



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

## **1st quarter (from January 1, 2017 to March 31, 2017)**

***Report include:***

1. General information about Milestone Medical Inc (“The Issuer”) and Subsidiary.
2. Condensed Consolidated quarterly financial statements prepared according to the accounting rules applicable to the Issuer together with information on accounting rules (policy) applied to the preparation of report.
3. Information on the rules applied to the preparation of the report, including information on changes to the applied accounting rules (policies).
4. Brief description of the most important achievements or failures of the Issuer and its Subsidiary during the period of the report as well as a description of the most important factors and events, 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, May 15, 2017

## 1. General information

**Table 1 General Information about the Issuer**

<b>THE ISSUER</b>	<b>MILESTONE MEDICAL INC.</b> <b>(earlier: Milestone Scientific Research and Development, Inc.)</b>
<b>Registered office/Office:</b>	220 South Orange Avenue, Livingston, NJ 07039, USA
<b>Telephone number:</b>	011-973-535-2717
<b>Facsimile number:</b>	011-973-535-2829
<b>E-mail:</b>	<a href="mailto:jdagostino@milestonescientific.com">jdagostino@milestonescientific.com</a>
<b>Main website address:</b>	<a href="http://www.medicalmilestone.com">www.medicalmilestone.com</a>

Source: The Issuer

### 1.1. Shareholding structure

In the table below shares issued are outstanding for computing the ownership percentage of shareholders holding at least 5% of votes at the General Meeting of Shareholders, applicable percentages are based on 22,000,000 shares outstanding on the date of this 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 at the date of the report.**

Name of Shareholder	Number of owned shares/votes	Shareholding/votes at General Meeting of Shareholders [%]
<b>MILESTONE SCIENTIFIC, INC.</b>	21,065,084	95.75%
<b>OTHERS (&lt;5%)</b>	934,916	4.25%
<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 one share of common stock for every two outstanding shares of Milestone Medical common stock. Through the report date, Milestone Scientific Inc. acquired additional 10,070,084 (45.77%) shares of the Issuer's outstanding share from various shareholders. Because of these transactions, Milestone Scientific Inc. owns approximately 96% 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>	70	Mar-11	Next Annual Meeting of Shareholders
<b>Zhu Yun</b>	52	Sep-13	Next Annual Meeting of Shareholders
<b>Martin S. Siegel</b>	73	Sep-14	Next Annual Meeting of Shareholders

\* On May 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. The next annual General Meeting of Shareholders is to occur on May 23, 2017*

*Source: The Issuer*

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

On March 31, 2017, the Issuer employed one full time employee and three (3) persons converted into full-time equivalents (“FTEs”). There is an open position for an additional one (1) full time employee: a Nurse Anesthesiologist. The Company has contracted with a Business development consultant for business activities in Europe and the Middle East in 2017. The open position is scheduled to be hired sometime in 2017.



**2. Consolidated quarterly financial statements prepared according to the accounting rules applicable to the Issuer and its Subsidiary together with information on accounting rules (policy) applied to the preparation of report**

**Milestone Medical Inc. and Subsidiary**

**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**As of and for three months ended March 31, 2017 and 2016 (unaudited)**

**And as of and for the year ended December 31, 2016 (audited)**

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MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED BALANCE SHEETS

	<u>March 31, 2017</u>	<u>December 31, 2016</u>
	(Unaudited)	(Audited)
<u>ASSETS</u>		
Current Assets:		
Cash and cash equivalents	\$ 14,189	\$ 13,187
Inventories	731,634	741,392
Advances on contracts	44,148	44,148
Prepaid expenses and other current assets	60,113	53,537
Total current assets	<u>850,084</u>	<u>852,264</u>
Equipment net of accumulated depreciation of \$194,400 as of March 31, 2017 and \$185,040 as of December 31, 2016	52,215	61,576
Intangible asset	1,500,000	1,500,000
Total assets	<u>\$ 2,402,299</u>	<u>\$ 2,413,840</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current Liabilities:		
Accounts payable	\$ 89,797	\$ 183,095
Accrued expenses and other payables	451,116	432,313
Advances on line of credit from Milestone Scientific Inc.	2,800,000	2,800,000
Due to related party	4,551,004	3,857,870
Total current liabilities	<u>7,891,917</u>	<u>7,273,278</u>
Commitments and Contingencies		
Stockholders' Equity Deficit		
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at March 31, 2017 and December 31, 2016	2,200	2,200
Additional paid-in capital	6,879,438	6,861,634
Accumulated deficit	(12,371,256)	(11,723,272)
Total equity deficit	<u>(5,489,618)</u>	<u>(4,859,438)</u>
Total liabilities and stockholders' equity deficit	<u>\$ 2,402,299</u>	<u>\$ 2,413,840</u>

See Notes to Condensed Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three months ended March 31, 2017 (Unaudited)	Three months ended March 31, 2016 (Unaudited)
Product sales, net	\$ -	\$ 6,000
Cost of products sold	-	4,337
Gross profit	-	1,663
Selling, general and administrative expenses	562,318	705,758
Depreciation	9,360	15,761
Shared services	17,804	60,867
Research and development expenses	34,844	47,595
Total operating expenses	624,326	829,981
Loss from operations	(624,326)	(828,318)
Interest expense	(22,908)	(22,933)
Loss before income tax	(647,234)	(851,251)
Provision from tax	750	-
Net loss	\$ (647,984)	\$ (851,251)

See Notes to Condensed Consolidated Financial Statements



MILESTONE MEDICAL INC. AND SUBSIDIARY  
 CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY  
 (Unaudited)

	<u>Common Stock</u>		Additional Paid-in Capital	Accumulated Deficit	Total
	<u>Shares</u>	<u>Amount</u>			
Balance, January 1, 2017	22,000	\$ 2,200	\$ 6,861,634	\$ (11,723,272)	\$ (4,859,438)
Contributed Capital-MilestoneScientific Inc. Shared Services Expenses			17,804		17,804
Net loss				(647,984)	(647,984)
Balance, March 31, 2017	22,000	\$ 2,200	\$ 6,879,438	\$ (12,371,256)	\$ (5,489,618)

See Notes to Condensed Consolidated Financial Statements



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

	Three Months Ended March 31, 2017	Three Months Ended March 31, 2016
	(Unaudited)	(Unaudited)
Cash flows from operating activities:		
Net loss	\$ (647,984)	\$ (851,251)
Adjustments to reconcile net cash used in operating activities:		
Depreciation expense	9,360	15,761
Contributed capital - Milestone Scientific, Inc. shared services expense	17,804	60,867
Changes in operating assets and liabilities:		
Decrease in inventories	9,758	9,987
(Increase) to advances on contracts		(624)
(Increase) to prepaid expenses and other current assets	(6,576)	(5,447)
Increase due to related parties	693,134	580,304
(Decrease) in accounts payable and accrued expenses	(74,494)	(84,686)
Net cash provided (used in) operating activities	1,002	(275,089)
Cash flows from investing activities:		
Purchases of property and equipment	-	(3,787)
Net cash (used in) investing activities	-	(3,787)
Cash flows from financing activities:		
Proceeds from line of credit	-	300,000
Net cash provided by investing activities	-	300,000
Net increase in cash and cash equivalents	1,002	21,124
Cash and cash equivalents at beginning of period	13,187	1,222
Cash and cash equivalents at end of period	\$ 14,189	\$ 22,346

See Notes to Condensed Consolidated Financial Statements



## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three month ended March 31, 2017 and 2016 (unaudited)  
and the year ended December 31, 2016 (audited)

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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, and a group of other investors contributed \$1.5 million to the Company.

In September 2014, the Company established a special purpose Polish company called Milestone Medical Poland Sp. z.o.o. The purpose of which is for the application and acceptance of Polish Government Grants for research and development of current and future improvement to the epidural and intra-articular instruments. Milestone Medical Poland Sp. z.o.o., is seventy – five percent owned by the Company. As of December 31, 2016, Milestone Medical Poland Sp. z.o.o. has not received any grants from the Polish Government.

As of March 31, 2017, 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 for the epidural and intra-articular instruments. 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 in September 2015. In December 2016, the Company received notification from the FDA that based upon the 510(k) application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, the Company did not adequately document that the device met the equivalency standard required for 510(k) clearance. Following consultation with the FDA Office of Device Evaluation, the Company intends to provide additional data, which could include a new Human Factor Validation study (HFV Study) in support of a new 510(k) application for the device. An HFV Study demonstrates the ease of use of a product. The cost to generate this incremental data is estimated to be approximately \$100,000.

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.

On June 17, 2016, Milestone Scientific initiated a share exchange program pursuant to which would exchange one share of Milestone Scientific Inc. common stock for every two outstanding shares of Milestone Medical common stock. As of March 31, 2017, 5,035,042 shares of Milestone Scientific common stock have been issued in exchange for 10,070,084 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owned approximately 96% of Milestone Medical at March 31, 2017.

In March 2017 on the ESPI 3/2017 report the Company announced it has begun its clinical rollout for the epidural instrument in the Middle East and North Africa (MENA) regions, by initiating clinical evaluations at key hospitals in the United Arab Emirates and in Lebanon. Given the extensive published clinical data supporting successful epidural catheter placement in patients with complex comorbidities, clinicians and key opinion leaders in these territories have expressed further interest in broadening the technique scope into challenging thoracic epidural procedures, as well as extending its use into pediatric cases.

The Company is also continuing its collaboration with key opinion leaders in Italy with a focus on expanding its clinical utilization at key hospitals in Rome, Florence, Naples and Pesaro, which resulted in additional scientific data accepted for presentation at the upcoming meeting of the European Society for Anesthesiology

to be held in Geneva, Switzerland from June 3-5, 2017. Euroanaesthesia is Europe's largest annual event showcasing the latest and the most relevant knowledge with medical experts active in the fields of anesthesia, perioperative medicine, intensive care, emergency medicine and pain treatment.

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

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Milestone Medical Inc. has incurred significant operating losses since its inception as a development company. Milestone Medical Inc. had positive cash flows from operating activities for the three months ending March 31, 2017 of \$1,002. At March 31, 2017 Milestone Medical Inc. had cash of \$14,189 and a negative working capital of approximately \$7,041,000 as compared to negative working capital of \$6,421,000 at December 31, 2016.

As of March 31, 2017, (same as mentioned in previous periodic reports) Milestone Medical Inc. believes that it does not have sufficient cash reserves 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 FDA clearance process and to expand its business in the medical business sectors. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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 expected contracts for delivery of epidural and intra-articular instruments to both customers in EU countries and for when FDA clearance is ultimately obtained in the United States. Although the Company's instruments have progressed beyond the development stage, additional equity financing is necessary to fund the further commercialization of the medical instruments. To this end, the Company and Milestone Scientific, Inc. are currently in the process of pursuing additional financings. However, the Company and Milestone Scientific, Inc. can provide no assurance that additional financings will be consummated on acceptable terms, or at all.

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

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### **Basis of Presentation**

The accompanying consolidated 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 Sp. 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.

### **Inventory**

Inventories principally consist of finished goods stated at the lower of cost (first-in, first-out method) or market.

Inventory quantities on hand is reviewed on a quarterly basis and a provision for excess and obsolete inventory is recorded if required based on the status and expected timing of the FDA approval process in the U.S. and expected future sales both domestically and internationally.

### **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 spare parts required for both epidural and intra articular instruments repairs.

### **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 costs of maintenance and repairs are 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 is 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 8.25 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 recent 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 is expected to be commercialized in the two instruments. Accordingly, no impairment has been recorded as of March 31, 2017 and December 31, 2016.

### **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.

Accounting for uncertainty in income taxes 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 March 31, 2017, there are 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 audit.

### **Services Provided by Stockholder**

Management, financial, engineering, regulatory and accounting services are provided by the staff of Milestone Scientific, Inc. The Company formalized this agreement during the third quarter of 2014. The fair 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.

### **Recent Accounting Pronouncement**

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers.

In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. The FASB continues to release guidance clarifying certain aspects of the revenue guidance. We do not believe that this new accounting pronouncement will have a material impact on our financial statements.

In November 2015, the FASB issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented. The Company has adopted this pronouncement as of January 1, 2017, and applied retrospectively, for its provision for income taxes disclosure. The adoption will not have an impact on the presentation of the balance sheet, as the Company assigns a full valuation allowance to its net deferred tax asset.

In February 2016, the FASB issued a new standard Accounting Standards Update ("ASU ") No.2016-02, "Leases"(Topic 842). The new standard is intended to increase transparency and comparability among organizations to recognize lease assets and liabilities on the balance sheet and disclose key information about leasing arrangements. It will be effective for fiscal years beginning after December 15, 2018 and for interim periods within fiscal years beginning after December 15, 2020. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In March 2016, the FASB issued a new standard ASU No.2016-07, "Investments - Equity Method and Joint Ventures" (Topic 323): The new standard is intended to eliminate the requirement that when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership or degree of influence, results of operations and retained earnings retroactively on a step-by-step basis as if the equity method had been in effect all of the previous periods that the investment was held. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2016. The Company has adopted the standard, effective January 1, 2017, and has determined the adoption of this standard will not have an impact on its financial reporting.

In March 2016, the FASB issued a new standard ASU No.2016-09, "Compensation – Stock Compensation" (Topic 718): The new standard is intended, under FASB's Simplification Initiative, to address certain diversity of application within previous guidance. The new standard primarily addresses certain tax aspects in connection with the stock compensation held. It will be effective for fiscal years and interim periods, beginning after December 15, 2016. The Company has adopted the standard, effective January 1, 2017, and has determined the adoption of this standard does not have an impact on its financial reporting.

In June 2016, the FASB issued a new standard ASU No.2016-13, "Financial Instruments – Credit Losses" (Topic 326): The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2018. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.

In August 2016, the FASB issued a new standard ASU No.2016-15, "Statement Cash Flows "Classification of Certain Cash Receipts and Cash Disbursements" Topic 230). The new standard provides guidance as to the conformity of presentation of certain cash receipts and disbursements. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.



In October 2016, the FASB issued a new standard ASU No.2016-16, "Income Taxes Intra-Entity Transfers of Assets Other Than Inventory" (Topic 740). The new standard provides guidance as to address the deferred tax treatment on certain intra-entity transfer of assets, other than inventory. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

In October 2016, the FASB issued a new standard ASU No.2016-17, "Consolidation Interests Held through Related Parties That Are under Common Control"(Topic 810). The new standard provides guidance as to consideration of consolidation requirements of a primary beneficiary and variable interest entity that are part of related party group under common control. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2016. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

In November 2016, the FASB issued a new standard ASU No.2016-18, “Statement of Cash Flows – Restricted Cash” (Topic 230). The new standard provides guidance as to address the diversity of treatment of restricted cash on the statement of cash flows. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017 and interim periods therein. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

In January 2017, the FASB issued a new standard ASU No.2017-04, “Intangibles Goodwill and Other – Simplifying the Test for Goodwill Impairment” (Topic 350). The new standard provides guidance as to simplify the testing and, potential, measurement of impairment of goodwill. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2020. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

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**NOTE 4 - 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 which 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. is authorized by the Joint Venture Agreement to manage and oversee the development of the two medical instruments for the Company. In connection with this, Milestone Scientific, Inc. entered into an agreement with a vendor to develop the two instruments. Milestone Scientific, Inc. personnel monitored the development of the instruments with the third party vendors on a periodic basis thus ensuring that the instruments will be developed according to medical standards.

Milestone Scientific, Inc. has distribution responsibility in the U.S. and Canada, while Beijing 3H, an investee, 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 Medical Company owned forty (40) percent by Milestone Scientific, Inc.). 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 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. Borrowings under the line bear interest at a rate of 3.25%, the prime rate at the inception of the agreement. In September 2015, the company requested and received approval from the Board of Directors of Milestone Scientific Inc. to increase the limit of the line of credit to a maximum of \$2.5 million In January 2016, the credit agreement increased to \$3 million. As of March 31, 2017, 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 other 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 three months ending March 31, 2017 and 2016 were approximately \$18,000 and \$61,000 respectively.

As of March 31, 2017, the Company owes \$4,551,004 to Milestone Scientific, Inc. for expenses paid on the Company's behalf. As of December 31, 2016, the Company owed \$3,857,870 to Milestone Scientific, Inc. for expenses paid on the Company's behalf.

The company reported on ESPI report 6/2016 published on June 17, 2016 that Milestone Scientific initiated a share exchanged program pursuant to which would exchange one share of Milestone Scientific Inc. common stock for every two outstanding shares of Milestone Medical common stock. As of March 31, 2017, 5,035,042 shares of Milestone Scientific common stock have been issued in exchange for 10,074,084 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owned approximately 96% of Milestone Medical at March 31, 2017.

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**NOTE 6 - CONCENTRATIONS:**

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The Company has informal arrangements for the manufacture of its products, the epidural and intra-articular instruments are manufactured by Tricor Systems, Inc. pursuant to specific purchase orders. There are no open purchase orders for the manufacture of instruments as of March 31, 2017. The Company sub-contracts its research and development to a vendor, which accounted for 100%, and 55% of total expenses incurred for the three months ended March 31, 2017 and 2016, respectively. The epidural and intra-articular handpiece with needle are supplied to Milestone Medical by several independent contractors in the United States, which arrange for its manufacture in China.

The termination of the manufacturing relationship with any of the above manufacturers could have a material adverse effect on Milestone Medical's ability to produce and sell its products. Although alternate sources of supply exist and new manufacturing relationships could be established, Milestone Medical would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, whether or not as a result of termination of such a relationship, would adversely affect Milestone Medical.

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**NOTE 7 - SUBSEQUENT EVENTS:**

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Management has evaluated subsequent events up to May 15, 2017 the date that 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 first quarter of 2017 was prepared in accordance with the rules indicated in Exhibit 3 to the Alternative Trading System Rules “Current and Periodical Information in the Alternative Trading System on the NewConnect market”. Information on applied accounting rules (policies) are presented in Note 3 to the Financial Statement. During the first quarter of 2017, 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 first quarter, ending March 31, 2017, 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) continues to move forward at a pace that is slower than we expected. As of March 31, 2017, 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, 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 one position currently open, Anesthesiologist Registered Nurse. 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 Representatives for Europe and the Middle East are actively pursuing distribution partners. The company added an additional Medical device consultant in March 2017, for the specific focus on our Intra Articular instrument in the European Market. 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. At this time, Moss S.P.A. is continuing its distribution efforts in Italy with a number of hospitals. However Moss S.P.A. has not signed any customer purchase agreements to date. As such Moss S.P.A. has not purchased any instruments under this agreement.

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. The agreement with Trimed terminated in the fourth quarter of 2016, due to slow performance in the Polish Market.

For the quarter ended, March 31, 2017, the Issuer and its Subsidiary have generated a net loss of \$647,984. This loss was due to research and development costs of \$34,844 and to a high level of general and administrative expenses, which amounted to \$562,318. These expenses were incurred due to FDA clearance process in the United States, the marketing and commercialization of the instruments in Europe, as well as increased controlled expenses for travel and the addition of a Business Development Consultants for Europe and the Middle East.

The Issuer suspended its effort to raise capital in December 2015. The capital market in Poland was not conducive due to financial market turmoil in the fourth quarter of 2015. As such, the Issuer has little cash available to continue its operations. 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 reduced its cash expenditure in 2017, until additional capital has 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). In June 2016, the company terminated Baker Tilly Virchov, LLP and appointed Friedman LLP as its new auditors.

The company reported on ESPI report on 6/2016 published on June 17, 2016 that Milestone Scientific initiated a share exchange program pursuant to which would exchange one share of common stock for every two outstanding shares of Milestone Medical common stock. As of December 31, 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 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%.

In January 2017, the parent company continued its exchange program and exchanged 1,065,084 shares of Milestone Medical shares from a shareholder. After the exchange, Milestone Scientific will own approximately 96% of the shares in Milestone Medical.

## **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 process to market and sell 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 also completed the accompanying statistical analysis in July 2016, and the Issuer has filed the 510K application to the FDA for final market clearance for the epidural instrument.

The Company received notification from the FDA in December 2016 that based upon the 510(k) application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, the Company did not adequately document that the device met the equivalency standard required for 510(k) clearance. The Company provided an additional data submission to the FDA in April 2017, in support of a new 510(k) application for the device.

The Company intends to resubmit an application for a 510(k), for the Compu-Flo Intra Articular instrument and include focused attention on the area's that the FDA indicated shortfalls in the original application. The new 510(k) application for the Compu-Flo Intra Articular instrument will be processed in the second or third quarter of 2017.

In April 2017, the company reported on ESI 5/217 that Milestone Medical was granted market clearance for its epidural, intra-articular instruments and disposables in Australia. The Company is now in the process of selecting a distributor (s) to market these instruments in Australia.

**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