



## **Quarterly report of MILESTONE MEDICAL INC. and SUBSIDIARY**

(from October 1, 2015 to December 31, 2015)

### **Report include:**

1. General information about Milestone Medical Inc (the “Issuer”) and Subsidiary.
2. 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 impact 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, February 16, 2016

## 1. General information

**Table 1 General Information about the Issuer**

<b>THE ISSUER</b>	<b>MILESTONE MEDICAL INC.</b> (earlier: Milestone Scientific Research and Development, Inc.)
<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 quarterly 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**

Name of Shareholder	Number of owned shares/votes	Shareholding/votes at General Meeting of Shareholders [%]
<b>MILESTONE SCIENTIFIC, INC.</b>	10,995,000	49.98%
<b>WANG TAO</b>	2,600,000	11.82%
<b>ZHANG LIDONG</b>	2,000,000	9.09%
<b>ZHU YUN</b>	1,600,000	7.27%
<b>TOM CHENG*</b>	1,325,000	6.02%
<b>OTHERS (&lt;5%)</b>	3,480,000	15.82%
<b>TOTAL</b>	<b>22,000,000</b>	<b>100%</b>

Source: The Issuer

\*Holding directly 320,000 shares and indirectly 1,005,000 shares by his subsidiary United Systems Inc at December 31, 2015. In January 2016, Tom Cheng sold 250,000 shares to the CEO of Milestone Medical Inc.

### 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-13	Next Annual Meeting of Shareholders

Source: The Issuer

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

On December 31, 2015 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.

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**

### **CONSOLIDATED FINANCIAL STATEMENTS**

Years ended December 31, 2015 and 2014

And from March 8, 2011 (Inception) to December 31, 2014 (audited)

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MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS

<u>ASSETS</u>	December 31, 2015 (Unaudited)	December 31, 2014 (Audited)
Current Assets:		
Cash	\$ 1,222	\$ 1,080,035
Accounts receivable	45,075	-
Prepaid expenses and other current assets	179,154	86,906
Inventory	850,869	45,244
Advances to contractors	43,524	370,230
Total current assets	1,119,844	1,582,415
Equipment, net of accumulated depreciation of \$89,585 as of December 31, 2015 and \$32,492 as of December 31, 2014	119,006	93,737
Intangible asset	1,500,000	1,500,000
Total assets	\$ 2,738,850	\$ 3,176,152
<u>LIABILITIES AND STOCKHOLDERS' (DEFICIENCY) EQUITY</u>		
Current Liabilities:		
Accounts payable and accrued expense	\$ 752,499	\$ 962,656
Advance on line of credit from Milestone Scientific Inc.	2,500,000	-
Due to related party	998,453	-
Total current liabilities	4,250,952	962,656
Commitments and Contingencies		
Stockholders' (Deficiency) Equity		
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 December 31, 2015 and December 31, 2014	2,200	2,200
Additional paid-in capital	6,661,444	6,543,137
Accumulated deficit	(8,175,746)	(4,331,841)
Total stockholders' (deficiency) equity	(1,512,102)	2,213,496
Total liabilities and stockholders' (deficiency) equity	\$ 2,738,850	\$ 3,176,152

See Notes to Consolidated Financial Statements

MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF OPERATIONS

	<u>Three Months Ended</u> December 31, 2015 (Unaudited)	<u>Three Months Ended</u> December 31, 2014 (Unaudited)	<u>Year Ended</u> December 31, 2015 (Unaudited)	<u>Year Ended</u> December 31, 2014 (Audited)	<u>March 8, 2011</u> <u>(Inception) to</u> December 31, 2015 (Unaudited)
Revenue	\$ 10,425	\$ -	\$ 50,975	\$ -	\$ 50,975
Cost of products sold	(1,735)	-	13,084	-	13,084
Gross Profit	12,160	-	37,891	-	37,891
Research and development expenses	220,547	210,321	793,500	401,308	2,668,992
Expenses:					
Shared services	(21,760)	121,426	118,307	394,720	1,128,855
Depreciation	15,626	4,084	57,094	16,621	89,586
General and administrative expenses	487,339	360,729	2,872,565	1,083,848	4,285,587
Total expenses	701,752	696,560	3,841,466	1,896,497	8,173,020
Net loss from operations	(689,593)	(696,560)	(3,803,575)	(1,896,497)	(8,135,129)
Interest expense	19,637	215	40,330	287	40,618
Net loss	\$ (709,230)	\$ (696,775)	\$ (3,843,905)	\$ (1,896,784)	\$ (8,175,746)

See Notes to Consolidated Financial Statements

MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' (DEFICIENCY) EQUITY  
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares (in thousands)	Amount			
Balance, December 31, 2013	22,000	2,200	6,126,835	(2,435,057)	3,693,978
Contributed Capital-Milestone Scientific Inc Shared Service Expense	-	-	394,720	-	394,720
Contributed Capital-Fixed Assets, net	-	-	21,584	-	21,584
Net Loss	-	-	-	(1,896,784)	(1,896,784)
Balance, December 31, 2014	22,000	\$ 2,200	\$ 6,543,138	\$ (4,331,841)	\$ 2,213,497
Contributed Capital-Milestone Scientific, Inc. Shared Service Expense	-	-	118,306	-	118,306
Net Loss	-	-	-	(3,843,905)	(3,843,905)
Balance, December 31, 2015	22,000	\$ 2,200	\$ 6,661,444	\$ (8,175,746)	\$ (1,512,102)

See Notes to Consolidated Financial Statements

MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31, 2015	Year Ended December 31, 2014
	(Unaudited)	(Audited)
Cash flows from operating activities:		
Net loss	\$ (3,843,905)	\$ (1,896,784)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	57,094	16,621
Contributed capital - Milestone Scientific, Inc. shared services expense	118,306	394,720
Changes in operating assets and liabilities:		
Increase in accounts receivable	(45,075)	-
Increase in inventories	(805,625)	(45,244)
Decrease in advances to contractors	326,706	1,844
Increase to prepaid expenses and other current assets	(92,248)	(82,080)
(Decrease) Increase in accounts payable and accrued expenses	(210,156)	336,692
Increase due to related party	998,453	500,000
Net cash from operating activities	(3,496,450)	(774,231)
Cash flows from investing activities:		
Purchase of equipment	(82,363)	(27,644)
Net cash from investing activities	(82,363)	(27,644)
Cash flows from financing activities:		
Proceeds from Line of credit	2,500,000	-
Net cash from financing activities	2,500,000	-
 NET (DECREASE) INCREASE IN CASH	 (1,078,813)	 (801,875)
Cash at beginning of period	1,080,035	1,881,910
Cash at end of period	\$ 1,222	\$ 1,080,035
Supplemental disclosure of non cash activities:		
Contributed Capital - Milestone Scientific, Inc. Shared Services Expense	\$ 118,306	\$ 394,720
Contributed Capital-Fixed Assets, net	\$ -	\$ 21,584
See Notes to Consolidated Financial Statements		



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(UNAUDITED)**  
**For the years ended December 31, 2015 and 2014**

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**NOTE 1 - ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION:**

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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 and a group of individual investors including the controlling shareholders of Beijing 3H and a shareholder of Milestone Scientific, Inc. contributed \$1.5 million to the Company.

The Company is incorporated in the State of Delaware. As of December 31, 2015, 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 commercially market the instruments with the commitment to purchase 500 instruments (250 epidural and 250 intra-articular instruments) from the instrument manufacturer. All 500 instruments were delivered 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 first two instruments (epidural) were shipped to a Polish distributor in June 2015, an Italian distributor was shipped five epidural instruments in September 2015. Once the Company’s planned principal operations commence, its focus will be on marketing its two instruments throughout the world.

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 December 31, 2015, Milestone Medical Poland S.P. z.o.o. has not received any grants from the Polish Government.

The Company has incurred operating losses since its inception. The Company has used cash in operations since inception of approximately \$8.2 million. In October and November 2013, the Company raised \$2.4 million in net proceeds (gross funding was \$3 million) through a Private Placement Offering. The offering resulted in the issuance of 2 million shares of common stock at \$1.50 (4.65 PLN) per share in a private placement in Poland. Although the Company’s instruments have progressed beyond the development stage, additional equity financing will be necessary to fund final regulatory approval and commercialization of the medical instruments. To this end, the Company is currently in the process of pursuing an additional equity financing through a public offering in Poland.

In December 2015, the company obtained approval of a Prospectus filed with the regulatory authority in Poland to raise an additional \$4 million of capital and to uplist the Company to the Warsaw Stock Exchange from the New Connect Market (Alternative Trading System). The capital raise is currently on hold until financial conditions improve in Poland.

In December 2014, the Company obtained a \$2,000,000 line of credit from Milestone Scientific, Inc. to provide bridge financing to assist in the financing of the cost of a clinical study and the private placement transaction, and to meet short term working capital needs until permanent financing is secured. The line of credit agreement provides for the Company to obtain advances from Milestone Scientific, Inc. up to \$2 million through April 2016. Advances on the line bear interest at a rate of 3.25% per annum, and the line matures on April 2016. In September 2015, Milestone Scientific Inc. requested and received approval from their Board of Directors to increase the limit of the line of credit to a maximum of \$2.5 million (an increase of \$500,000.) As at December 31, 2015, \$2,500,000 was outstanding on the line. All other terms in the line of credit agreement remained unchanged, except for the following. The Company intends to convert a portion of the outstanding credit agreement to common shares in the private placement offering upon the successful completion of public offering of common shares. One million of the outstanding balance (\$2.5 million) will be repaid at a later date, not earlier than after obtaining the approval of the FDA clearance. The remaining balance (including interest) will be converted into common stock of the Company at a market rate at the time of the capital raise. In January 2016, the credit agreement was increased by \$300,000 to \$2.8 million. 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.

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**NOTE 1- ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION:**

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The unaudited interim consolidated financial statements of Milestone Medical Inc., have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements.

These unaudited interim consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2014 included in Milestone Medical Inc.'s Annual Report.

In the opinion of management, the accompanying unaudited financial statements contain all adjustments necessary to fairly present Milestone Medical Inc.'s financial position as of December 31, 2015 and the results of its operations for the three and three months then ended.

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 twelve months ending December 31, 2015 of \$3,496,000 and a negative cash flow of \$1,079,000 for the twelve months ended December 31, 2015. At December 31, 2015 Milestone Medical Inc had cash of \$1,222 and a negative working capital of \$3,131,000 as compared to positive working capital of \$620,000 at December 31, 2014. The working capital decreased by \$3,751,000 as compared to December 31, 2014. The change in working capital is primarily due to a decrease in cash, increase in accounts receivable and inventories, decrease in advances on contract and a significant increase in current liabilities. 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 both customers in EU countries and for obtaining FDA clearance in the United States.

As of December 31, 2015, 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.

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

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**Basis of Accounting**

The accompanying financial statements have been prepared on the accrual basis of accounting 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 deposits its cash in a National Bank on a daily basis.

**Inventory**

Inventory costing, obsolescence and physical control are significant to the on-going operation of the business. 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 a total of five hundred (500) instruments. The total commitment

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

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under this purchase order is \$888,750. A total of \$350,000 was previously advanced in 2013 for the long lead time parts. All the instruments were manufactured at September 30, 2015, and advances to contractor were reduced accordingly.

**Equipment**

Equipment (molds for pre-production and commercialized instruments) 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 is five years. The depreciation expense was approximately \$16,000 and \$57,094 for three and twelve months ending December 31, 2015, respectively. The depreciation expense was approximately \$4,000 and \$17,000 for three and twelve months ending December 31, 2014, respectively. The costs of maintenance and repairs are charged to operations as incurred.

**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's estimated useful life will be based on the average remaining life of the underlying patents. Currently the remaining useful life of the patents is approximately 9.5 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 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 and more 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 has 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 are sub-contracted to vendors and progress is 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.

**Accounting for Uncertain Tax Positions**

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 December 31, 2015, no significant income tax uncertainties have been included in the Company's financial statements. The Company's policy is to recognize interest and penalties 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 is provided management, financial, engineering and accounting services by the staff of Milestone Scientific. The value related to these services is charged to the Company on a periodic basis and is included in the consolidated financial statements as shared service expense at Milestone Scientific cost. Additional paid in capital has 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 this transaction to assess the technological feasibility of the products being developed. 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. was 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 are being 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 - STOCKHOLDERS' EQUITY:**

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In June 2013, Milestone Medical Inc. entered an agreement with an agent in Poland to provide assistance in raising capital in a Private Placement (PP). Such amount raised in the PP, were subject to the Company's approval and subsequent listing on the NewConnect system of the Warsaw Stock Exchange in Poland. The agreement called for a service fee payable to the agent upon consummation and the amount was deducted as described below. In addition, the Company entered a three year advisory agreement with a firm in Poland for their services provided capital is raised and shares of common stock are listed on the stock exchange.

In October and November 2013, the Company completed the sale of 2 million shares of the Company's common stock at \$1.50 (4.65 PLN) per share (\$3 million capital raised – net proceeds of \$2,363,006) in a private placement in Poland.

In December 2015, the company obtained approval of a Prospectus filed with the regulatory authority in Poland to raise an additional \$4 million of capital and to uplist the Company to the Warsaw Stock Exchange from the New Connect Market (Alternative Trading System). The Prospectus was approved by the Polish Regulatory authorities, however the anticipated capital raise was placed on hold until financial conditions improve in Poland. Milestone Medical Inc. entered an agreement with investment companies in Poland to provide assistance in raising the capital through a public offering of its shares in Poland (with Graviton Capital S.A., Vestor Dom Maklerski S.A. and Biuro Maklerskie ALIOR BANK S.A.)

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**NOTE 5- RELATED PARTY TRANSACTIONS:**

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On December 31, 2014, Milestone Scientific Inc., executed a \$2 million line of credit agreement to provide bridge financing to the Company through April 15, 2016. Interest is being charged 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). As of December 31, 2015, Milestone Scientific, Inc. has advanced \$2,500,000 to Milestone Medical. The Company intends to convert a portion of the outstanding credit agreement to common shares in the private placement offering upon the successful completion of public offering of common shares. One million of the outstanding

balance (\$2.5 million) will be repaid at a later date, not earlier than after obtaining the approval of the FDA clearance.

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**NOTE 5-RELATED PARTY TRANSACTIONS:**

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The remaining balance (including interest) will be converted into common stock of the Company at a market rate at the time of the capital raise. In January 2016, the credit agreement was increased by \$300,000 to \$2.8 million. 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 Company is provided management, financial, engineering and accounting services by the staff of Milestone Scientific, Inc. In October 2014, the Company purchased tooling equipment for \$25,645 from the same supplier.

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 years ended December 31, 2015 and 2014 were \$118,307 and \$394,720 respectively.

As of December 31, 2015 the Company owes \$998,453 to Milestone Scientific, Inc. for expenses paid on the Company's behalf of 2015. The expenses relate to financial and accounting services performed by Milestone Scientific Inc.'s employees at the cost to Milestone Scientific Inc. These fees are payable to Milestone Scientific Inc.

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**NOTE 6 - PROVISION FOR INCOME TAXES:**

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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. The income tax provision or credit is the tax payable or refundable for the period plus or minus the change during the period in deferred tax assets and liabilities.

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**NOTE 7- CONCENTRATIONS:**

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The Company sub-contracts its research and development to a vendor which accounted for 46%, of total expenses incurred for twelve months ended December 31, 2015. If the vendor or the Company terminated the current arrangement, additional expenses may be incurred for further research and development to occur. As of December 31, 2015, there are no known circumstances which would lead to termination by either party.

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**NOTE 8 - COMMITMENTS AND OTHER:**

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In July 2013, Milestone Scientific, Inc. (as an agent for Milestone Medical Inc.), entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare in the United States. During the three year strategic partnership, the distributor will hold the exclusive rights to market, resell, label and distribute Milestone's CompuFlo injection technology for use in epidural applications for childbirth and other pain management needs in hospitals in the U.S. This agreement was terminated in June 2015, due to a delay in receiving FDA clearance on the epidural instrument.

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**NOTE 9- SUBSEQUENT EVENTS:**

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In January 2016, the Company requested an increase of \$300,000 from Milestone Scientific Inc. to the existing credit agreement. Milestone Scientific Inc. advanced the additional funds, under the same conditions and terms as previously agreed by the parties. Milestone Scientific Inc is not obligated to advance any funds to Milestone Medical Inc.

### **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 fourth quarter of 2015 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 2 to the Financial Statement. During the fourth quarter of 2015, 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 impact the achieved results.**

During the fourth quarter ending December 31, 2015, 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. As of December 31, 2015 the Issuer is in the process of clinical studies at several premier sites in the U.S. Successful completion of the studies is 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 280 Patents in the clinical study in the USA. 220 Patents have completed the enrollment in the pain management study and over 60 Patents have completed the labor and delivery enrollment process to date.

The Company currently employs one full time employee the President, who is also the President of Milestone Scientific Inc, however he provides essentially all of his time to the Company. The Company has two positions currently open, Director of Sales/Business Development and Anesthesiologist Registered Nurse as of December 31, 2015. Additionally, the Company is continuing its efforts to identify and meet with potential distributors for both instruments throughout the world. The Issuer’s President and a contracted Business Development Representative are actively pursuing distribution partners. As a result 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. 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.

The marketing of both instruments is an ongoing process. As announced last year, the Issuer already had a distribution channel in place with one of the largest specialty distributors of healthcare products in the U.S. to market and sell the Company epidural instrument. The Company terminated this agreement in June 2015 due to delays in receiving FDA clearance by the Company.

For the year ended, December 31, 2015, the Issuer and its Subsidiary have generated a net loss of \$3,843,905. This loss was caused mainly due to research and development costs of \$793,500 and to a high level of general and administrative expenses, which amounted to \$2,872,565. These expenses were incurred due to 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 additional funds to the Issuer. As such the Issuer will reduce its cash expenditure in 2016, until additional capital is raised or revenues increase to cover these costs.

## 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 approval has reached over 270 patients. The results thus far have been 100% successful in locating the epidural space.

As announced in the previous year, the Company's Board of Directors have approved plans for the Issuer to uplist from NewConnect Market (Alternative Trading System) to the Main Market of the Warsaw Stock Exchange, which the Company expected to occur in the fourth quarter of 2015, subject to approval of the Company's prospectus. Transitioning to the Main Market of the Warsaw Stock Exchange will be an important development for the Issuer as the Issuer believes this will help increase awareness and expand the number of potential investors in the company. In tandem with the uplisting, the Issuer expects to complete a public offering of the Company's shares.

The Prospectus referred to in the previous paragraph was approved by the Polish Regulators in December 2015. However, the planned capital raise was suspended in December 2015, due to turmoil in the Polish financial markets. The Issuer plans to continue raising capital in the first quarter of 2016.

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. Recruitment for the clinical trial is underway and over 280 patients have now taken part in the study. The Company has also disclosed that five prominent university and pain management sites in the United States have received Ethical Committee (Institutional Review Board) approvals which enable the initiation of site enrollment. For fourth quarter 2015, the clinical trial for the Issuer's epidural instrument has reached an enrollment of 280 patients.

The Company plans to enroll approximately 400 patients in the trial at five separate sites in the U.S. Upon achieving full enrollment, the Company expects the clinical trial and accompanying statistical analysis to be completed in the second quarter of 2016, at which time the Issuer will return 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**

<b>SUBSIDIARY</b>	<b>MILESTONE MEDICAL POLAND SP. Z.O.O.</b>
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