



# **Consolidated Quarterly report of**

## **MILESTONE MEDICAL INC. and SUBSIDIARY**

### **3<sup>rd</sup> quarter (from July 1, 2016 to September 30, 2016)**

***Report include:***

1. General information about Milestone Medical Inc.
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, in particular 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, 2016

## 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 22,100,000 shares outstanding on the date of this quarterly report. 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>	20,000,000	90.91%
<b>OTHERS (&lt;5%)</b>	2,000,000	9.09%
<b>TOTAL</b>	<b>22,000,000</b>	<b>100%</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 on share of common stock for every two outstanding shares of Milestone Medical common stock.. Through the report date, Milestone Scientific Inc. acquired additional 9,005,000 (40.93%) shares of the Issuer's outstanding share from various shareholders. Because of these transactions, Milestone Scientific Inc. owns 90.91% of the outstanding shares of the Issuer.

### 1.2. Board of Directors

**Table 3 Board of Directors**

NAME OF DIRECTOR	CURRENT AGE	DIRECTOR SINCE	END OF TERM
<b>Leonard A. Osser</b>	69	Mar-11	Next Annual Meeting of Shareholders
<b>Zhu Yun</b>	51	Sep-13	Next Annual Meeting of Shareholders
<b>Martin S. Siegel</b>	72	Sep-14	Next Annual Meeting of Shareholders

\* on May 25,2016 the Annual General Meeting of Shareholders adopted the resolution on the appointment of three 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, 2016 the Issuer, employed one full time employee and three (3) persons converted into full-time equivalents (“FTEs”). There are open positions for an additional two (2) full time employees: a Business Development Manager and a Nurse Anesthesiologist. These positions are scheduled to be hired sometime in 2016 or early 2017.

**1.4. A position on the probability of achievement of published forecasts of financial results**

The Issuer has not published forecasts of financial results.

**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**

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**Milestone Medical Inc. and Subsidiary**

**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**For the three and nine months ended September 30, 2016 and 2015 (unaudited) and  
As September 30, 2016 (unaudited) and December 31, 2015 (audited)**

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MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED BALANCE SHEETS

<u>ASSETS</u>	<u>September 30, 2016</u> (Unaudited)	<u>December 31, 2015</u> (Audited)
Current Assets:		
Cash	\$ 7,719	\$ 1,222
Accounts receivable	14,303	45,075
Prepaid expenses and other current assets	22,648	42,637
Inventory	827,262	885,961
Advances to contractors	44,148	43,524
Total current assets	<u>916,080</u>	<u>1,018,419</u>
Equipment, net of accumulated depreciation of \$169,669 as of September 30, 2016 and \$122,320 as of December 31, 2015	76,946	119,006
Intangible asset	1,500,000	1,500,000
Total assets	<u>\$ 2,493,026</u>	<u>\$ 2,637,425</u>
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Current Liabilities:		
Accounts payable and accrued expense	\$ 782,967	\$ 815,651
Advance on line of credit from Milestone Scientific Inc.	2,800,000	2,500,000
Due to Milestone Scientific	3,131,203	998,453
Total current liabilities	<u>6,714,170</u>	<u>4,314,104</u>
Commitments and Contingencies		
Stockholders' Deficit		
Preferred stock, par value \$.0001; authorized 5,000,000 shares; 0 shares issued	-	-
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at September 30, 2016 and December 31, 2015	2,200	2,200
Additional paid-in capital	6,851,102	6,693,000
Accumulated deficit	<u>(11,074,446)</u>	<u>(8,371,879)</u>
Total stockholders' deficit	<u>(4,221,144)</u>	<u>(1,676,679)</u>
Total liabilities and stockholders' deficit	<u>\$ 2,493,026</u>	<u>\$ 2,637,425</u>

See Notes to Unaudited Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	September 30, 2016 (Unaudited)	September 30, 2015 (Unaudited)	September 30, 2016 (Unaudited)	September 30, 2015 (Unaudited)
Revenue	\$ 9,253	\$ 29,000	\$ 9,728	\$ 40,550
Cost of products sold	5,313	11,144	4,222	14,819
Gross Profit	3,940	17,856	5,506	25,731
Research and development expenses	211,811	217,138	335,616	572,954
Expenses:				
Shared services	34,063	90,159	158,102	140,067
Depreciation	15,807	15,664	47,349	41,467
General and administrative expenses	594,336	859,395	2,097,584	2,385,224
Total expenses	856,017	1,182,356	2,638,651	3,139,712
Net (Loss) from operations	(852,077)	(1,164,500)	(2,633,145)	(3,113,981)
Interest expense	23,372	17,196	69,422	20,693
Net (loss)	\$ (875,449)	\$ (1,181,696)	\$ (2,702,567)	\$ (3,134,674)

See Notes to Unaudited Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares (in thousands)	Amount			
Balance, January 1, 2015	22,000	\$ 2,200	\$ 6,543,138	\$ (4,331,841)	\$ 2,213,497
Contributed Capital-Milestone Scientific, Inc. Shared Service Expense	-	-	149,862	-	149,862
Net (Loss)	-	-	-	(4,040,038)	(4,040,038)
Balance, January 1, 2016	22,000	\$ 2,200	6,693,000	(8,371,879)	(1,676,679)
Contributed Capital-Milestone Scientific, Inc. Shared Service Expense	-	-	158,102	-	158,102
Net (Loss)	-	-	-	(2,702,567)	(2,702,567)
Balance, September 30, 2016	22,000	\$ 2,200	\$ 6,851,102	\$ (11,074,446)	\$ (4,221,144)

See Notes to Unaudited Consolidated Financial Statements



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

	Nine Months Ended	Nine Months Ended
	September 30, 2016	September 30, 2015
	(Unaudited)	(Unaudited)
Cash flows from operating activities:		
Net (loss)	(2,702,567)	\$ (3,134,674)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	47,349	41,467
Contributed capital - Milestone Scientific, Inc. shared services expenses	158,102	140,067
Changes in operating assets and liabilities:		
Decrease (Increase) in accounts receivable	30,772	(40,550)
Decrease (Increase) in inventories	58,699	(824,625)
(Increase) Decrease in advances to contractors	(624)	326,795
Decrease (Increase) to prepaid expenses and other current assets	19,989	(81,905)
Increase in due to Milestone Scientific Inc.	2,132,750	494,265
Decrease (Increase) in accounts payable and accrued expenses	(32,684)	123,881
Net cash used in operating activities	(288,214)	(2,955,280)
Cash flows from investing activities:		
Purchase of equipment	(5,289)	(82,362)
Net cash used in investing activities	(5,289)	(82,362)
Cash flows from financing activities:		
Proceeds from Line of credit	300,000	2,000,000
Net cash from financing activities	300,000	2,000,000
NET INCREASE (DECREASE) IN CASH	6,497	(1,037,642)
Cash at beginning of period	1,222	1,080,035
Cash at end of period	\$ 7,719	\$ 42,393
Supplemental disclosure of non cash activities:		
Contributed Capital - Milestone Scientific, Inc. Shared Services Expenses	\$ 158,102	\$ 140,067

See Notes to Unaudited Consolidated Financial Statements



(UNAUDITED)

**Three and nine months ended September 30, 2016 and 2015**

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**NOTE 1 – ORGANIZATION AND BUSINESS UNCERTAINTIES:**

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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, a shareholder of Milestone Scientific, Inc. 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 S.p. z.o.o., is seventy – five percent owned by the Company. As of September 30, 2016, Milestone Medical Poland S.p. z.o.o. has not received any grants from the Polish Government.

As of September 30, 2016, the Company has not yet obtained U.S. Food and Drug Administration (“FDA”) regulatory clearance. However, as of September 2014, the company did receive European Union (CE) clearance to market the instruments in the European Market. The Company is now awaiting final regulatory marketing clearance in the U.S. by the FDA. In 2014, the Company began to prepare for commercialization with the commitment to purchase 500 instruments (250 epidural and 250 intra-articular instruments) from the instrument manufacturer. All 500 instruments ordered were received by September 30, 2015. In the interim of receiving final FDA approval, introductory meetings are being held with medical device distributors within the foreign market. The Company’s focus will be on marketing its two instruments throughout the world.

The company reported on ESPI report on 6/2016 published on June 17, 2016 that Milestone Scientific initiated a share exchanged program pursuant to which would exchange on share of common stock for every two outstanding shares of Milestone Medical common stock. As of September 30, 2016, 5,035,042 shares of common stock have been issued in exchange for 9,005,000 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owns approximately 91% of Milestone Medical at September 30, 2016. It is expected that the acquisition of remaining shares would be completed in the first quarter of 2017.

Milestone Medical Inc. has incurred significant operating losses since its inception as a development company. Milestone Medical Inc. had negative cash flows from operating activities for the nine months ended September 30, 2016 of approximately \$288,000 At September 30, 2016 Milestone Medical Inc. had cash of \$7,719 and a negative working capital of approximately \$5,796,000 as compared to negative working capital of \$3,296,000 at December 31, 2015. The working capital decreased by \$2,500,000 as compared to December 31, 2015.

Milestone Medical’s management continues to examine all areas of the business to manage its cash flow.

Milestone Medical Inc. is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue based upon management’s assessment of present contracts for delivery of epidural and intra-articular instruments to both customers in EU countries and for obtaining FDA clearance in the United States. Although the Company’s instruments have progressed beyond the development stage, additional equity financing will be necessary to fund the further commercialization of the medical instruments. To this end, the Company is currently in the process of pursuing an additional equity financing.

As of September 30, 2016, (same as mentioned in previous periodic reports) Milestone Medical Inc. believes that it does not have sufficient cash reserves or collections of accounts receivable to meet all of its anticipated obligations for the next twelve months. Milestone Medical Inc. will continue to manage its cash position while

taking strategic steps to finalize the clinical studies and to expand its business in the medical business sectors. Milestone Scientific Inc. will continue to finance the necessary cash requirements to complete the FDA clearance process. At December 31, 2015, a qualification was issued within the audit opinion as the Company carries a going concern uncertainty.

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## **NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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### **Basis of Presentation**

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

### **Basis of Consolidation**

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

### **Cash**

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

### **Accounts Receivable**

Milestone Medical Inc. records accounts receivable at estimated net realizable value, and closely monitors the extension of credit to its customers while maintaining allowances, if necessary, for potential credit losses. On a periodic basis, Milestone Medical Inc. evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit conditions. Management has provided a reserve that it believes is sufficient to record accounts receivable at net realizable value as of September 30, 2016, and December 31, 2015 respectively.

### **Inventory**

Inventories principally consist of finished goods stated at the lower of cost (first-in, first-out method) or market. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess and obsolete inventory is recorded if required based on past and expected future sales.

### **Use of Estimates**

In preparing financial statements in conformity with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and revenues and expenses during the reporting period. Actual results could differ from those estimates.

### **Advances to Contractors**

The advances to contractors represent funding to a subcontractor, for spares parts required for both epidural and intra articular instruments repairs. In February 2014, the Company issued a purchase order for the manufacture of the epidural and intra articular instruments for the production of five hundred (500) instruments. The company has received all manufactured instruments as of December 31, 2015.

### **Equipment**

Equipment (molds for pre-production and commercialized instruments) are recorded at cost, less accumulated depreciation. Depreciation expense are computed using the straight-line method over the estimated useful lives of the assets, which is five years. The costs of maintenance and repairs is charged to operations as incurred.

### **Revenue Recognition**

Revenue from product sales are recognized net of discounts and allowances to distributors on the date of shipment for essentially all shipments, since the shipment terms are FOB warehouse. In all cases, the price to the buyer is fixed and the collectability are reasonably assured. Further, Milestone Medical Inc. has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Medical Inc. only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit are returned within the warranty period.

### **Intangible Asset**

In connection with the formation and capitalization of the Company, the business was valued at inception using the discounted cash flow method, which resulted in a valuation of approximately \$3 million. The Company allocated the business valuation between the cash that investors agreed to contribute (\$1.5 million) and the remaining \$1.5 million was allocated to Milestone Scientific, Inc.'s contribution of a royalty-free right to use its patented CompuFlo technology (intangible asset). The Company will begin amortizing the intangible asset contributed when either of the two medical devices has been fully commercialized which includes obtaining final FDA approval. The asset estimated useful life is based on the average remaining life of the underlying patents. Currently the remaining useful life of the patents is approximately 9 years. The Company assesses the intangible asset for impairment at each reporting period or sooner if there are indicators that trigger an earlier assessment. The Company's impairment assessment are 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 and recently feedback received from professionals as the Company applies for FDA clearance. CE clearance was received in September 2014. All these factors indicate that the technology continues to be feasible to be used in the two instruments being developed. Accordingly, no impairment have been recorded in these financial statements for the periods being reported.

### **Research and Development**

Research and development costs are expensed as incurred. A portion of the Company's research and development efforts is sub-contracted to vendors and progress are monitored periodically.

### **Income Taxes**

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets, including tax loss and credit carryforwards, and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will be realized.

The Company follows the Income Taxes Topic of the FASB Accounting Standards Codification, which provides clarification on accounting for uncertainty in income taxes recognized in the Company's financial statements. The guidance prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return, and also provides guidance on derecognition, classification, interest and penalties, disclosure and transition.

At September 30, 2016, there are no significant income tax uncertainties have been included in the Company's Milestone Medical, Inc. and Subsidiary

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.

### **Services Provided by Stockholder**

The Company provides management, financial, engineering and accounting services by the staff of Milestone Scientific, Inc. The Company formalized this agreement in writing during the third quarter of 2014. The value related to these services will be charged to the Company on a periodic basis. These charges are included in the financial statements as shared service expense. Additional Paid in Capital have been credited for the rendered services

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### **NOTE 3 - 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. patented its CompuFlo technology,
- The patents were generic for use in the medical and dental markets when granted.
- The capabilities to use this technology existed from CompuFlo technology and as technology evolved, the Company has improved the technology over a number of years.
- The Director of Clinical Affairs of the Company has had significant involvement in developing these patents initially and his conclusions are that technology is feasible for use in medical devices.

Milestone Scientific, Inc. 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 Beijing 3H was to distribute products exclusively in the PRC, Macao, Hong Kong and other regions of Asia. In September 2014, the Company terminated its distribution agreement with Beijing 3H upon the resignation of Mr. Feng Yulin as a director of the Company. The Company entered a new distribution agreement with Milestone China Ltd, (a Hong Kong Company owned forty (40) percent by Milestone Scientific, Inc. a significant shareholder of the Company). The distribution agreement is similar to that of Beijing 3H and it includes both the epidural and the intra-articular instruments. The Company will have distribution responsibilities for the rest of the world.

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### **NOTE 4- 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 (an increase of \$500,000). In January 2016, the credit agreement increased to \$3 million As of September 30, 2016, Milestone Scientific, Inc. has advanced \$2,800,000 to Milestone Medical. All other terms in the line of credit agreement remain unchanged. Milestone Scientific Inc. is not legally obligated to provide any funding to Milestone Medical 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 at September 30, 2016, were approximately \$34,000 and \$158,000 respectively. The shared expenses for the three and nine months ended September 30, 2015 were \$90,159 and \$140,067 respectively.

As of September 30, 2016, the Company owes \$3,131,203 to Milestone Scientific, Inc. for expenses paid on the Company's behalf in 2016 and 2015. The expenses relate to financial and accounting services performed by Milestone Scientific Inc.'s employees at the cost to Milestone Scientific Inc.

The company reported on ESPI report 6/2016 published on June 17, 2016 that Milestone Scientific initiated a share exchange program pursuant to which would exchange on share of common stock for every two outstanding shares of Milestone Medical common stock. Milestone Scientific Inc. increased its ownership in the Issuer to 90.91% of the outstanding shares. Milestone Scientific Inc. acquired the additional 5% of the outstanding shares of Milestone Medical Inc. Milestone Scientific Inc also has entered in agreements to exchange an additional 1,633,084 shares of Milestone Medical common shares in 2017.

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**NOTE 5 - CONCENTRATIONS:**

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The Company sub-contracts its research and development to a vendor, which accounted for 24%, and 13% of total expenses incurred for the three and nine months ended September 30, 2016, respectively. The Company sub-contracts its research and development to a vendor, which accounted for 18%, and 18% of total expenses incurred for the three and nine months ended September 30, 2015, respectively. The Company has informal arrangements for the manufacture of its product, epidural and Tricor Systems, Inc. manufactures intra-articular instruments for Milestone Medical pursuant to specific purchase orders. The intra-articular handpiece with needle are supplied to Milestone Medical by a contractor in the United States, which arranges 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, whether, or not as a result of termination of such a relationship, would adversely affect Milestone Medical.

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**NOTE 6 - SUBSEQUENT EVENTS:**

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The company has evaluated subsequent events and has determined that there are no events to be disclosed.



**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 2016 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” (text according to legal condition at 8 August 2016). Information on applied accounting rules (policies) are presented in Note 2 to the Financial Statement. During the third quarter of 2016, there was no change to the applied accounting rules.

**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, in particular atypical ones, which affect the achieved results.**

During the third quarter, ending September 30, 2016, the Issuer and its Subsidiary continued the process of obtaining regulatory approval for the two medical instruments (Epidural and Intra-Articular Injections Systems) in the United States of America. The regulatory approval process for the USA (FDA) is moving forward at a pace that is slower than we expected. As of September 30, 2016, the Issuer completed the process of a clinical study at the remaining premier sites in the U.S. Successful completion of the studies was a necessary step in obtaining FDA clearance to market the instrument in the USA. The Issuer received CE clearance for both instruments in September 2014. The company has enrolled over 400 patients in the clinical study in the USA. As of September 30, 2016, 220 patients have completed the enrollment in the pain management study and over 200 patients have completed the labor and delivery enrollment process to date.

The Company currently employs one full time employee, the Senior Vice President of Marketing and Sales, who also holds the same position in Milestone Scientific Inc; however, he provides essentially all of his time to the Issuer. The Issuer has two positions currently open, Director of Sales/Business Development and Anesthesiologist Registered Nurse as of September 30, 2016. Additionally, the Issuer is continuing its efforts to identify and meet with potential distributors for both instruments throughout the world. The Issuer’s Senior Vice President of Marketing and Sales, and a contracted Business Development Representative for Europe and the Middle East are actively pursuing distribution partners. Because of the above activities performed by the Issuer, the Company during the second quarter 2015 signed a Memorandum of Understanding with Fidia Farmaceutici SpA (“Fidia”), a specialty pharmaceutical company based in Italy, for the co-development and manufacture of a custom intra-articular drug delivery instrument for Fidia’s hyaluronic acid formulations. Additionally, during the second quarter of 2015 the Company reported on EBI report no. 25/2015 published on June 10, 2015 that a medical distributor in Italy, Moss S.P.A. agreed to a three-year agreement that included minimum purchases of the epidural instrument and disposals for the Italian market.

In the second quarter of 2015, the Issuer also commenced the first shipments of its CompuFlo™ Epidural Instrument to distributors and key opinion leaders in Europe. Since receiving CE Mark marketing clearance for the Company’s epidural instrument, the Issuer has been in negotiations with distributors in a number of countries in Europe and, as previously announced, signed an exclusive agreement with TRIMED Sp.z.o.o. (“Trimed”), one of the largest distributors of diagnostic equipment in Poland (EBI report no. 12/2015, published on March 23, 2015). Trimed has purchased a small number of instruments, initially for internal use and training purposes as it ramps up for a formal launch later this year.

For the quarter ended, September 30, 2016, the Issuer and its Subsidiary have generated a net loss of \$875,449. This loss was due to research and development costs of \$211,811 and to a high level of general and administrative expenses, which amounted to \$594,336. These expenses were incurred due to FDA clearance process in the United States the market and commercialization of the instruments in Europe as well as increasing the headcount of the Company. 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. In January 2016, the Issuer borrowed an additional \$300,000 from Milestone Scientific Inc. However Milestone Scientific Inc. is not legally obligated to loan Milestone Medical, Inc. and Subsidiary

additional funds to the Issuer. As such, the Issuer reduced its cash expenditure in 2016, until additional capital have been raised or revenues increase to cover these costs.

The company reported on EBI report no 13/2016 May 16, 2016 that the Issuer concluded an agreement with Navigator Capital S.A. with its registered office in Warsaw on rendering services of an Authorized Adviser to the Company. The subject of the agreement includes cooperation with the Company in fulfilling its disclosure obligations set out in the Alternative Trading System Rules and advising the Issuer in the scope of Company's presence in Alternative Trading System on the NewConnect Market. The agreement becomes effective on the day of signing.

The company reported on EBI report no 16/2016 resolutions adopted by the Annual General Meeting of Shareholders on May 25, 2016 (among others the resolution about appointment of an entity authorized to audit financial statements for the year 2016 - Baker Tilly Virchov, LLP).

The company reported on ESPI report on 6/2016 published on June 17, 2016 that Milestone Scientific initiated a share exchanged program pursuant to which would exchange on share of common stock for every two outstanding shares of Milestone Medical common stock. As of September 30, 2016, Milestone Scientific through the exchange program acquired a total 9,005,000 additional shares of Milestone Medical. Milestone Scientific Inc. has also entered agreements to exchange an additional 1,633,084 shares of Milestone Medical Inc. common shares later in 2016 and 2017.

The Warsaw Stock Exchange announced, that based on the Management Board resolution no. 452/2007 of July 3, 2007, as amended, following the trading session on June 21, 2016, there will be an extraordinary adjustment and shares of the Issuer (ISIN USU6005B1045) will be excluded from the portfolio of NCIndex. The Issuer no longer meets criteria of the above-mentioned index, because their free float is lower than 10%.

## **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 Issuer began the marketing and selling of its epidural instruments in the European market upon receiving CE clearance in September 2014. Two medical distribution agreements for the epidural instrument and disposables have been signed in 2015. The USA marketing clearance process is continuing to move forward at a slower rate than previously anticipated but the direction is still positive. The clinical study supporting the FDA submission have been completed. The results thus far have been very successful in locating the epidural space.

As announced in the previous year, the Issuer cancelled plans to uplist from NewConnect Market (Alternative Trading System) to the Main Market of the Warsaw Stock Exchange, in the fourth quarter of 2015.

In the beginning of March 2015, the Issuer announced the start of its pivotal clinical trial for its epidural instrument at a major pain management center in the United States. The Company has also met FDA 801 requirements for submission of the clinical trial information to the Director of the National Institutes of Health (NIH) for inclusion in the registry and results database established via ClinicalTrials.gov for its CompuFlo Epidural Computer Controlled System for assessing the safety and effectiveness of the instrument for identifying the epidural space. The Company also disclosed that six prominent university and pain management sites in the United States had received Ethical Committee (Institutional Review Board) approvals, which enable the initiation of site enrollment.

The Company completed the clinical trial study in the second half of 2016, the Company completed the accompanying statistical analysis in July 2016, and the Issuer has filed the 510K application to the FDA for final market clearance.

## **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. During this quarter, there were no new initiatives.

**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:	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 A. Osser  
Chief Executive Officer