



# **Condensed Consolidated Quarterly report of MILESTONE MEDICAL INC. and its SUBSIDIARY**

## **3rd quarter (from July 1, 2018 to September 30, 2018)**

***Report include:***

1. General information about Milestone Medical Inc (“Issuer”; the Company”) and Milestone Medical Poland Sp. z o.o. (the Subsidiary).
2. Condensed Consolidated quarterly 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, 2018

## 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.**

Name of Shareholder	Number of owned shares/votes	Shareholding/votes at General Meeting of Shareholders [%]
<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**

NAME OF DIRECTOR	CURRENT AGE	DIRECTOR SINCE	END OF TERM
<b>Zhu Yun</b>	52	Sep-13	Next Annual Meeting of Shareholders
<b>Martin S. Siegel</b>	73	Sep-14	Next Annual Meeting of Shareholders

\* On May 30, 2018 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.

On July 10, 2017 Leonard Osser resigned as a member of the Board of Directors of the Issuer. In December 2017, Leonard Osser rejoined the Management of Milestone Medical Inc. as Interim Chief Executive Officer. Mr. Osser was not nominated as a member of the Board of Directors in 2018.

Source: The Issuer

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

In February and March 2018, Milestone Scientific Inc. added two key employees for Milestone Medical Inc. We added an Executive VP of Global Marketing and Sales and a Vice President of USA Sales. These two employees will promote direct market support for Milestone Medical and assist on moving the medical business forward on an accelerated track. In July 2018, Milestone Scientific added a Director of Marketing, a fulltime position to assist in the domestic and international marketing plan to the potential customer base. As of September 30, 2018, the Issuer employed three (3) full time employee and four (4) persons converted into full-time equivalents (“FTE”).

**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 the three and nine months ended September 30, 2018 and 2017 (unaudited)**

**And as of and for the year ended December 31, 2017 (audited)**

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MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2018 (Unaudited)	December 31, 2017 (Audited)
<u>ASSETS</u>		
Cash and cash equivalents	\$ 3,050	\$ 19,272
Inventories, net	253,815	500,313
Advances on contracts	44,148	44,148
Prepaid expenses and other current assets	65,954	57,154
Total current assets	366,967	620,887
Equipment, net	17,882	34,626
Intangible asset, net	1,125,000	1,350,000
Total assets	\$ 1,509,849	\$ 2,005,513
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Accounts payable	\$ 147,149	\$ 56,978
Accrued expenses and other payables	621,256	445,258
Advances on line of credit from Milestone Scientific Inc.	7,666,891	6,123,067
Due to related party	2,800,000	2,800,000
Total current liabilities	11,235,296	9,425,303
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at September 30, 2018 and December 31, 2017	2,200	2,200
Additional paid-in capital	6,931,861	6,931,861
Accumulated deficit	(16,659,508)	(14,353,851)
Total stockholders' deficit	(9,725,447)	(7,419,790)
Total liabilities and stockholders' deficit	\$ 1,509,849	\$ 2,005,513

See Notes to Condensed Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS  
(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Product sales, net	\$ -	\$ -	\$ 76,100	
Cost of products sold	-	-	257,332	
Gross profit	-	-	(181,232)	-
Selling, general and administrative expenses	451,776	486,774	1,740,725	1,555,435
Depreciation & Amortization	77,530	5,515	246,885	21,436
Shared services	-	17,375	-	52,727
Research and development expenses	-	8,274	65,008	116,793
Total operating expenses	529,306	517,938	2,052,618	1,746,391
Loss from operations	(529,306)	(517,938)	(2,233,850)	(1,746,391)
Interest expense	(23,537)	(23,397)	(69,807)	(69,462)
Loss before income tax	(552,843)	(541,335)	(2,303,657)	(1,815,853)
Provision for income tax	-	-	2,000	750
Net loss	\$ (552,843)	\$ (541,335)	\$ (2,305,657)	\$ (1,816,603)

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, 2018	22,000	2,200	\$ 6,931,861	\$ (14,353,851)	\$ (7,419,790)
Net loss			-	(2,305,657)	(2,305,657)
Balance, September 30, 2018	22,000	2,200	\$ 6,931,861	\$ (16,659,508)	\$ (9,725,447)

See Notes to Condensed Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
	(unaudited)	(unaudited)
Cash flows from operating activities:		
Net loss	\$ (2,305,657)	\$ (1,816,603)
Adjustments to reconcile net cash provided by (used in) operating activities:		
Depreciation and amortization expense	246,885	21,436
Contributed capital - Milestone Scientific, Inc. shared services expense	-	52,727
Increase inventories allowance	234,350	-
Changes in operating assets and liabilities:		
Decrease in inventories	12,148	4,049
Increase to prepaid expenses and other current assets	(8,800)	(24,154)
Increase (Decrease) in accounts payable and accrued expenses	266,169	(33,354)
Net cash provided by (used in) operating activities	(1,554,905)	(1,795,899)
Cash flows from investing activities:		
Purchases of property and equipment	(5,141)	-
Net cash (used in) investing activities	(5,141)	-
Cash flows from financing activities:		
Increase in advance from related parties	1,543,824	1,817,793
Net cash provided by investing activities	1,543,824	1,817,793
Net increase (decrease) in cash and cash equivalents	(16,222)	21,894
Cash and cash equivalents at beginning of period	19,272	13,187
Cash and cash equivalents at end of period	\$ 3,050	\$ 35,081

See Notes to Condensed Consolidated Financial Statements



**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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**NOTE 1 - ORGANIZATION:**

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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. As of September 30, 2018, 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.

The Company received notification from the FDA in December 2016 that based upon the 510(k)-application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, the Company 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. The Company resubmitted an application for a 510(k) (in June 2018), for the Compu-Flo Intra Articular instrument and include focused attention on the area that the FDA indicated shortfalls in the original application.

The Company is in the process of introductory meetings with medical device distributors within the United States (for the Epidural instrument) and European markets. The Company’s overall focus will be on marketing both instruments throughout the world. The immediate marketing focus by the Company in the United States and internationally is on the Epidural instrument.

On June 17, 2016, Milestone Scientific initiated a share exchange program pursuant to which would exchange one share of Milestone Scientific Inc. common stock for every two outstanding shares of Milestone Medical common stock. As of September 30, 2018, 5,344,539 shares of Milestone Scientific common stock have been issued in exchange for 10,689,078 shares of Milestone Medical common stock. Because of these exchanges, Milestone Scientific owned approximately 99% of Milestone Medical at September 30, 2018. 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.

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

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Milestone Medical Inc. has incurred significant operating losses since its inception as a development company. At September 30, 2018, Milestone Medical Inc. had cash of \$3,050 and a negative working capital of approximately \$10,868,329 as compared to negative working capital of approximately \$8,804,416 at December 31, 2017.

As of September 30, 2018, Milestone Medical Inc. believes that it 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 regarding 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, throughout the world and obtain regulatory approval of Intra-Articular instrument.

Although the Company's instruments have progressed beyond the development stage, additional equity financing is necessary to fund the commercialization of the medical instruments. To this end, the Company and Milestone Scientific, Inc. are currently 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.

These condensed consolidated financial statements have been prepared with the assumption that the Company will continue as a going concern and will be able to realize its assets and discharge its liabilities in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the inability of the Company to continue as a going concern.

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

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**1. Basis of Presentation**

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted ("GAAP") in the United States of America. Accordingly, they do not include all the information and footnotes required by GAAP for complete annual financial statements. In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present such interim results. Interim results are not necessarily indicative of the results of operations which may be expected for a full year or any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2017, included in Milestone Medical's Annual Report.

**2. 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.

**3. Cash**

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

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

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**4. Inventory**

Inventories principally consist of pre-launch instrument finished goods 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 potential technological obsolescence and product expiration requests and obsolete inventory is recorded, if required, based on past and expected future sales both domestically and internationally.

**5. Use of Estimates**

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

**6. 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.

**7. 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, handpieces, and other related products. The Company sells 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.

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

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**Sales Returns**

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

**Financing and Payment**

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

**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 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 consolidated statements of operations.

**8. 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, 2018 and 2017 was \$2,530 and \$5,515 and \$21,885 and \$21,436, respectively. The costs of maintenance and repairs are charged to operations as incurred.

**9. Intangible Asset**

The Company began amortizing the intangible asset contributed when the first medical device supported by the intangible obtained final FDA approval, which occurred in June 2017 when the Epidural instrument received 510k clearance from the FDA. The asset's estimated useful life is 5 years based on the estimated useful life of the underlying patented technology. Intangibles are amortized utilizing the straight-line method over estimated useful life of 5 years. Amortization expense for the three and nine months ended September 30, 2018 was \$75,000 and \$225,000, respectively. Amortization expense for the three and nine months ended September 30, 2017 was \$0.

The Company assesses the intangible asset valuation when there is an indicator of impairment. During the period the Company assessed the intangible for impairment because the marketing efforts relating to the Medical instruments has not been fully realized and the cash flow expected following FDA approval has been delayed as a result. The Company's impairment assessment is based on several factors including the progress made in developing the two medical instruments, the results from the research performed by the vendor, the Company's ability to use its technical capabilities to forecast the outcome of the research being performed, recent feedback received from professionals and projected cash flows from the use of the royalty free right to use CompuFlo technology. Based on these current projections, no impairment has been recorded as of September 30, 2018 and December 31, 2017.

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

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**10. 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.

**11. Income Taxes**

The Company 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.

As of September 30, 2018, and 2017, 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 since inception are subject to audit by federal and state jurisdictions

**12. Recent Accounting Pronouncements**

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

In February 2018, the FASB issued ASU No. 2018-02, "Income Statement – Reporting Comprehensive Income (Topic 220)", which amends the previous guidance to allow for certain tax effects "stranded" in accumulated other comprehensive income, which are impacted by the Tax Cuts and Jobs Act (the "Act"), to be reclassified from accumulated other comprehensive income into retained earnings. This amendment pertains only to those items impacted by the new tax law and will not apply to any future tax effects stranded in accumulated other comprehensive income. This standard is effective for fiscal years beginning after December 15, 2018 and allows for early adoption. The Company does not anticipate that the adoption of this standard will have a material impact on the Company's consolidated balance sheet.

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**NOTE 4 - INVENTORY:**

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Inventory at September 30, 2018 and December 31, 2017 consisted of the following:

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
Inventories consist of the following:		
Epidural instruments	\$ 209,329	\$ 240,918
Intra-Articular instruments net allowance	-	234,367
Component parts and other materials	44,486	25,028
Total	<u>\$ 253,815</u>	<u>\$ 500,313</u>

The reserve against inventory was \$454,183 at September 30, 2018 and \$219,834 at December 31, 2017.

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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 several 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 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.) 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, 2018, and December 31, 2017, Milestone Scientific, Inc. has advanced \$2,800,000 to Milestone Medical classified as Due to Milestone Scientific Inc. on the accompany Condensed Consolidated Balance Sheets. All other terms in the line of credit agreement remain unchanged. Milestone Scientific Inc. is not legally obligated to provide any other funding to Milestone Medical Inc.

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 Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs will receive payments of 5% of the total sales of products using certain other of the technologies until the expiration of the last patent carried by Milestone Scientific Inc.

The shared expenses relate to the management, financial, engineering and accounting services provided by the staff of Milestone Scientific Inc. These expenses relate to the costs incurred related to obtaining CE and FDA approval and represent additional contributions from Milestone Scientific. The shared expenses for the three and nine months ended September 30, 2018 and 2017 were approximately \$0 and \$17,375, and \$0 and \$ 52,727 respectively.

As of September 30, 2018, and December 31, 2017, the Company owes \$7,666,891 and \$6,123,067, respectively, to Milestone Scientific, Inc. for expenses paid on the Company's behalf. These advances are non-interest bearing.

On July 10, 2017, Mr. 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, "Consulting Agreement" an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten-year term.

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**NOTE 6 RELATED PARTY TRANSACTIONS:**

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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 suspended his consulting agreement (US Asian Consulting Group, LLC) with Milestone Medical to rejoin Milestone Scientific Inc and Milestone Medical as Interim Chief Executive Officer. Mr. Osser will not receive or earn any compensation under his consulting agreement during his appointed time as Interim CEO and the terms of the Consulting Agreement will continue once he is no longer Interim Chief Executive Officer.

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**NOTE 7 - CONCENTRATIONS**

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The Company has informal arrangements for the manufacture of its products. The Epidural and Intra-Articular instruments are manufactured by Tricor Systems, Inc. pursuant to specific purchase orders. There are no open purchase orders for the manufacture of instruments as of September 30, 2018. The Epidural and Intra-Articular handpiece with needle components are supplied to Milestone Medical by several independent contractors in the United States, which arrange for its manufacture in China.

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

There was no revenue for the three months ended September 30, 2018. For the nine months ended September 30, 2018, an aggregate of approximately 92% of Milestone Medical's net product sales were to two distributors. For the three and nine months ended September 30, 2017, Milestone Medical had no sales.

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**NOTE 8 - COMMITMENTS AND CONTINGENCIES:**

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On July 10, 2017, Mr. 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 18, 2017, Milestone Medical announced the appointment of Leonard Osser as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer.

Mr. Osser will enter into a similar employment contract that he received in 2017 before he resigned his position as CEO of the company. Mr. Osser placed on hold on his consulting agreement (US Asian Consulting Group, LLC) with Milestone Medical to rejoin Milestone Scientific Inc and Milestone Medical as Interim Chief Executive Officer. Mr. Osser will not receive or earn any compensation under his consulting agreement during his appointed time as Interim CEO and the terms of the agreement will continue once he is no longer Interim Chief Executive Officer.

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**NOTE 9 – SUBSEQUENT EVENTS:**

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After September 30, 2018 Milestone Scientific Inc., advanced Milestone Medical approximately \$728,000 to continue the commercialization of 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 additional funds to the Issuer. As such, the Issuer reduced its cash expenditure in 2018 and will continue to monitor expenses until additional capital has been raised or revenues increase to cover these costs.

In October 2018, Milestone Medical signed a Distributor Agreement in the USA. This agreement provides that this Distributor will purchase and hold an inventory of the CompuFlo® Epidural instrument and disposables for sale. At this time there have been no minimum purchase established with the Distributor. The Distributor identified above purchased five (5) CompuFlo® Epidural instruments and disposables after executing the Agreement.



**1. 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 2018 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 second quarter of 2018, the company adopted the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, “Revenue from Contracts with Customers (Topic 606)” (ASC 606.) adoption of this new standards did not have an impact on our financial statements.

**2. 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.**

In June 2018, the Issuer and its Parent filed a 510k of the Intra-Articular instrument USA (FDA). The 510k application is currently in review process at the USA (FDA).

The Company currently employs three (3) full time employee. In February and March 2018, Milestone Scientific Inc. added two key employees for Milestone Medical Inc. We added an Executive VP of Global Marketing and Sales and a Vice President of USA Sales. These two employees will promote direct market support for Milestone Medical and assist on moving the medical business forward on an accelerated track. Additionally, the Issuer is continuing its efforts to identify and meet with potential distributors for both instruments throughout the world. The Issuer’s Executive VP of Global Marketing and Sales, Senior Vice President of Marketing and Sales, and a contracted Business Development Representatives for Europe and the Middle East are actively pursuing distribution partners. In July 2018, Milestone Scientific added a Director of Marketing, a fulltime position to assist in the domestic and international marketing plan to the potential customer base. The Company added an additional Medical device consultant in March 2017, for the specific focus on our Intra Articular instrument in the European Market. In July 2017, the issuer added a new medical business consultant for the Epidural instrument. This consultant terminated his position at June 30, 2018, the position will be cover by the existing Business Consultant in Europe. In late 2017, the Issuer terminated a Distributor Agent with Moss. S.P.A. for lack of performance. At the same time the Issuer engaged a new Italian Distributor, who has purchased first instruments and is introducing the Epidural Instrument to its customer base.

The Company is in the process of identifying distributors in the USA for the Epidural instruments, now that USA (FDA) clearance has been received.

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 identified above purchased five (5) instruments and disposables after signing the agreement.

For the three months ended, September 30, 2018 the Issuer and its Subsidiary have generated a net loss of \$552,843. This loss was due to a high level of general and administrative expenses, which amounted to \$451,776. These expenses were incurred due to administrative and product trials with various clinical sites, the marketing and commercialization of the instruments in Europe, as well as increased expenses for travel and the addition of a Business Development Consultants for Europe and the Middle East. The Issuer suspended its effort to raise capital in December 2015. The capital market in Poland was not conducive due to financial market turmoil in the fourth quarter of 2015. As such, the Issuer has little cash available to continue its operations. As such, the Issuer reduced its cash expenditure in 2017, and into 2018, until additional capital has been raised or revenues increase to cover these costs.

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

The Issuer began the process to market and sell its epidural instruments in the European market upon receiving CE clearance in September 2014.

Because of several years of diligent effort, on June 23, 2017 Milestone Scientific was notified by FDA (USA) that the Epidural instrument received marketing clearance in the USA.

The Company received notification from the FDA in December 2016 that based upon the 510(k)-application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, the Company 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 Company received additional questions from the FDA and provided responses to these questions on a timely basis.

The Company resubmitted an application for a 510(k), for the Compu-Flo Intra Articular instrument and include focused attention on the area's that the FDA indicated shortfalls in the original application in June 2018. The FDA has raised new questions on the submission. Milestone Scientific is reviewing these questions and formulating responses, to their inquiry.

In April 2017, the company reported on ESPI 5/2017 that Milestone Medical was granted market clearance for its Epidural, Intra-Articular instruments and disposables in Australia. On 2018, clearance to sell the Epidural Instrument in Canada. The Company is now in the process of selecting a distributor to market these instruments in Australia.

### **4. 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. During this quarter, the Company hired a Director of Marketing. This new hire will assist in the domestic and international marketing plan to the potential customer base.

### **5. 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:	Plac 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 consolidated financial statements with this subsidiary according to laws and regulations applicable to the Issuer.

Leonard Osser  
Interim Chief Executive Officer