

## **Condensed Consolidated Quarterly report of**

### MILESTONE MEDICAL INC. and its SUBSIDIARY

3rd quarter (from July 1, 2017 to September 30, 2017)

#### Report include:

- 1. General information about Milestone Medical Inc ("Issuer") and Milestone Medical Poland Sp. Z o.o. (the Subsidiary).
- 2. Condensed Consolidated quarterly financial statements prepared according to the accounting rules applicable to the Issuer together with information on accounting rules (policy) applied to the preparation of report.
- 3. Information on the rules applied to the preparation of the report, including information on changes to the applied accounting rules (policies).
- 4. Brief description of the most important achievements or failures of the Issuer and its Subsidiary during the period of the report as well as a description of the most important factors and events, in particular atypical ones, which affect the achieved results.
- 5. A description of the status of implementation of activities and investments of the Issuer and its Subsidiary and the timetable of their implementation.
- 6. If the Issuer and its Subsidiary took initiatives to develop, its activities aimed to implement innovative solutions at the enterprise during the period of the report information on such activities.
- 7. Description of the organization of the group indicating consolidated entities.

New Jersey, November 14, 2017



#### 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				
Telephone number:	011-973-535-2717				
Facsimile number:	011-973-535-2829				
E-mail:	jdagostino@milestonescientific.com				
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 at the date of the report.

Name of Shareholder	Number of owned shares/votes	Shareholding/votes at General Meeting of Shareholders [%]			
MILESTONE SCIENTIFIC, INC.	21,689,078	98.59%			
OTHERS (<5%)	310,922	1.41%			
TOTAL	22,000,000	100%			

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 10,638,084 (48.35%) shares of the Issuer's outstanding share from various shareholders. The company reported on ESPI report 8/2017 published on August 8, 2017 that Milestone Scientific increased its shareholding in the Company and reached 98.33% of total number of votes at the Company's Shareholders' Meeting. An additional 55,994 shares (0.25%) are in the process of exchange as of the date of this report.

In January 2017, and June 2017 the parent company continued its exchange program and exchanged 1,625,084 shares of Milestone Medical shares from a shareholder. After the exchange, Milestone Scientific will own approximately 98.59% of the shares in Milestone Medical.



#### 1.2. Board of Directors

**Table 3 Board of Directors** 

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

<sup>\*</sup> On May 23, 2017 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.

On July 10, 2017 Leonard Osser resigned as a member of the Board of Directors of the Issuer. An addition to the Board of Directors will be nominated in the fourth quarter of 2017. Source: The Issuer

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

On June 30, 2017 the Issuer employed one (1) 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. An additional consultant for the European market was added in July 2017. The open position is under review at this time.

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 and nine months ended September 30, 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

	Septe	mber 30, 2017	December 31, 2016	
	J)	Jnaudited)	(Audited)	
<u>ASSETS</u>				
Current Assets:				
Cash and cash equivalents	\$	35,081	\$	13,187
Inventories		737,344		741,392
Advances on contracts		44,148		44,148
Prepaid expenses and other current assets		77,690		53,537
Total current assets		894,263		852,264
Equipment net of accumulated depreciation of \$206,476 as of				
September 30, 2017 and \$185,040 as of December 31, 2016		40,139		61,576
Intangible asset		1,500,000		1,500,000
Total assets	\$	2,434,402	\$	2,413,840
LIABILITIES AND STOCKHOLDERS' EQUITY				<u>.</u>
Current Liabilities:				
Accounts payable	\$	111,280	\$	183,095
Accrued expenses and other payables		470,773		432,313
Advances on line of credit from Milestone Scientific Inc.		5,675,663		3,857,870
Due to related party		2,800,000		2,800,000
Total current liabilities		9,057,716		7,273,278
Commitments and Contingencies				
Stockholders' Deficit				
Common stock, par value \$.0001; authorized 50,000,000 shares;				
22,000,000 shares issued and outstanding at September 30, 2017 and				
December 31, 2016		2,200		2,200
Additional paid-in capital		6,914,361		6,861,634
Accumulated deficit		(13,539,875)		(11,723,272)
Total equity deficit		(6,623,314)		(4,859,438)
Total liabilities and stockholders' equity deficit	\$	2,434,402	\$	2,413,840



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

	Three months ended September 30,			Nine months ended September 30,				
		2017		2016		2017		2016
Product sales, net	\$	-	\$	9,253	\$	-	\$	9,728
Cost of products sold		-		5,313		-		4,222
Gross profit		-		3,940		-		5,506
Selling, general and administrative expenses		486,774		594,336		1,555,435		2,097,584
Depreciation		5,515		15,807		21,436		47,349
Shared services		17,375		34,063		52,727		158,102
Research and development expenses		8,274		211,811		116,793		335,616
Total operating expenses		517,938		856,017		1,746,391		2,638,651
Loss from operations		(517,938)		(852,077)		(1,746,391)		(2,633,145)
Interest expense		(23,397)		(23,372)		(69,462)		(69,422)
Loss before income tax		(541,335)		(875,449)		(1,815,853)		(2,702,567)
Provision from tax		-				(750)		
Net loss	\$	(541,335)	\$	(875,449)	\$	(1,816,603)	\$	(2,702,567)



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

Common Stock Additional Paid-in Accumulated Shares Capital Deficit Total Amount Balance, January 1, 2017 22,000 \$ 2,200 6,861,634 (11,723,272)(4,859,438) Contributed Captial-MilestoneScientific Inc. Shared Services Expenses 52,727 52,727 Net loss (1,816,603) (1,816,603) Balance, September 30, 2017 22,000 \$ 2,200 \$ 6,914,361 (13,539,875) (6,623,314)



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

	Nine Months Ended September 30, 2017 (unaudited)		Nine Months Ended September 30, 2016 (unaudited)		Year Ended 2016  December 31, 2016  (audited)	
Cash flows from operating activities:						
Net loss	\$	(1,816,603)	\$	(2,702,567)	\$	(3,351,392)
Adjustments to reconcile net cash provided by (used in) operating activities:						
Depreciation expense		21,436		47,349		62,720
Contributed capital - Milestone Scientific, Inc. shared services expense		52,727		158,102		168,634
Changes in operating assets and liabilities:						
Decrease in accounts receivable		-		30,772		45,075
Decrease in inventories		4,049		58,699		144,569
Increase to advances on contracts		-		(624)		(624)
Increase to prepaid expenses and other current assets		(24,154)		19,989		(10,900)
Decrease in accounts payable and accrued expenses		(33,354)		(32,684)		(200,243)
Net cash provided by (used in) operating activities		(1,795,899)		(2,420,964)		(3,142,161)
Cash flows from investing activities:		_		_		
Purchases of property and equipment				(5,289)		(5,290)
Net cash (used in) investing activities		-		(5,289)		(5,290)
Cash flows from financing activities:						
Increase due to related parties		1,817,793		2,132,750		2,859,416
Proceeds from line of credit				300,000		300,000
Net cash provided by investing activities		1,817,793		2,432,750		3,159,416
Net increase in cash and cash equivalents		21,894		6,497		11,965
Cash and cash equivalents at beginning of period		13,187		1,222		1,222
Cash and cash equivalents at end of period	\$	35,081	\$	7,719	\$	13,187



#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS For three and nine months ended September 30, 2017 and 2016 (unaudited) and the year ended December 31, 2016 (audited)

#### **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. Additionally, Beijing 3H, and a group of other investors contributed \$1.5 million to the Company.

In September 2014, the Company established a special purpose Polish company called Milestone Medical Poland Sp. z.o.o. The purpose of which is for the application and acceptance of Polish Government Grants for research and development of current and future improvement to the epidural and intra-articular instruments. Milestone Medical Poland Sp. z.o.o., is seventy – five percent owned by the Company. As of September 30, 2017, Milestone Medical Poland Sp. z.o.o. has not received any grants from the Polish Government. Milestone Medical Poland Sp. z.o.o. is inactive at this time.

On June 12, 2017 the company announced that the CompuFlo® Epidural Computer Controlled Anesthesia System has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). The CompuFlo® Epidural System provides anesthesiologists and other Health Care Providers for the first time, the ability to quantitatively determine and document the pressure at the needle tip in real-time. The CompuFlo® Epidural's proprietary DPS Dynamic Pressure Sensing Technology<sup>TM</sup> (DPS) allows the CompuFlo® Epidural to provide objective visual and audible in-tissue pressure feedback that allows anesthesiologists to identify the epidural space.

The Company received notification from the FDA in December 2016 that based upon the 510(k) application submitted for the Company's Compu-Flo Intra Articular Computer Controlled Injection System, the Company did not adequately document that the device met the equivalency standard required for 510(k) clearance. The Company provided an additional data submission to the FDA in April 2017, in support of a resubmission 510(k) application for the device. At this time, the Company is expecting a follow up response from the FDA, based on supplemental information provide in the third quarter 2017

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 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 fourth quarter of 2017.

The Company is in the process of introductory meetings with medical device distributors within the United States and European markets. The Company's focus will be on marketing its two instruments throughout the world. The current marketing focus by the Company in the United States is on the Epidural instrument.

On June 17, 2016, Milestone Scientific initiated a share exchange program pursuant to which would exchange one share of Milestone Scientific Inc. common stock for every two outstanding shares of Milestone Medical common stock. As of September 30, 2017, 5,319,042 shares of Milestone Scientific common stock have been issued in exchange for 10,638,084 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owned approximately 99% of Milestone Medical at September 30, 2017. The company reported on ESPI report 8/2017 published on

Milestone Medical, Inc.



August 8, 2017 that Milestone Scientific increased its shareholding in the Company and reached 98.59% of total number of votes at the Company's Shareholders' Meeting.

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 morbidities, clinicians and key opinion leaders in these territories have expressed further interest in broadening the technical scope into the 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 recent meeting of the European Society for Anesthesiology to be held in Geneva, Switzerland.

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

Milestone Medical Inc. has incurred significant operating losses since its inception as a development company. At September 30, 2017 Milestone Medical Inc. had cash of \$35,081 and a negative working capital of approximately \$8,161,000 as compared to negative working capital of approximately \$6,421,000 at December 31, 2016.

As of September 30, 2017, Milestone Medical Inc. believes that it does not have sufficient cash to meet all of its anticipated obligations for the next twelve months from the financial statement release date. Milestone Medical Inc. will continue to manage its cash position while taking strategic steps to commercialize the Epidural instrument in the USA and throughout the world. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Although the Company's instruments have progressed beyond the development stage, additional equity financing is necessary to fund the commercialization of the medical instruments. To this end, the Company and Milestone Scientific, Inc. are currently in the process of pursuing additional financings. However, the Company and Milestone Scientific, Inc. can provide no assurance that additional financings will be consummated on acceptable terms, or at all.

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

#### **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 pre-launch instrument 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 the 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.'s 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 (including a sale of an instrument) 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 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. The Company received FDA clearance in June 2017 for the epidural instrument. CE clearance was received in September 2014 for both the epidural and intra articular instruments. All these factors indicate that the technology is expected to be commercialized. Accordingly, no impairment has been recorded as of September 30, 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 September 30, 2017 there are no significant income tax uncertainties that 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.

#### **Recent Accounting Pronouncements**

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. 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 did 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. Milestone Scientific is in the process of determining what impact, 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 is 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 is effective for fiscal years and interim periods, beginning after December 15, 2016. The Company has adopted the standard, effective January 1, 2017, and the adoption did not have a material effect 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 Scientific 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 Scientific 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 is effective for fiscal years and interim periods, beginning after December 15, 2016.



Milestone Medical has adopted the standard, effective January 1, 2017, which did not have an impact on its financial reporting.

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 Scientific does not expect the adoption of this ASU to have a material effect on its presentation within the statement of cash flows.

In January 2017, the FASB issued a new standard ASU No.2017-01, "Business Combinations" (Topic 805). The new standard provides guidance to clarify the definition of a 'business', and assist entities in evaluation whether a transaction should be accounted for as an acquisition/disposal of assets or a business. It will be effective for public entities for fiscal years and interim periods, beginning after December 15, 2017, with limited early application. Milestone Scientific 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 May 2017, the FASB issued a new standard ASU No.2017-09, "Compensation – Stock Compensation" (Topic 718). The new standard provides guidance and clarity for modification to equity based compensation programs. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017. Milestone Scientific 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.

#### **NOTE 4 – 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 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. 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 Milestone China Ltd, (a Hong Kong Medical Company related to Milestone Scientific, Inc.) at that time is to distribute products exclusively in the PRC and other regions in Asia. The Company has distribution responsibilities for the rest of the world.



#### 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. Borrowings under the line bear interest at a rate of 3.25%, the prime rate at the inception of the agreement. In September 2015, the company requested and received approval from the Board of Directors of Milestone Scientific Inc. to increase the limit of the line of credit to a maximum of \$2.5 million in January 2016, the credit agreement increased to \$3 million. As of September 30, 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 the three months ended September 30, 2017 and 2016 were approximately \$17,375 and \$34,063 respectively. The shared expenses for the nine months ended September 30, 2017 and 2016 were approximately \$52,727 and \$158,102 respectively.

As of September 30, 2017, the Company owes \$5,675,663 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 September 30, 2017, 5,319,042 shares of Milestone Scientific common stock have been issued in exchange for 10,638,084 shares of Milestone Medical common stock. As a result of these exchanges, Milestone Scientific owned approximately 99% of Milestone Medical at September 30, 2017. The company reported on ESPI report 8/2017 published on August 8, 2017 that Milestone Scientific increased its shareholding in the Company and reached 98.33% of total number of votes at the Company's Shareholders' Meeting.

#### **NOTE 6 - CONCENTRATIONS:**

The Company has informal arrangements for the manufacture of its products, the epidural and intraarticular instruments are manufactured by Tricor Systems, Inc. pursuant to specific purchase orders. There are no open purchase orders for the manufacture of instruments as of September 30, 2017. The Company sub-contracts its research and development to a vendor, which accounted for 100%, and 55% of research and development expenses incurred for the three and nine months ended September 30, 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.



#### **NOTE 7 - COMMITMENTS AND CONTINGENCIES:**

On July 10, 2017, Mr. Osser resigned from his positions of Chairman of the Board, Chief Executive Office and President of Milestone Medical. Upon his resignation, Milestone Medical entered in a consulting agreement with U.S. Asian Consulting Group LLC, an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten- year term. Pursuant to the consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive \$100,000 per year for Mr. Osser's services. For the nine months ended September 30, 201, we expenses \$25,000 relating to this agreement. On the same day Mr. Daniel Goldberger was appointed for the position of Chief Executive Officer of the Company.

#### **NOTE 8 – SUBSEQUENT EVENT:**

On October 5, 2017, the Company announced that Daniel Goldberger had resigned as Chief Executive Officer effective October 2, 2017.

On October 5, 2017, the Company also announced the appointment of Leslie Bernhard, as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer.



# 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 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 third 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 impact the achieved results.

During the third quarter, ending September 30, 2017 the Issuer and its Parent obtained USA (FDA) regulatory approval for the Epidural medical instrument. The re submission for regulatory approval of the Intra-Articular instrument is in the beginning process of a new 510k submission.

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. In July 2017, the issuer added a new medical business consultant for the Epidural instrument. The new consultant will focus his attention in the UK, Germany, and France. 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 codevelopment 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.

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

For the quarter ended, September 30, 2017 the Issuer and its Subsidiary have generated a net loss of \$541,335. This loss was due to research and development costs of \$8,274 and to a high level of general and administrative expenses, which amounted to \$486,774. These expenses were incurred due to obtaining FDA clearance 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 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 June 30, 2017, Milestone Scientific through the exchange program acquired a total 10,638,084 additional shares of Milestone Medical. Milestone Scientific Inc. has also entered agreements to exchange an additional 55,994 shares of Milestone Medical Inc. common shares later in 2017.

In 2017 the parent company continued its exchange program and exchanged 1,625,084 shares of Milestone Medical shares from a shareholder. After the exchange, Milestone Scientific will own approximately 99% of the shares in Milestone Medical. The company reported on ESPI report 8/2017 published on August 8, 2017 that Milestone Scientific increased its shareholding in the Company and reached 98.59% of total number of votes at the Company's Shareholders' Meeting.

On May 23, 2017 the Annual General Meeting of Shareholders adopted the resolution on the approval and ratification of Friedman LLP as an entity authorized to audit consolidated financial statements of the Company for the fiscal year 2017. Friedman LLP was approved and recommended as independent auditor by the Audit Committee of the Board.

On July 10, 2017, Mr. Osser resigned from his positions of Chairman of the Board, Chief Executive Office and President of Milestone Medical. Upon his resignation, Milestone Medical entered in a consulting agreement with U.S. Asian Consulting Group LLC, an entity controlled by Mr. Osser, pursuant to which he will provide specific services to Milestone Medical for a ten- year term. Pursuant to the consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive \$100,000 per year for Mr. Osser's services. On the same day Mr. Daniel Goldberger was appointed for the position of Chief Executive Officer.

On October 5, 2017, the Company announced that Daniel Goldberger had resigned as Chief Executive Officer effective October 2, 2017.

On October 5, 2017, the Company also announced the appointment of Leslie Bernhard, as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer.

# **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 were signed in 2015.

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.

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

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

Milestone Medical, Inc.



additional questions from the FDA and provided responses to these questions on a timely basis. The Company is now waiting for a response from the FDA on the second round of questions.

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 is expected to be processed in the fourth quarter of 2017.

In April 2017, the company reported on ESPI 5/2017 that Milestone Medical was granted market clearance for its epidural, intra-articular instruments and disposables in Australia. 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.				
Registerd office/Office:	Plac Powstancow Slaskich 1/201, 53-329 Wrocław				
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.

Leslie Bernhard Interim Chief Executive Officer