



Consolidated Quarterly report of
MILESTONE MEDICAL INC. and SUBSIDIARY
3rd quarter (from July 1, 2015 to September 30, 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, November 9, 2015

1. General information

Table 1 General Information about the Issuer

THE ISSUER	MILESTONE MEDICAL INC. (earlier: Milestone Scientific Research and Development, Inc.)
Registered office/Office:	220 South Orange Avenue, Livingston, NJ 07039, USA
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Main website address:	www.medicalmilestone.com

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 [%]
MILESTONE SCIENTIFIC, INC.	10,995,000	49.98%
WANG TAO	2,600,000	11.82%
ZHANG LIDONG	2,000,000	9.09%
ZHU YUN	1,600,000	7.27%
TOM CHENG*	1,325,000	6.02%
OTHERS (<5%)	3,480,000	15.82%
TOTAL	22,000,000	100%

Source: The Issuer

*Holding directly 320,000 shares and indirectly 1,005,000 shares by his subsidiary United Systems Inc.

1.2. Board of Directors

Table 3 Board of Directors

NAME OF DIRECTOR	CURRENT AGE	DIRECTOR SINCE	END OF TERM
Leonard A. Osser	68	March 2011	Next Annual Meeting of Shareholders
Zhu Yun	49	September 2013	Next Annual Meeting of Shareholders
Martin S. Siegel	70	September 2013	Next Annual Meeting of Shareholders

Source: The Issuer

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

On September 30, 2015 the Issuer employed two full time employees and three (3) persons converted into full-time equivalents (“FTEs”).

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

**For the three and nine months ended September 30, 2015 and 2014 (unaudited) and
As of September 30, 2015 (unaudited) December 31, 2014 (audited)**

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MILESTONE MEDICAL INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

<u>ASSETS</u>	September 30, 2015 (Unaudited)	December 31, 2014 (Audited)
Current Assets:		
Cash	\$ 42,393	\$ 1,080,035
Accounts receivable	40,550	-
Prepaid expenses and other current assets	168,811	86,906
Inventory	869,869	45,244
Advances to contractors	43,435	370,230
Total current assets	1,165,058	1,582,415
Equipment, net of accumulated depreciation of \$106,693 as of September 30, 2015 and \$32,492 as of December 31, 2014	134,632	93,737
Intangible asset	1,500,000	1,500,000
Total assets	<u>\$ 2,799,690</u>	<u>\$ 3,176,152</u>
 <u>LIABILITIES AND STOCKHOLDERS' (DEFICIENCY) EQUITY</u>		
Current Liabilities:		
Accounts payable and accrued expense	\$ 956,920	\$ 462,656
Advance on line of credit from Milestone Scientific Inc.	2,000,000	-
Due to related party	623,881	500,000
Total current liabilities	3,580,801	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 September 30, 2015 and December 31, 2014	2,200	2,200
Additional paid-in capital	6,683,204	6,543,137
Accumulated deficit	(7,466,515)	(4,331,841)
Total stockholders' (deficiency) equity	(781,111)	2,213,496
Total liabilities and stockholders' (deficiency) equity	<u>\$ 2,799,690</u>	<u>\$ 3,176,152</u>

See Notes to Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30, 2015 (Unaudited)	Three Months Ended September 30, 2014 (Unaudited)	Nine Months Ended September 30, 2015 (Unaudited)	Nine Months Ended September 30, 2014 (Unaudited)
Revenue	\$ 29,000	\$ -	\$ 40,550	\$ -
Cost of products sold	11,144	-	14,819	-
Gross Profit	17,856	-	25,731	-
Research and development expenses	217,138	75,726	572,954	190,987
Expenses:				
Shared services	90,159	82,658	140,067	263,009
Depreciation	15,664	3,850	41,467	11,550
General and administrative expenses	859,395	330,135	2,385,224	783,007
Total expenses	1,182,356	492,369	3,139,712	1,248,553
Net loss from operations	(1,164,500)	(492,369)	(3,113,981)	(1,248,553)
Interest expense	(17,196)	(72)	(20,693)	(72)
Net loss	\$ (1,181,696)	\$ (492,441)	\$ (3,134,674)	\$ (1,248,625)

See Notes to Consolidated Financial Statements



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

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Deficit	Total
	<u>Shares</u>	<u>Amount</u>			
	(in thousands)				
Balance, December 31, 2014	22,000	\$ 2,200	\$ 6,543,137	\$ (4,331,841)	\$ 2,213,496
Contributed Capital-Milestone Scientific, Inc.					
Shared Service Expense	-	-	140,067	-	140,067
Net Loss	-	-	-	(3,134,674)	(3,134,674)
Balance, September 30, 2015	22,000	\$ 2,200	\$ 6,683,204	\$ (7,466,515)	\$ (781,111)

See Notes to Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30, 2015 (Unaudited)	Nine Months Ended September 30, 2014 (Unaudited)
Cash flows from operating activities:		
Net loss	\$ (3,134,674)	\$ (1,248,625)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	41,467	11,550
Contributed capital - Milestone Scientific, Inc. shared services expense	140,067	274,009
Changes in operating assets and liabilities:		
Increase in accounts receivable	(40,550)	-
Increase in inventories	(824,625)	(12,319)
Decrease in advances to contractors	326,795	1,844
Increase to prepaid expenses and other current assets	(81,905)	(55,268)
Increase in accounts payable and accrued expenses	494,264	176,735
Increase due to related party	123,881	-
Net cash from operating activities	<u>(2,955,280)</u>	<u>(852,074)</u>
Cash flows from investing activities:		
Purchase of equipment	<u>(82,362)</u>	<u>-</u>
Net cash from investing activities	<u>(82,362)</u>	<u>-</u>
Cash flows from financing activities:		
Proceeds from Line of credit	<u>2,000,000</u>	<u>-</u>
Net cash from financing activities	<u>2,000,000</u>	<u>-</u>
NET DECREASE IN CASH	(1,037,642)	(852,074)
Cash at beginning of period	1,080,035	1,881,910
Cash at end of period	<u>\$ 42,393</u>	<u>\$ 1,029,836</u>
Supplemental disclosure of non cash activities:		
Contributed Capital - Milestone Scientific, Inc. Shared Services Expense	<u>\$ 140,067</u>	<u>\$ 274,009</u>

See Notes to Consolidated Financial Statements

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)**

Three and nine months ended September 30, 2015 and 2014

NOTE 1 - ORGANIZATION:

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 September 30, 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. Regulatory clearance was received in September 2014 in the CE. In 2014, the Company began to commercially market the instruments with the 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 75% owned by the Company. As of September 30, 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 \$5.8 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 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 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. At September 30, 2015, \$2,000,000 was outstanding on the line. 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.) All other terms in the line of credit agreement remained unchanged. This line of credit facility is expected to be repaid upon the successful completion of the fore mentioned public offering.

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 consolidated financial statements contain all adjustments necessary to fairly present Milestone Medical Inc.'s financial position as of September 30, 2015 and the results of its operations for the three and nine months then ended.

The results reported for the three and nine months ended September 30, 2015 are not necessarily indicative of the results of operations which may be expected for a full year.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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 75% of a special purpose company organized in Poland, Milestone Medical Poland S.P. Z.o.o., which is not active at this time.

Cash and Cash Equivalents

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

Inventory

Inventory costing, obsolescence and physical control are significant to the on-going operation of the business. Inventories principally consist of finished goods and component parts 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 2015, 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 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.

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 \$21,000 and \$41,000 for three and nine months ending September 30, 2015, 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 9.75 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 September 30, 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 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 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. Additional paid in capital has been credited for the rendered services.

NOTE 3 - JOINT VENTURE AGREEMENT:

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 was involved significantly 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 on a timely basis.

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 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.

NOTE 4 - STOCKHOLDERS' EQUITY:

In June 2013, Milestone Medical 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 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.

NOTE 5 - RELATED PARTY TRANSACTIONS:

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). All other terms in the line of credit agreement remain unchanged. As of September 30, 2015, Milestone Scientific, Inc. has advanced \$2,000,000 to Milestone Medical.

The Company is provided management, financial, engineering and accounting services by the staff of Milestone Scientific, Inc.

In December 2012, the Company purchased equipment for \$77,000 from a supplier who is also an investor in the Company and Milestone Scientific Inc. In October 2014, the Company purchased tooling equipment for \$25,645 from the same supplier.

The shared expenses are related to the Company providing management, financial, engineering and accounting services to the staff of Milestone Scientific Inc.; its joint venture partner. These expenses relate to the costs incurred related to obtaining CD and FDA approval and represent additional contributions from Milestone Scientific Inc. The shared expenses for the three and nine months ended September 30, 2015 were \$90,159 and \$140,067 respectively.

As of September 30, 2015 the Company owes \$623,881 to Milestone Scientific, Inc. for expense paid on the Company's behalf of 2015. The expenses relate to financial and accounting services performed by Milestone Scientific Inc. employees. These fees are payable to Milestone Scientific Inc.

Milestone Scientific, Inc. charged expenses to the Company based on estimated time expended on the development, supervision and management of the project. Milestone Scientific Inc. Expensed \$44,415 and \$175,868 on behalf of Milestone Medical for the three and nine months ended September 30, 2015, respectively, for legal expenses related to seeking U.S. Food and Drug

Administration marketing clearance for the epidural and intra-articular instruments under section 510K. As part of the joint venture agreement, Milestone Scientific Inc. Agreed to pay all the legal fees related to the FDA clearance process. For the three and nine months ended September 30, 2015 the Company expended approximately \$85,000 and \$180,000 on regulatory clinical fees (FDA Regulations) in time charges relating to the project. These charges have been credited to additional paid-in capital.

NOTE 6 - PROVISION FOR INCOME TAXES:

Milestone Medical accounts for income taxes pursuant to the asset and liability method which requires deferred income tax assets and liabilities to be computed for temporary differences between the financial statement and tax basis of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. 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.

NOTE 7 - CONCENTRATIONS:

The Company sub-contracts its research and development to a vendor which accounted for 46%, of total expenses incurred for nine months ended September 30, 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 September 30, 2015, there are no known circumstances which would lead to termination by either party.

NOTE 8 - COMMITMENTS AND OTHER:

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.

NOTE 9 - SUBSEQUENT EVENTS:

Management has evaluated subsequent events through November 9, 2015, the date the financial statements are available to be issued, for inclusion or disclosure in the financial statements.

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 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 third 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 third quarter ending September 30, 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 September 30, 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 hired three full time employees; President, a Director of Sales and Business Development (open position as of September 30, 2015) and an instrument trainer. 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 one employee 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. This agreement, concluded by Milestone Scientific Inc. was terminated in June 2015 due to delays in receiving FDA clearance by the Company. The Issuer looks forward to creating similar agreements in other markets this year. Apart from above, there was no other failures noted during this quarter.

For the nine months ended, September 30, 2015, the Issuer and its Subsidiary have generated net losses of \$3,134,674. This loss was caused mainly due to a high level of general and administrative expenses, which amounted to \$2,385,225. These expenses were incurred due to the market and commercialization of the instruments in Europe as well as increasing the headcount of the Company.

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 220 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 to the Main Market of the Warsaw Stock Exchange, which the Company expects 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 shares, which the Company expects will occur at a substantial premium to the Company prior offering.

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 220 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 third quarter 2015, the clinical trial for the Issuer's epidural instrument has reached an enrollment of 220 patients.

The Company plans to enroll up to 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 fourth quarter of 2015, 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, other than those described in Item #4 and Item #5, above.

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