

# Condensed Consolidated report of

## **MILESTONE MEDICAL INC. and its SUBSIDIARY** 3rd quarter (from July 1, 2019 to September 30, 2019)

*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 14, 2019

## 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>	220 South Orange Avenue, Livingston, NJ 07039, 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

### 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 June 17, 2016 that Milestone Scientific initiated a share exchanged program pursuant to which would exchange one share of common stock 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. An additional 55,994 shares (0.25%) are in the process of exchange as of the date of this report. After the exchange, Milestone Scientific will own approximately 98.59% of the shares in Milestone Medical.

## 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>	74	Sep-14	Next Annual Meeting of Shareholders

*\* On October 3, 2019 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

On September 30, 2019 the Issuer employed three (3) full time employees and three (3) persons converted into full-time equivalents (“FTEs”). There is an open position for an additional one (1) full time employee: A Medical Device Trainer. The Company has contracted with one Business Development Consultant for business activities in Europe and the Middle East in 2018. Milestone Medical has three fulltime employees as of September 30, 2019; an Executive VP of Global Marketing and Sales, a Vice President of USA Sales, and a Director of Marketing. These three employees will promote direct market support for Milestone Medical and assist on moving the medical business forward on an accelerated track.

In September 30, 2019 the Parent Company engaged a new President. The President will also be responsible for the growth of the Medical segment (Milestone Medical Inc). At about the same time, the Executive VP of Global Marketing and Sales, and the Director of Marketing offered their resignation effective in the middle of October 2019. The resignation dates provided a smooth transition from the departing employees to the new President. The new President will evaluate the business and marketing operations of Milestone Medical Inc over the next few months, and make the changes required to expedite the sales of the Epidural instrument in the USA and other countries in the world.

**2. 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 three and nine months ended September 30, 2019 and 2018 (unaudited)**

**For the Year Ended December 31, 2018 (audited)**

<b><u>Contents</u></b>	<b><u>Page</u></b>
Condensed Consolidated Financial Statements:	
Condensed Consolidated Balance Sheets.....	5
Condensed Consolidated Statements of Operations.....	6
Condensed Consolidated Statements of Changes in Stockholders' Deficit.....	7
Condensed Consolidated Statements of Cash Flows.....	8
Notes to Condensed Consolidated Financial Statements.....	9 - 17

Milestone Medical Inc. And Subsidiary  
Condensed Consolidated Balance Sheets

	September 30, 2019 (Unaudited)	December 31, 2018 Audited
<u>ASSETS</u>		
Cash and cash equivalents	\$ 7,992	\$ 1,037
Inventories, net	198,248	234,427
Advances on contracts	193,889	44,148
Prepaid expenses and other current assets	103,662	31,963
Total current assets	503,791	311,575
Furniture, fixture and equipment, net	9,209	16,633
Intangible asset, net	825,000	1,050,000
Total assets	\$ 1,338,000	\$ 1,378,208
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Accounts payable	\$ 153,563	\$ 113,380
Accrued expenses and other payables	676,465	660,500
Customer advance	16,000	-
Advances from Milestone Scientific Inc.	10,119,326	8,224,747
Due to Milestone Scientific, Inc.	2,800,000	2,800,000
Total current liabilities	13,765,354	11,798,627
<u>COMMITMENTS AND CONTINGENCIES</u>		
Stockholders' deficit		
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at September 30, 2019 and December 31, 2018	2,200	2,200
Additional paid-in capital	6,931,861	6,931,861
Accumulated deficit	(19,361,415)	(17,354,480)
Total stockholders' deficit	(12,427,354)	(10,420,419)
Total liabilities and stockholders' deficit	\$ 1,338,000	\$ 1,378,208

See Notes to Condensed Consolidated Financial Statements

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

	2019	2018	2019	2018
Product revenue, net	\$ 15,500	\$ -	\$ 31,000	\$ 76,100
Cost of products sold	12,108	-	20,897	257,332
Gross profit	<u>3,392</u>	<u>-</u>	<u>10,103</u>	<u>(181,232)</u>
Selling, general and administrative expenses	547,896	451,776	1,604,047	1,740,725
Depreciation and amortization	77,402	77,530	232,424	246,885
Research and development expenses	7,940	-	109,815	65,008
Total operating expenses	<u>633,238</u>	<u>529,306</u>	<u>1,946,286</u>	<u>2,052,618</u>
Loss from operations	(629,846)	(529,306)	(1,936,183)	(2,233,850)
Interest expense	<u>(23,710)</u>	<u>(23,537)</u>	<u>(70,241)</u>	<u>(69,807)</u>
Loss before income tax	<u>(653,556)</u>	<u>(552,843)</u>	<u>(2,006,424)</u>	<u>(2,303,657)</u>
Income tax expense	-	-	(511)	(2,000)
Net loss	<u>\$ (653,556)</u>	<u>\$ (552,843)</u>	<u>\$ (2,006,935)</u>	<u>\$ (2,305,657)</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, 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)
Balance, January 1, 2018	22,000,000	2,200	6,931,861	(14,353,851)	(7,419,790)
Net loss				(807,145)	(807,145)
Balance, March 31, 2018	22,000,000	2,200	6,931,861	(15,160,996)	(8,226,935)
Net loss				(945,676)	(945,676)
Balance, June 30, 2018	22,000,000	2,200	6,931,861	(16,106,672)	(9,172,611)
Net loss				(552,843)	(552,843)
Balance, September 30, 2018	22,000,000	\$ 2,200	\$ 6,931,861	\$ (16,659,515)	\$ (9,725,454)

See Notes to Condensed Consolidated Financial Statements



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

	Nine months ended September 30, 2019	Nine months ended September 30, 2018
Cash flows from operating activities:		
Net loss	\$ (2,006,935)	\$ (2,305,657)
Adjustments to reconcile net cash (used in) operating activities:		
Depreciation and amortization expense	232,424	246,885
(Decrease) increase inventories allowances		234,350
Changes in operating assets and liabilities:		
Decrease in inventories	36,179	12,148
Decrease (Increase) to advances on contracts	(149,741)	-
Decrease (increase) to prepaid expenses and other current assets	(71,698)	(8,800)
Increase in accounts payable and accrued expenses	56,147	266,169
Increase in customer advance	16,000	-
Net cash used in operating activities	<u>(1,887,624)</u>	<u>(1,554,905)</u>
Cash flows from investing activities:		
Purchases of property and equipment	-	(5,141)
Net cash used in investing activities	<u>-</u>	<u>(5,141)</u>
Cash flows from financing activities:		
Related party advances	1,894,579	1,543,824
Net cash provided by investing activities	<u>1,894,579</u>	<u>1,543,824</u>
Net increase in cash and cash equivalents	6,955	(16,222)
Cash and cash equivalents at beginning of period	1,037	19,272
Cash and cash equivalents at end of period	<u>\$ 7,992</u>	<u>\$ 3,050</u>

See Notes to Condensed Consolidated Financial Statements



**NOTES TO 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 this report, Milestone Medical Poland Sp. z.o.o. has not received any grants from the Polish Government. Milestone Medical Poland Sp. z.o.o. is inactive currently.

On June 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.

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 510K original application filed with FDA lapsed in January 2019. Following consultation with the FDA’s Office of Device Evaluation, we intend to file a new 510(k) application for the device when the Company secures additional funding sometime in 2020.

The Company is 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. The Company’s focus will be on marketing the Epidural medical and trainer instruments in the United States and throughout the world.

In January 2019, the Company filed on the ESPI 1/2019 a report that announced New Clinical Trial Findings for the CompuFlo® Epidural Instrument. The pivotal study confers that the CompuFlo® Epidural instrument is a highly effective alternative to standards of care. The instrument avoids patient radiation exposure when compared to fluoroscopy and demonstrated greater accuracy when compared to loss of resistance. In April 2019, the Company entered the medical education market with the introduction of the CompuFlo® Epidural Trainer as our instructional instrument that uses pressure sensing technology to improve epidural placement success. The Company has signed an agreement to distribute the CompuFlo Trainer with American 3B Scientific, a leading supplier of didactic material for medical education.

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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. At September 30, 2019 Milestone Medical Inc. had cash of \$7,992 and a working capital deficit of approximately \$13.3 million. As of September 30, 2019, 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 medical instruments in the USA, throughout the world and obtain regulatory approval of Intra-Articular instrument in the USA.

Additional financing is necessary to fund the commercialization of the Epidural medical and trainer instruments and continue the Intra-Articular regulatory process. To this end, the Company and Milestone Scientific, Inc. are in the process of pursuing additional financings. However, the Company and Milestone Scientific, Inc. can provide no assurance that additional financings will be consummated on acceptable terms, or at all. If the Company and Milestone Scientific, Inc. are unsuccessful in obtaining additional financing on a timely basis there would most 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.

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

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**Basis of Presentation**

The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information with the instructions for Form 10Q of Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present such interim results. Interim results are not necessarily indicative of the results of operations which may be expected for a full year or any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2018, included in Milestone Medical's Annual Report (published on March 21, 2019).

**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.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

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**Reclassifications**

Certain reclassifications have been made to the 2018 financial statements to conform to the condensed consolidated 2019 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

**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 and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence and product expiration requirements.

**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 inventory valuation, cash flow assumptions, evaluations for impairment of long-lived assets, 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 both epidural and intra articular instruments for the manufacturing of new instruments and repair parts. At September 30, 2019 and December 31, 2018 advances to contractors was \$193,889 and \$44,148, respectively.

**Furniture, Fixture and Equipment**

Furniture, fixtures and 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 depreciation expense for the three and nine months ended September 30, 2019 was \$2,402, and \$7,424, respectively. The depreciation expense for the three and nine months ended September 30, 2018 was \$2,530, and \$21,885, respectively. The costs of maintenance and repairs are charged to operations as incurred.

**Revenue Recognition**

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

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

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- 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.

The Company derives its revenues from the sale of its medical instruments, disposables, and other related trainer instruments. The Company expects to sell its products through a global distribution network that includes non-exclusive distribution agreements with third parties.

Revenue from product sales are recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has no obligation on product sales for any installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Medical's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

We generally do not accept non-defective returns from our customers. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Company's warranty policy. Returns not within the warranty policy are evaluated and the customer is charged for repair.

**Financing and Payment**

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

**Costs to Obtain or Fulfill a Customer Contract**

Sales commissions are expensed when incurred. These costs are recorded in selling, general and administrative expense in the 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.

**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

**Disaggregated Revenue Information**

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Product sales, net				
Domestic				
EPI Devices	\$ -	\$ -	\$ -	\$ -
EPI Devices - Trainer	-	-	10,800	-
Handpieces/Disposables - EPI	-	-	-	-
Handpieces/Disposables - EPI Trainer	-	-	300	-
Product sales domestic	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 11,100</u>	<u>\$ -</u>
International				
EPI Devices	\$ 8,000	\$ -	\$ 8,000	\$ 70,500
EPI Devices - Trainer	-	-	-	-
Handpieces/Disposables - EPI	7,500	-	11,500	5,600
Accessories	-	-	400	-
Product sales international	<u>\$ 15,500</u>	<u>\$ -</u>	<u>\$ 19,900</u>	<u>\$ 76,100</u>
Total Product sales	<u>\$ 15,500</u>	<u>\$ -</u>	<u>\$ 31,000</u>	<u>\$ 76,100</u>

**Intangible Asset**

The intangible assets for the medical indications have an estimated useful life of 5 years. Intangibles are amortized utilizing the straight-line method which resulted in amortization expense for the three and nine months ended September 30, 2019 of, \$75,000 and \$225,000, respectively. Amortization expense for the three and nine months ended September 30, 2018 of, \$75,000 and \$225,000, respectively.

Long-lived tangible 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 underperformance relative to expected historical or projected future operating results,
- significant changes in the manner of our use of the assets or the strategy for our overall business,
- significant negative industry or economic trends,
- 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. During 2018, the Company assessed the intangible for impairment because the marketing and sales efforts relating to the Epidural instrument have not met the original expectations following the 2017 approval and no impairment was deemed necessary. The Company's impairment assessment is based on several factors including projected

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

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cash flows from the Epidural instruments. There were no indicators through September 30, 2019 and therefore no assessment was performed.

**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.

At September 30, 2019 and 2018, no significant income tax uncertainties have been included in the Company's financial statements. The Company's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the statement of operations. Tax returns for 2015, 2016, 2017 and 2018 years are subject to audit by federal and state jurisdictions.

**Recently Adopted Accounting Pronouncements**

On January 1, 2019 the Company adopted Accounting Standards Update ("ASU ") No.2016-02, "Leases"(Topic 842). The new standard is intended to increase transparency and comparability among organizations to recognize lease assets and liabilities on the balance sheet and disclose key information about leasing arrangements. Milestone Medical determined that the adoption of this ASU did not have a material effect on its financial position, results of operations and cash flows.

On November 28, 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-13, Fair Value Measurement: Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement (Topic 820), which changes the fair value measurement disclosure requirements of ASC 820. This ASU removes certain disclosure requirements regarding the amounts and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy and the policy for timing of transfers between the levels. This ASU also adds disclosure requirements regarding unrealized gains and losses included in Other Comprehensive Income for recurring Level 3 fair value measurements and the range and weighted average of unobservable inputs used in Level 3 fair value measurements. ASU 2018-13 is effective for all entities with fiscal years beginning after December 15, 2019, including interim periods therein. Early adoption is permitted for any eliminated or modified disclosures upon issuance of ASU 2018-13. The Company is currently evaluating the impact of adopting this standard.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

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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 entities for fiscal years and interim periods, beginning after December 15, 2019. We are currently evaluating the impact of adopting this guidance on our consolidated balance sheet, results of operation and financial condition.

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**NOTE 4 - INVENTORY:**

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Inventory as of September 30, 2019 and December 31, 2018 consisted of the following:

	September 30, 2019	December 31, 2018
Inventories consist of the following:		
Epidural instruments	\$ 136,314	\$ 188,133
Epidural instruments trainer	4,878	-
Intra-articular instruments, net reserve	-	-
Handpiece/Disposables-Epidural	1,290	2,061
Component parts and other materials	55,766	44,233
Total	<u>\$ 198,248</u>	<u>\$ 234,427</u>

The reserve against Intra-articular instrument was approximately \$450,000 and \$454,000 as of September 30, 2019 and December 31, 2018.

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**NOTE 5 - JOINT VENTURE AGREEMENT:**

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Pursuant to the Joint Venture Agreement, 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 and a group of individual investors contributed \$1.5 million to the Company. At inception, the Company reviewed the transaction to assess the technological feasibility of the product being develop. Based on the following factors, the Company believed the technology was feasible from inception.

Milestone Scientific, Inc. is authorized by the Joint Venture Agreement to manage and oversee the development of the two medical instruments for the Company. In connection with this, Milestone Scientific, Inc. entered into an agreement with a vendor to develop the two instruments. Milestone Scientific, Inc. personnel monitored the development of the instruments with the third-party vendors on a periodic basis thus ensuring that the instruments will be developed according to medical standards.

Milestone Scientific, Inc. has distribution responsibility in the U.S. and Canada, while Milestone China Ltd, (a Hong Kong Medical Company related to Milestone Scientific, Inc.) at that time is to distribute products exclusively in the PRC and other regions in Asia. The Company has distribution responsibilities for the rest of the world.

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**NOTE 6 - 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 increased to \$3 million. As of September 30, 2019 and December 31, 2018, Milestone Scientific, Inc. has advanced \$2.8 million to Milestone Medical under this line of credit which is classified as Due to Milestone Scientific Inc. on the accompanying Condensed Consolidated Balance Sheets. All other terms in the line of credit agreement remain unchanged. Milestone Scientific Inc. has not demanded payment of the line of credit. Milestone Scientific Inc. is not legally obligated to provide any other funding to Milestone Medical Inc.

As of September 30, 2019, and December 31, 2018, the Company owes approximately \$10.1 million and \$8.2 million, respectively, to Milestone Scientific, Inc. for expenses paid on the Company's behalf in addition to amounts owed on the line of credit discussed above. These advances are non-interest bearing and due on demand.

The technology underlying the CompuFlo®, and an improvement to the controls for CompuDent® were developed by the Director of Clinical Affairs of Milestone Scientific and assigned to Milestone Scientific by the Director of Clinical Affairs. Milestone Medical purchased this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs is entitled to receive payments of 5% of the total sales of Milestone Medical instruments and disposables until the expiration of the last patent carried by Milestone Scientific Inc related to Milestone Medical.

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**NOTE 7 - CONCENTRATIONS:**

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The Company has informal arrangement with the Tricor Systems who manufacturers, the epidural and intra-articular instruments are under a specific purchase orders but without any long-term contract or minimum purchase commitment. Consequently, advances on contracts have been classified as current at September 30, 2019 and December 31, 2018. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on the Company'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.

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. For the three and nine months ended September 30, 2018 net product sales were to two customers/distributors in the amount of zero, and \$76,100, respectively.

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**NOTE 8 - COMMITMENTS AND CONTINGENCIES:**

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In July 2017, Leonard Osser resigned from his positions of Chairman of the Board, Chief Executive Office and President of Milestone Medical. Upon his resignation, Milestone Medical entered in a consulting agreement with U.S. Asian Consulting Group LLC, an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten- year term. Pursuant to the consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive \$100,000 per year for Mr. Osser's services. On December 19, 2017, Mr. Osser placed on hold his



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**NOTE 8 - COMMITMENTS AND CONTINGENCIES:**

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consulting agreement with Milestone Medical to rejoin Milestone Medical Inc. as Interim Chief Executive Officer and will not receive or earn any compensation under the consulting agreement until he is no longer Interim Chief Executive Officer.

As of September 30, 2019, we have an open purchase order of \$299,000 for 100 instruments with Tricor Systems and have advanced \$89,700 as of September 30, 2019 against these purchase commitments.

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**NOTE 9 – SUBSEQUENT EVENT:**

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Subsequent to September 30, 2019, Milestone Scientific Inc., has advanced Milestone Medical approximately \$190,000 to continue 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 and Note 6.

**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 2019 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. During the third quarter of 2019, the company adopted the FASB issued Accounting Standards Update (“ASU”) No. 2016-02, Leases Topic 842. Adoption of this standard did not have a significant impact on our financial statements.

**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 continues 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 company has signed an agreement to distribute the CompuFlo Trainer with American 3B Scientific, a leading supplier of didactic material for medical education. Zach Montgomery, Managing Director of American 3B Scientific commented, "Pairing 3B Scientific's didactic learning materials and advanced simulators with CompuFlo's objective verification is a game changer for training. Medical residency programs and simulation labs now have the ultimate training tool to accelerate the epidural procedure's learning curve, which holds big promise not only for training but clinical practice." 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 signed a Distributor Agreement in the USA in October 2018. The Agreement referred that the Distributor purchase and hold inventory of the CompuFlo® Epidural instruments and disposables. The Distributor purchased five (5) instruments and disposables after signing the agreement.

The Company continues to focus sales effort in the medical education space with medical schools and skill labs with the introduction of the Epidural Trainer instrument

In September 2019, the Parent Company (Milestone Scientific Inc) engaged a new President. The President has a strong medical background and will be responsible for the growth of the Medical segment (Milestone Medical Inc). At about the same time, the Executive VP of Global Marketing and Sales, and the Director of Marketing offered their resignations effective in the middle of October 2019. The length of the resignation period provided a smooth transition from the departing employees to the new President.

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

Milestone demonstrated accurate placement for any technique to more than 1,000 acute pain physicians at the American Society of Regional Anesthesia (ASRA) and Acute Pain Medicine's 44th annual conference. At ASRA 2019, attendees participated in demonstrations of the CompuFlo Manometry Technique that pairs the traditional loss-of-resistance syringe with CompuFlo's objective detection of tissue pressure that is imperceptible by touch. Providers can complement their tactile feel with quantifiable, visual feedback for additional verification. This technique is achieved simply by connecting the CompuFlo instrument to a loss-of-resistance syringe with a 3-way valve. With the new manometry method, these benefits can be achieved for any technique-from traditional loss-of-

resistance with saline, saline with an air pocket or intermittent pressure to an epidural needle with constant pressure.

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

**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