September 30, 2019
Product sales, net	\$ 6,000	\$ 15,500	\$ 15,800	\$ 31,000
Cost of products sold	2,765	12,108	7,511	20,897
Gross profit	<u>3,235</u>	<u>3,392</u>	<u>8,289</u>	<u>10,103</u>
Selling, general and administrative expenses	792,193	547,896	2,061,532	1,604,047
Research and development expenses	23,209	77,402	238,833	232,424
Depreciation and amortization	674	7,940	5,007	109,815
Total operating expenses	<u>816,076</u>	<u>633,238</u>	<u>2,305,372</u>	<u>1,946,286</u>
Loss from operations	(812,841)	(629,846)	(2,297,083)	(1,936,183)
Interest expense	<u>(24,032)</u>	<u>(23,710)</u>	<u>(71,475)</u>	<u>(70,241)</u>
Loss before income tax	<u>(836,873)</u>	<u>(653,556)</u>	<u>(2,368,558)</u>	<u>(2,006,424)</u>
		-		-
Provision (benefit) for income taxes	-	-	-	(511)
Net loss	<u>\$ (836,873)</u>	<u>\$ (653,556)</u>	<u>\$ (2,368,558)</u>	<u>\$ (2,006,935)</u>

See Notes to Condensed Consolidated Financial Statements

Milestone Medical, Inc. and Subsidiary  
Condensed Consolidated Statements of Changes in Stockholders' Deficit  
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, January 1, 2020	22,000,000	\$ 2,200	\$ 6,931,861	\$ (20,849,184)	\$ (13,915,123)
Net loss				(693,608)	(693,608)
Balance, March 31, 2020	22,000,000	\$ 2,200	\$ 6,931,861	\$ (21,542,792)	\$ (14,608,731)
Net loss				(838,077)	(838,077)
Balance, June 30, 2020	22,000,000	\$ 2,200	\$ 6,931,861	\$ (22,380,869)	\$ (15,446,808)
Net loss				(836,873)	(836,873)
Balance, September 30, 2020	22,000,000	\$ 2,200	\$ 6,931,861	\$ (23,217,742)	\$ (16,283,681)
	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, January 1, 2019	22,000,000	\$ 2,200	\$ 6,931,861	\$ (17,354,480)	\$ (10,420,419)
Net loss				(589,824)	(589,824)
Balance, March 31, 2019	22,000,000	\$ 2,200	\$ 6,931,861	\$ (17,944,304)	\$ (11,010,243)
Net loss				(763,555)	(763,555)
Balance, June 30, 2019	22,000,000	\$ 2,200	\$ 6,931,861	\$ (18,707,859)	\$ (11,773,798)
Net loss				(653,556)	(653,556)
Balance, September 30, 2019	22,000,000	\$ 2,200	\$ 6,931,861	\$ (19,361,415)	\$ (12,427,354)

See Notes to Condensed Consolidated Financial Statements



Milestone Medical, Inc. and Subsidiary  
Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	Nine Months ended September 30, 2020	Nine Months ended September 30, 2019
Cash flows from operating activities:		
Net loss	\$ (2,368,558)	\$ (2,006,935)
Adjustments to reconcile net cash (used in) operating activities:		
Depreciation and amortization expense	5,007	232,424
Changes in operating assets and liabilities:		
Decrease in accounts receivable	2,600	-
(Increase) decrease in inventories	(222,094)	36,179
(Increase) decrease in advance to contracts	(99,624)	(149,741)
Increase to prepaid expenses and other current assets	(57,348)	(71,698)
(Decrease) increase in accounts payable and accrued expenses	289,851	(11,915)
Increase in accrued interest due to Milestone Scientific Inc.	68,311	68,062
Increase in customer advance	-	16,000
Net cash used in operating activities	\$ (2,381,855)	\$ (1,887,624)
Cash flows from investing activities:		
Purchases of equipment	(5,743)	-
Net cash used in investing activities	\$ (5,743)	\$ -
Cash flows from financing activities:		
Related party advances from Milestone Scientific, Inc.	2,396,829	1,894,579
Net cash provided by financing activities	\$ 2,396,829	\$ 1,894,579
Net increase in cash and cash equivalents	9,231	6,955
Cash and cash equivalents at beginning of period	8,773	1,037
Cash and cash equivalents at end of period	\$ 18,004	\$ 7,992

See Notes to Condensed Consolidated Financial Statements



**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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**NOTE 1 – ORGANIZATION AND BUSINESS:**

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In March 2011, Milestone Medical, Inc. (the “Company”) was organized pursuant to a joint venture agreement (the “Joint Venture Agreement”) between Milestone Scientific, Inc., a Delaware corporation, and Beijing 3H Scientific Technology Co., Ltd. (“Beijing 3H”), a People’s Republic of China (“PRC”) Company. At inception, Milestone Scientific, Inc. contributed an exclusive worldwide royalty-free license for the development and commercialization of intra-articular and epidural drug delivery instruments, utilizing its patented CompuFlo technology. Additionally, Beijing 3H, and a group of other investors contributed \$1.5 million to the Company.

In September 2014, the Company established a special purpose Polish company called Milestone Medical Poland Sp. z.o.o. The purpose of which is for the application and acceptance of Polish Government Grants for research and development of current and future improvement to the epidural and intra-articular instruments. Milestone Medical Poland Sp. z.o.o., is seventy – five percent owned by the Company. Through the date of the financial statements, Milestone Medical Poland Sp. z.o.o. has not received any grants from the Polish Government and is not active.

In December 2016, the Company received notification from the FDA that based upon the 510(k)-application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. The Company provided an additional data submission to the FDA in April 2017, in support of a resubmission 510(k) application for the device. The 510(k) original application filed with FDA lapsed in January 2019. Following consultation with the FDA Office of Device Evaluation, we intended to file a new 510(k) application for the device in 2020. Due to the COVID-19 Pandemic, this process is under review at this time.

On September 12, 2017, the company announced that the CompuFlo® Epidural Computer Controlled Anesthesia System has received 510(k) clearances from the U.S. Food and Drug Administration (FDA). The CompuFlo® Epidural System provides anesthesiologists and other Health Care Providers for the first time, the ability to quantitatively determine and document the pressure at the needle tip in real-time. The CompuFlo® Epidural's proprietary DPS Dynamic Pressure Sensing Technology™ (DPS) allows the CompuFlo® Epidural to provide objective visual and audible in-tissue pressure feedback that allows anesthesiologists to identify the epidural space.

On April 21, 2020, Milestone Medical, Inc., announced on ESPI/14/2020 that it has validated and integrated the new CathCheck™ feature into the CompuFlo® Epidural System. Using CathCheck™, physicians and nurses can monitor the placement of a catheter to determine the presence or absence of a pulsatile waveform (heartbeat) providing new information that can be used to determine if the catheter is in place or has become dislodged from the epidural space. This can be performed within seconds by measuring the pulsatile waveform within the epidural space.

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**NOTE 1 – ORGANIZATION AND BUSINESS:**

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On October 13, 2020, Milestone Medical, Inc. announced a Group Purchasing Agreement with Premier a leading healthcare improvement company, utilizing an alliance of approximately 4,100 U.S. hospitals and 200,000 other providers, to transform healthcare. The Agreement is effective November 1, 2020, and 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™. The Agreement expires on February 28, 2022.

The coronavirus (COVID-19) that was reported to have surfaced in Wuhan, China in December 2019 and that has now spread to other countries throughout the world could adversely impact our operations or those of our third-party partners. In the first, second and third quarters of 2020, the effects of COVID-19 have dramatically reduced our direct marketing capabilities at Hospitals and Medical Centers in the USA and worldwide.

The Company was in the process of attending Medical device trade shows and attending introductory meetings with medical device distributors within the United States, Europe, and other International markets. However, due to the Coronavirus Pandemic, such trade shows have been cancelled through 2020. The Company is now in the process of re-energizing its direct sales efforts with select hospitals and end user meetings as the Pandemic surge has slowed in the USA. The Company's focus will be on marketing the Epidural medical instruments in the United States.

Beginning in September 2020, selective states in the USA have opened their facilities to elective medical procedures and to allow non-employee Sales Representative to enter their facilities. The Vice President of Sales and Territory Sales Managers have started to reengage with targeted medical customers. However, this process is slow and subject to change based on the future impact of a COVID-19 resurgence.

The extent to which the coronavirus impacts our operations or those of our third-party partners will depend on future developments, which are still highly uncertain and cannot be predicted with confidence. The continued possible spread and/or resurgence of the virus could negatively impact the manufacture, supply, distribution, marketing efforts, and sale of our products and our financial results.

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**NOTE 2 - LIQUIDITY AND GOING CONCERN:**

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The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. Milestone Medical, Inc. has incurred significant operating losses since its inception. On September 30, 2020 and December 31, 2019 Milestone Medical, Inc. had cash on hand of \$18,004 and \$8,773 and a negative working capital of approximately \$16.3 million and \$13.9 million, respectively.

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**NOTE 2 - LIQUIDITY AND GOING CONCERN:**

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As of September 30, 2020, Milestone Medical, Inc. does not have sufficient cash to meet all its anticipated obligations for the next twelve months from the financial statement release date. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Milestone Medical, Inc. will continue to manage its cash position while taking strategic steps to commercialize the Epidural instrument in the USA and throughout the world and obtain regulatory approval of Intra-Articular instrument when sufficient funds are available.

During the second quarter of 2020 the Company's parent Milestone Scientific, Inc. raised gross proceeds of approximately \$19.7 million from the sale of Milestone Scientific common stock and warrants. Milestone Scientific, Inc intends to advance additional funds to the Company for manufacturing, marketing, sales, and distribution of its CompuFlo® Epidural System and development of new products and new product uses as well as to help mitigate the risks related to COVID-19.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

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However, Milestone Scientific, Inc. is under no obligation to advance any or all of such funds and may be required to utilize some or all of the funds to support Milestone Scientific Inc.'s other working capital requirements and for general corporate purposes

If Milestone Scientific, Inc. is unable to advance appropriate amounts and Milestone Medical is unable to obtain other sources of funding in adequate amounts there would likely be a material adverse effect on the Company. The financial statements do not include any adjustments relating to the recoverability and classification of assets carrying amounts or the amounts and classification of liabilities that might result should the Company be unable to continue as a going concern.

**Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

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 financial statements and notes thereto for the year ended December 31, 2019, included in Milestone Medical's Annual Report.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

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**Basis of Consolidation**

The Company owns seventy-five percent of a special purpose company organized in Poland, Milestone Medical Poland Sp. z.o.o., which is not active at this time.

**Cash and Cash Equivalents**

The Company considers all liquid investments purchased with an original maturity of three months or less to be cash equivalents.

**Inventory**

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, 2020, and December 31, 2019, inventory was recorded net of a valuation allowance for slow moving of approximately \$450,000, respectively. See Note 4.

**Use of Estimates**

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

**Advances to Contractors**

The advances to contractors represent funding to a subcontractor, for parts required for epidural instrument manufacturing and repairs. On September 30, 2020, and December 31, 2019 advances to the contractor were approximately \$373,000 and \$273,000, respectively.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

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**Furniture, Fixture and Equipment**

Furniture, fixtures, and equipment are 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. Depreciation expense the three and nine months ended September 30, 2020 and 2019 were \$674 and \$5,007 and \$2,402 and \$7,242, respectively. The costs of maintenance and repairs are charged to operations as incurred.

**Revenue Recognition**

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps:

- i. identification of the promised goods or services in the contract;
- ii. determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
- iii. measurement of the transaction price, including the constraint on variable consideration;
- iv. allocation of the transaction price to the performance obligations based on estimated selling prices; and
- v. recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606.

The Company derives its revenues from the sale of its products, primarily medical instruments, disposables, and other related products. The Company sells its products through a global distribution network that includes both exclusive and non-exclusive distribution agreements with third parties. Revenue from product sales is recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery.

The Company has no obligation on product sales for any installation, set-up, or maintenance, these being the responsibility of the buyer. The Company's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period

*Sales Returns*

The Company records allowances for product returns as a reduction of revenue at the time product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the customers' return rights and the Company's historical experience with returns and the amount of product in the distribution channel not consumed by end users and subject to return.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

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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.

*Costs to Obtain or Fulfill a Customer Contract*

Sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in selling, general and administrative expense in the unaudited condensed consolidated statements of operations.

Shipping and handling costs, if any, are paid by or billed to customers at the time of shipment. Domestic and international shipments are FOB warehouse; therefore, no costs are incurred by Milestone Medical. The Company accounts for any shipping and handling activities related to contracts with customers as fulfillment costs which are included in cost of products sold in the condensed consolidated statements of operations.

*Disaggregated Revenue Information*

	Three months ended September 30,	
	2020	2019
Product sales, net		
Domestic		
Epidural devices	\$ -	\$ -
Handpieces/disposables-EPI	-	-
Total	<u>\$ -</u>	<u>\$ -</u>
International		
Epidural devices	\$ -	\$ 8,000
Handpieces/disposables-EPI	6,000	7,500
Total	<u>\$ 6,000</u>	<u>\$ 15,500</u>
Total Product sales	<u>\$ 6,000</u>	<u>\$ 15,500</u>

**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

	Nine months ended September 30,	
	2020	2019
Product sales, net		
Domestic		
Epidural devices	\$ -	\$ -
Epidural devices-Trainer	-	10,800
Handpieces/disposables-EPI	2,000	300
Total	<u>\$ 2,000</u>	<u>\$ 11,100</u>
International		
Epidural devices	\$ 7,600	\$ 8,000
Epidural devices-Trainer		
Handpieces/disposables-EPI	6,200	11,500
Accessories		400
Total	<u>\$ 13,800</u>	<u>\$ 19,900</u>
Total Product sales	<u>\$ 15,800</u>	<u>\$ 31,000</u>

**Intangible Asset**

The Company amortizes the intangible asset contributed which is comprised of platform technology over its estimated useful life of 5 years. In the fourth quarter of 2019, the marketing and sales efforts relating to the Epidural instrument had not met the expectations as forecasted for the year. Based on forecasts, the Company did not expect to realize the carrying value of the asset before the estimated useful life expired and, as a result, recorded an impairment charge of \$750,000, on the asset in the fourth quarter of 2019. During the three- and nine-months ending September 30, 2019 amortization expense was \$75,000 and \$225,000, respectively. There was no amortization expense recognized during the three and nine months ended September 30, 2020.

**Research and Development**

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

**Income Taxes**

Milestone Medical 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.



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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

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The Company evaluates uncertainty in income tax positions based on a more-likely-than-not recognition standard. If that threshold is met, the tax position is then measured at the largest amount that is greater than 50% likely of being realized upon ultimate settlement. If applicable, the Company records interest and penalties as a component of income tax expense.

As of September 30, 2020, and December 31, 2019, there were no accruals for uncertain tax positions. Tax returns for 2016, 2017, and 2018 years are subject to audit by federal and state jurisdictions.

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**NOTE 4 - INVENTORY:**

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Inventory, net as of September 30, 2020 and December 31, 2019 consisted of the following:

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Inventories consists of the following:		
Epidural instruments	\$ 162,267	\$ 139,090
Epidural instruments - Trainer	1,626	4,879
Intra-articular instruments, net reserve	-	-
Epidural instrument Disposables	4,411	-
Component parts and other materials	267,696	69,892
Component parts and other materials - Trainer	1,245	1,290
Total	<u>\$ 437,245</u>	<u>\$ 215,151</u>

The reserve against Intra-articular instrument was approximately \$450,000 as of September 30, 2020 and December 31, 2019, respectively.

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**NOTE 5 - RELATED PARTY TRANSACTIONS:**

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On December 31, 2014, Milestone Scientific, Inc. executed a \$2 million line of credit agreement to provide bridge financing to the Company through April 15, 2016. Borrowings under the line bear interest at a rate of 3.25%, the prime rate at the inception of the agreement. In September 2015, the company requested and received approval from the Board of Directors of Milestone Scientific, Inc. to increase the limit of the line of credit to a maximum of \$2.5 million. In January 2016, the credit agreement was again increased to \$2.8 million hold.

The technology underlying the CompuFlo®, and an improvement to the controls for CompuDent® were developed by the Director of Clinical Affairs and assigned to Milestone Scientific. Milestone Medical purchased a license to this technology pursuant to an agreement dated January 1, 2005.



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**NOTE 5 - RELATED PARTY TRANSACTIONS:**

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The Director of Clinical Affairs will receive payments of 5% of the total sales of the Company's products until the expiration of the last patent carried by Milestone Scientific, Inc. The Director of Clinical Affairs' royalty fee was approximately \$300 for the three months, and \$790 for the nine months ended September 30, 2020. The Director of Clinical Affairs' royalty fee was approximately zero for the three months and \$755 for the nine months ended September 30, 2019.

As of September 30, 2020, and December 31, 2019, the Company owes approximately \$13.2 million and \$10.8 million, respectively, to Milestone Scientific, Inc. for expenses paid on the Company's behalf. These advances are non-interest bearing and due on demand. As of the financial report issuance date, Milestone Scientific, Inc. has not demanded payment of the advances.

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**NOTE 6 – CONCENTRATIONS AND SUPPLY UNCERTAINTIES:**

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The Company has informal arrangements for the manufacture of its products, the epidural, epidural trainer, and intra-articular instruments are manufactured by Tricor Systems, Inc., a United States based Company, pursuant to specific purchase orders.

The Company sub-contracts its research and development to a various vendor, the three- and nine-months ending September 30, 2020 the Company recorded research and development expenses of approximately \$23,000, and \$239,000, respectively. The three- and nine-months ending September 30, 2019 the Company recorded research and development expenses of approximately \$7,940 and \$109,000, respectively.

The epidural and intra-articular handpiece with no needles are supplied to Milestone Medical by several independent contractors in the United States, which arrange for its manufacture in China. In December 2019, and through the date of financial statement issuance, the outbreak of the Wuhan Coronavirus (COVID-19), and the continuing spread of the illness in China and other parts of the world, did not result in a and disruption in the supply chain of raw Materials, through September 30, 2020. In the event that the outbreak of the Wuhan Coronavirus continues to expand (Pandemic), the possibility of factory quarantines and imposing shipping and travel restrictions, could interfere with our delivery of parts and other components required for the production of our medical instruments and disposable kits, and could adversely impact our financial condition and results of operations. As of the date of this report the Chinese factories that we depend on for the delivery of parts and components to produce our medical instruments and disposable kits are operational.

The termination or interruption of the manufacturing relationship with any of the above manufacturers could have a material adverse effect on Milestone Medical's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Medical would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay.

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**NOTE 6 – CONCENTRATIONS AND SUPPLY UNCERTAINTIES:**

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Any curtailment or interruption of the supply would adversely affect Milestone Medical.

For the three and nine months ended September 30, 2020 100% of net product sales were to one and three customers, respectively. For the three and nine months ended September 30, 2019 net product sales were to one and three customers/distributors in the amount of \$15,500, and \$31,000, respectively.

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**NOTE 7 - COMMITMENTS AND CONTINGENCIES:**

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In August 2019, the company entered a new purchase commitment for the delivery of 100 Epidural instruments beginning in 2020. As of September 30, 2020, we have an open purchase order of \$299,000 for 100 Epidural instruments and have advanced \$166,645 against this purchase commitment.

In July 2020, the company entered a new purchase commitment for the delivery of 110 cases of Epidural disposable kits beginning in November 2020. As of September 30, 2020, we have an open purchase order of \$30,395 for 55 cases Epidural disposable kits and have advanced \$21,197 against this purchase commitment.

The company also has advances on an open purchase order for long lead items for a future purchase order for the manufacturing of Epidural instrument in 2021 of \$184,839.

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**NOTE 8 – SUBSEQUENT EVENT:**

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After September 30, 2020, Milestone Scientific Inc., has advanced Milestone Medical approximately \$160,000 to support the commercialization process for the epidural instrument and other expenses necessary for the day to day operations of Milestone Medical. Milestone Scientific Inc. is not legally obligated to loan or advance additional funds to the Issuer. See Note 2.

On October 13, 2020, Milestone Medical, Inc. announced a Group Purchasing Agreement with Premier a leading healthcare improvement company, utilizing an alliance of approximately 4,100 U.S. hospitals and 200,000 other providers, to transform healthcare. The Agreement is effective November 1, 2020, and 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™. The Agreement expires on February 28, 2022.

The Company announced on October 22, 2020 on ESPI/23/2020 a video interview with a key opinion leader, Dr Ayman A. Alian, MBChB, Associate Professor of Anesthesiology and Division Chief of Obstetric & Gynecologically Anesthesiology at the Yale School of Medicine. Dr Alian discussed the benefits of the CompuFlo® Epidural System and CathCheck™, including verification of epidural placement during an epidural procedure and confirmation of catheter placement.

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**NOTE 8 – SUBSEQUENT EVENT:**

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The other advantages of CompuFlo® Epidural System and CathCheck™ include improving the block, helping the medical practitioner to decide, decreasing complications and the length of stay in the hospital as well as improving patient satisfaction. The Company is grateful to Dr Alian for his leadership in adopting the CompuFlo® Epidural System and CathCheck™ as part of his practice. The Company believes the support from Dr Alian and other anaesthesiologists is further validation of its technology and advances towards the goal of CompuFlo® and CathCheck™ becoming the new standard of care.

**3. Information on the rules applied to the preparation of the report, including information on the changes in applied account rules (policies)**

Consolidated quarterly report for the third quarter of 2020 was prepared in accordance with the rules indicated in Exhibit 3 to the Alternative Trading System Rules “Current and Periodical Information in the Alternative Trading System on the NewConnect market”. Information on applied accounting rules (policies) are presented in Note 3 to the Financial Statement.

**4. Brief description of the most important achievements or failures of the Issuer and its Subsidiary during the period of the report as well as a description of the most important factors and events, atypical ones, which impact the achieved results.**

The Company intends to continue to work with the medical education market with the introduction of the CompuFlo® Epidural Trainer (CompuFlo Trainer), an instructional instrument that uses pressure sensing technology to improve epidural placement success. The COVID -19 Pandemic has reduced our access to this segment of the Medical business since earlier this year. The company has signed an agreement to distribute the CompuFlo Trainer with American 3B Scientific, a leading supplier of didactic material for medical education. 3B's customers include universities, schools, ministries or authorities of health and education, hospitals, practitioners, educational and medical distributors, and medical students. The CompuFlo Epidural Trainer is for training purposes only and not intended for clinical use. The Company will continue to address sales effort on the medical education space with medical schools and skill labs with the introduction of the Epidural Trainer instrument.

The Company added three Territory Sales Managers (in the USA) in 2020 to focus on the USA Market for Hospitals and Medical Centers. Unfortunately, the COVID-19 Pandemic has significantly reduced the effectiveness of the new additions to staff, by severely limiting access of these individuals to potential users of the CompuFlo Epidural instrument.

On September 9, the Company provided on ESPI/21/2020 a business update regarding the commercial roll-out of its CompuFlo® Epidural System and CathCheck™ technology. With COVID-19 infections declining in certain regions, and several hospitals re-opening to outside vendors, the Board of Directors of the Company is advancing sales efforts around the CompuFlo® Epidural System and CathCheck™ technology. To support the hospitals in performing procedures during the pandemic, the Board of Directors of the Issuer decided to make the CompuFlo instrument more readily available to hospitals by lending the instrument to the hospital, in exchange for a commitment to purchase a minimum number of disposables. This offering is limited to the first hospitals that sign up for this program. At the same time, the Company is partnering with anesthesiologists, to approach the purchasing departments of the hospitals together. The Board of Directors of the Company believes that the current strategy allows the Issuer to streamline the Value Analysis Team (VAT) approval process, and thereby shorten the sales cycle. The response thus far has been encouraging, and the Company is increasing new trials in major hospitals over the coming weeks. The Board of Directors of the Company looks forward to finalizing agreements with several premier hospitals soon as the sales pipeline is more robust than ever.

On October 13, 2020, Milestone Medical, Inc. announced a Group Purchasing Agreement with Premier a leading healthcare improvement company, utilizing an alliance of approximately 4,100 U.S. hospitals and 200,000 other providers, to transform healthcare. The Agreement is effective November 1, 2020, and 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™. The Agreement expires on February 28, 2022.

##### **5. A description of the status of implementation of activities and investments of the Issuer and its Subsidiary and the timetable of their implementation**

The Company has made technical improvements to its products, which the Issuer believes will support the commercial efforts going forward. On April 21, 2020, the Company reported on ESPI/14/2020 Milestone announced that it has validated and integrated the new CathCheck™ feature into the CompuFlo® Epidural System. Using CathCheck™, physicians and nurses can monitor the placement of a catheter to determine the presence or absence of a pulsatile waveform (heartbeat) providing new information that can be used to determine if the catheter is in place or has become dislodged from the epidural space. This can be performed within seconds by measuring the pulsatile waveform within the epidural space. This capability saves time and money and provides better patient care. In fact, a major university hospital familiar with CompuFlo was attracted to new CathCheck technology, given its ability to minimize contact between the patient and provider, which is especially important during the COVID-19 pandemic.

On April 15, 2020, the company reported on ESPI/12/2020 Milestone announced that it has validated the new "Quick Start," which has been implemented into the CompuFlo® Epidural System. The Quick Start feature simplifies and provides an alternative pathway to reduce the procedure preparation time for the CompuFlo® instrument prior to the procedure.

The Issuer also announced on April 17, 2020 on ESPI/13/2020 the first major study to clearly validate the cost benefits of CompuFlo within labor and delivery versus the traditional loss of resistance technique using the hypodermic syringe. This study has become be an important tool as we present the value proposition of our instrument to hospitals across the country, indicating an average cost saving of \$504 per hospital stay related to a lower rate of accidental dural puncture complications with our instrument.

On May 13, 2020 the Company announced on ESPI/15/2020 that a study was published in the Open Journal of Anesthesiology validating the efficacy of the CompuFlo® CathCheck™ System to confirm the correct placement and positioning of an epidural catheter for use during and after an epidural procedure. This is another validation that the CathCheck™ feature will help to significantly reduce time and cost for the institution by providing a more reliable way to re-check the catheter throughout the day to ensure that the catheter has not been displaced.

##### **6. If the Issuer and its Subsidiary took initiatives to develop its activities aimed to implement innovative solutions at the enterprise during the period of the report – information on such activities.**

The Issuer and its Subsidiary continues to consider and where appropriate include innovative initiatives for its two medical instruments in the EU community. The Company continues to work and introduce the Epidural instrument in key medical institutions in the United States.

**7. Description of the organization of the group indicating consolidated entities**

Up to the date of this report completion, the Issuer does have a special purpose subsidiary Milestone Medical Poland Sp. z.o.o. The purpose of this company is the application and acceptance of Polish Government Grants for research and development of the current and future improvements to the two instruments.

Below the Issuer presents some basic information about its subsidiary: **Table 6 General information about Subsidiary of the Issuer**

SUBSIDIARY	MILESTONE MEDICAL POLAND SP. Z.O.O.
Registered office/Office:	Place Powstancow Slaskich 1/201, 53-329 Wroclaw
Telephone number:	48 (71 )79 11 555
Facsimile number:	48 (71) 79 11 556
Percentage share of the Issuer in share capital	75 percent

Source: The Issuer

Milestone Medical Poland Sp. z.o.o. was established in September 2014 and is not active at the time. The Issuer has prepared Condensed Consolidated Financial Statements with this subsidiary according to laws and regulations applicable to the Issuer.

Leonard Osser  
Interim Chief Executive Officer