



**Consolidated Annual report of**  
**MILESTONE MEDICAL, INC. AND SUBSIDIARY**  
for the Year Ended  
December 31, 2015

***The Report includes:***

1. The letter of the Board of Director and Management
2. Statements of the Board of Directors and Management
3. General information about Milestone Medical
4. Selected financial information
5. Audited annual financial statements
6. Report on the Milestone Medical's activities in year 2015
7. Report with the opinion on the audit of the annual financial statements
8. Application of corporate governance rules

New Jersey, April 15, 2016



## 1. THE LETTER OF THE BOARD OF DIRECTORS AND MANAGEMENT

To Our Valued Shareholders,

We are pleased to report significant progress on a number of fronts in 2015 and beyond regarding the commercial rollout of Company's epidural location and intra-articular drug delivery instruments. Highlights include the signing of two distribution agreements for the European markets, continued progress on clinical trials of our epidural instrument in the United States and the approval of our Prospectus as important steps towards transitioning to the Main Market of the Warsaw Stock Exchange.

Since receiving CE Mark marketing clearance for the Company's epidural instrument in September 2014, we began pursuing distribution partners in a number of countries in Europe. In March we finalized an exclusive agreement with TRIMED Sp.z o.o, one of the largest distributors of diagnostic equipment in Poland. Trimed has purchased a small number of instruments for internal use and training purposes as it ramps up for a formal launch later this year. The addressable market for epidurals in Poland is estimated to be over 8 million people, many of whom experience chronic pain. Since July 2015, the number of epidural injections increased significantly due to National Health Fund reimbursement of natural childbirth.

In May, we signed a Memorandum of Understanding with Fidia Farmaceutici SpA, 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 for joint pain.

Additionally, in June, a medical distributor in Italy, Moss S.P.A. signed a three year agreement that included minimum purchases of the epidural instrument and disposals for the Italian market. The addressable market in Italy encompasses over 1 million epidural procedures per year and over 60,000 epidural procedures for childbirth per year.

In the second quarter of 2015, we commenced the first shipments of our epidural instrument to distributors and key opinion leaders in Europe to provide important independent validation regarding the instrument's efficacy. Upon completion of these pilot programs and the additional validation that we anticipate will come from the U.S. clinical trials, we expect to launch an aggressive European roll-out strategy this year.

We are also making progress advancing U.S clinical trials of our epidural instrument at several premier sites in the U.S as part of the FDA regulatory pathway to demonstrate the accuracy of our CompuFlo® technology in identifying and confirming the epidural space location. To date, the clinical study has reached over 360 patients with the goal of up to 400 patients at five separate sites. We are now entering the final stage of our clinical trial that will be in labor and delivery. Upon successful completion of the clinical trial later this year and statistical analysis of the studies, we will return to the FDA for final marketing clearance for our epidural instrument. The expected timing of FDA clearance for the epidural and IA instruments is the second and third quarters of 2016, respectively.

We are pleased to announce that the abstracts describing the initial results of the Company's prospective, open labeled, clinical trial assessing the CompuFlo® technology in correctly identifying the epidural space during an epidural procedure were approved for publication in prestigious pain management journals. The authors of these abstracts, leading anesthesiologists and key opinion leaders, will present the findings during the premier American and European pain management society meetings in 2016 in the USA (New Orleans and Austin) and in Europe (London) between March and May of 2016.

We also hosted an event on November 20th in Miami for a group of leading anesthesiologists and key opinion leaders to present the interim results from our COMPASS clinical study (CompuFlo® Assessment Study) for the epidural instrument. Based on the initial outcomes of our COMPASS clinical study for chronic pain management, we remain convinced that CompuFlo® technology has the potential to successfully replace the current standard of medical care, utilizing fluoroscopy, as our technology has the added benefit of avoiding patient and staff exposure to radiation without compromising procedure safety or efficacy. The analysis demonstrated that the instrument correctly identified the epidural space location and clearly achieved the goal set by the FDA IDE Investigational Plan.

The epidural market in the U.S. is estimated at over \$7 billion annually. Over 2.4 million women in the U.S. receive epidurals while in labor each year, while another 1.6 million women who give birth chose not to have an epidural, mainly due to safety concerns. The epidural instrument has been developed to improve the safety of epidural procedures, lower costs, and significantly reduce malpractice risk by eliminating guess work.



In addition to Europe and the United States, we also have access to the sizeable Chinese market through distribution agreements with Milestone China for both the epidural and intra-articular instruments. These agreements include guaranteed minimum purchases following CFDA marketing clearance. We plan to submit the documents to CFDA once we receive FDA marketing clearance in the United States.

In December 2015, we obtained approval of a Prospectus filed with the Polish Financial Supervisory Authority to uplist from the NewConnect market to the Main Market of the Warsaw Stock Exchange and raise an additional \$4 million of capital for continued expansion of our sales and marketing initiatives and additional working capital to accelerate the full rollout of our epidural and intra-articular instruments in United States and Europe in 2016. However, the planned capital raise was suspended in December 2015, due to turmoil in the Polish financial markets and was eventually cancelled. We are awaiting better stock market conditions in Poland to conduct the public offering. We consider transitioning to the Main Market of the Warsaw Stock Exchange an important development that will help increase awareness and expand the number of potential investors in the company. At the same time we are also pursuing grant funding from the European Union to expand our production and R&D capabilities in Europe.

Despite reporting first revenues in the second quarter of 2015, Milestone Medical is still in the development stage as we prepare for full commercial rollout of our medical instruments. We continue to carefully manage our expenses, which are mainly attributable to regulatory approval, pursuing new distribution partners and marketing of our medical instruments. Even with the line of credit of \$2.8 million from Milestone Scientific, we believe we require additional capital to finalize the FDA regulatory marketing clearance process.

We had a productive year at Milestone Medical and continue to make progress. We would like to thank our shareholders and employees for their continued support of our efforts and look forward to keeping you apprised of developments at Milestone Medical as they unfold.

**Sincerely,**

**Board of Directors**

**Leonard Osser - Chief Executive Officer**

**Joseph D'Agostino - Chief Financial Officer**



## **2. STATEMENTS OF THE BOARD OF DIRECTORS AND MANAGEMENT**

The management of the Company declare that, the annual consolidated financial statements and comparable data present a true and fair view of the Company and its Subsidiary's property and financial situation and their financial results and that the report on the Company and its Subsidiary's activities presents a fair view of the Company and its Subsidiary's situation, including a description of basic exposures and risks.

As of December 31, 2015, the Company believes that it does not have sufficient cash reserves or collections of accounts receivable to meet all of its anticipated obligations for the next twelve months. The Company will continue to manage its cash position while taking strategic steps to finalize the clinical studies and to expand its business in the medical business sectors.

On behalf of the Board of Directors and management of the Company:

Leonard Osser – Chief Executive Officer

Joseph D'Agostino – Chief Financial Officer

The Board of Directors and management of Milestone Medical, Inc. and Subsidiary ("The Company") declares that, the authorized entity to audit financial statements, Baker Tilly Virchow Krause, LLP , which audited the annual consolidated financial statements, was selected in accordance with legal regulations and that this entity and certified auditors, who audited these financial statements met conditions to express their impartial and independent opinion on the audit, in accordance with standards of the U.S. Public Company Accounting Oversight Board.

On behalf of the Board of Directors and management of the Company:

Leonard Osser – Chief Executive Officer

Joseph D'Agostino – Chief Financial Officer

### 3. GENERAL INFORMATION

**Table 1: Basic information about Milestone Medical Inc.**

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

Source: The Issuer

#### 3.1. Shareholding structure on the date of annual report preparations

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**

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

Source: The Issuer

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

Additionally, at the end of January 2015, Dong Bing Mei sold her shares to two existing shareholders, Wang Tao, (1,000,000 shares) and Zhang Li Dong, (1,000,000 shares). As a result of this sale, Wang Tao owns 2,600,000 shares (11.8%) and Zhang LiDong owns 2,000,000 shares (9.1%), respectively.

#### 3.2. Board of Directors

**Table 3 Board of Directors**

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

Source: The Issuer

\*The Company intends to add two independent members, making a total of five independent directors, to Board of Directors upon the anticipated uplisting of the Company's shares to the Warsaw Stock Exchange in 2016.

#### 3.3. Information on the number of persons employed by the Company converted into FTEs



On December 31, 2015 the Issuer employed one full time employee and three (3) persons converted into full-time equivalents ("FTEs"). There are open positions for an additional two (2) full time employees; a Business Development Manager and a Nurse Anesthesiologist. These positions are scheduled to be hired sometime in 2016

#### 4. SELECTED FINANCIAL INFORMATION

##### 4.1. Selected financial data from Balance Sheet

Balance sheet items presented in euros converted at the closing exchange rate of EUR/USD on dates:

31.12.2015: 1 EUR = 1,0866 USD

31.12.2014: 1 EUR = 1,2156 USD

**Table 4 Selected consolidated financial data of the balance sheet of Milestone Medical as of December 31, 2015 with comparable consolidated data for year 2014.**

Selected consolidated financial data from the balance sheet	USD		EUR	
	31.12.2015	31.12.2014	31.12.2015	31.12.2014
Current Assets	1,018,419	1,582,415	937,253	1,301,757
Cash	1,222	1,080,035	1,125	888,479
Prepaid expenses and other current assets	42,637	86,906	39,239	71,492
Inventory	885,961	45,244	815,352	37,219
Accounts receivable	45,075	-	41,483	-
Advance to contractors	43,524	370,230	40,056	304,566
Equipment, net depreciation	119,006	93,737	109,521	77,112
Intangible Assets	1,500,000	1,500,000	1,380,453	1,233,959
Current Liabilities	4,314,104	962,655	3,970,278	791,918
Common Stock	2,200	2,200	2,025	1,810
Accumulated paid-in-capital	6,693,000	6,543,138	6,159,580	5,382,641
Accumulated deficit during the development stage	(8,371,879)	(4,331,841)	(7,704,656)	(3,563,542)
Stockholder's Equity	(1,676,679)	2,213,497	(1,543,051)	1,820,909

Source: The Issuer

##### 4.2. Selected consolidated financial data from Statement of Operations

Statement of Operations items presented in euros converted at the arithmetic average of an exchange rate of EUR/USD for periods:

01.01.2015 to 31.12.2015: 1 EUR = 1,0198 USD

01.01.2014 to 31.12.2014: 1 EUR = 1,3293

USD

**Table 5 Selected consolidated financial data of the statement of operations of Milestone Medical Inc. from January 1, 2015 to December 31, 2015 with comparable consolidated data for year 2014.**

Selected consolidated financial data from income statement	USD		EUR	
	31.12.15	31.12.14	31.12.15	31.12.14
Revenue	50,975	-	49,985	-
Cost of Goods	13,037	-	12,784	-
Gross Profit	37,938	-	37,201	-
Depreciation	57,094	16,621	55,985	12,504
Research and development expenses	791,397	401,308	776,031	301,894
Other expenses	3,189,155	1,478,568	3,127,237	1,112,291
Total Expenses	4,037,646	1,896,497	3,959,253	1,426,688
Interest Expense	40,330	287	39,547	216
Net Loss	(4,040,038)	(1,896,784)	(3,961,599)	(1,426,904)

Source: The Issuer



**5. AUDITED ANNUAL CONSOLIDATED FINANCIAL STATEMENTS**  
**Year End (Annual) consolidated financial statements prepared according to the accounting rules applicable to the Company together with information on accounting rules (policy) applied to the preparation of this report**

**Milestone Medical Inc. And Subsidiary**

As of and for the Years ended December 31, 2015 and 2014

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## INDEPENDENT AUDITORS' REPORT

To the Shareholders and Board of Directors  
Milestone Medical, Inc.  
Livingston, New Jersey

We have audited the accompanying consolidated balance sheets of Milestone Medical, Inc. and Subsidiary (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of the Company's internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Milestone Medical, Inc. as of December 31, 2015 and 2014 and the results of their consolidated operations and cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*Baker Tilly Virchow Krause, LLP*

New York, New York  
April 15, 2016

MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS

<u>ASSETS</u>	<u>December 31, 2015</u>	<u>December 31, 2014</u>
Current Assets:		
Cash	\$ 1,222	\$ 1,080,035
Accounts receivable	45,075	-
Prepaid expenses and other current assets	42,637	86,906
Inventory	885,961	45,244
Advances to contractors	43,524	370,230
Total current assets	1,018,419	1,582,415
Equipment, net of accumulated depreciation of \$122,320 as of December 31, 2015 and \$65,225 as of December 31, 2014	119,006	93,737
Intangible asset	1,500,000	1,500,000
Total assets	\$ 2,637,425	\$ 3,176,152
<u>LIABILITIES AND STOCKHOLDERS' (DEFICIENCY) EQUITY</u>		
Current Liabilities:		
Accounts payable and accrued expense	\$ 815,651	\$ 462,655
Advance on line of credit from Milestone Scientific Inc.	2,500,000	-
Due to related party	998,453	500,000
Total current liabilities	4,314,104	962,655
Commitments and Contingencies		
Stockholders' (Deficit) Equity		
Preferred stock, par value \$.0001; authorized 5,000,000 shares; 0 shares issued	-	-
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at December 31, 2015 and December 31, 2014	2,200	2,200
Additional paid-in capital	6,693,000	6,543,138
Accumulated deficit	(8,371,879)	(4,331,841)
Total stockholders' (deficit) equity	(1,676,679)	2,213,497
Total liabilities and stockholders' (deficit) equity	\$ 2,637,425	\$ 3,176,152

See Notes to Consolidated Financial Statements

MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF OPERATIONS

	<u>Year Ended</u> December 31, 2015	<u>Year Ended</u> December 31, 2014
Revenue, net	\$ 50,975	\$ -
Cost of products sold	13,037	-
Gross Profit	37,938	-
Research and development expenses	791,397	401,308
Expenses:		
Shared services	149,862	394,720
Depreciation	57,094	16,621
General and administrative expenses	3,039,294	1,083,848
Total expenses	<u>4,037,646</u>	<u>1,896,497</u>
Net loss from operations	<u>(3,999,708)</u>	<u>(1,896,497)</u>
Interest expense	(40,330)	(287)
Net loss	<u>\$ (4,040,038)</u>	<u>\$ (1,896,784)</u>

See Notes to Consolidated Financial Statements

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares (in thousands)	Amount			
Balance, January 1, 2014	22,000	\$ 2,200	\$ 6,126,835	\$ (2,435,057)	\$ 3,693,977
Contributed Capital-Milestone Scientific Inc Shared Service Expense	-	-	394,720	-	394,720
Contributed Capital-Fixed Assets, net	-	-	21,584	-	21,584
Net Loss	-	-	-	(1,896,784)	(1,896,784)
Balance, December 31, 2014	22,000	\$ 2,200	\$ 6,543,138	\$ (4,331,841)	\$ 2,213,497
Contributed Capital-Milestone Scientific, Inc. Shared Service Expense	-	-	149,862	-	149,862
Net Loss	-	-	-	(4,040,038)	(4,040,038)
Balance, December 31, 2015	22,000	\$ 2,200	\$ 6,693,000	\$ (8,371,879)	\$ (1,676,679)

See Notes to Consolidated Financial Statements

MILESTONE MEDICAL INC. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended	Year Ended
	December 31, 2015	December 31, 2014
Cash flows from operating activities:		
Net loss	\$ (4,040,038)	\$ (1,896,784)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	57,094	16,621
Contributed capital - Milestone Scientific, Inc. shared services expense	149,862	394,720
Changes in operating assets and liabilities:		
Increase in accounts receivable	(45,075)	-
Increase in inventories	(840,717)	(45,244)
Decrease in advances to contractors	326,706	1,844
Increase to prepaid expenses and other current assets	44,269	(82,080)
Increase due to related party	498,453	500,000
(Decrease) Increase in accounts payable and accrued expenses	352,997	336,692
Net cash from operating activities	(3,496,450)	(774,231)
Cash flows from investing activities:		
Purchase of equipment	(82,363)	(27,644)
Net cash from investing activities	(82,363)	(27,644)
Cash flows from financing activities:		
Proceeds from Line of credit	2,500,000	-
Net cash from financing activities	2,500,000	-
NET (DECREASE) INCREASE IN CASH	(1,078,813)	(801,875)
Cash at beginning of year	1,080,035	1,881,910
Cash at end of year	\$ 1,222	\$ 1,080,035
Supplemental disclosure of non cash activities:		
Contributed Capital - Milestone Scientific, Inc. Shared Services Expense	\$ 149,862	\$ 394,720
Contributed Capital-Fixed Assets, net	\$ -	\$ 21,584

See Notes to Consolidated Financial Statements

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**NOTE 1 - ORGANIZATION:**

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In March 2011, Milestone Medical Inc. (the “Company”) was organized pursuant to a joint venture agreement (the “Joint Venture Agreement”) between Milestone Scientific, Inc., a Delaware corporation, and Beijing 3H Scientific Technology Co., Ltd. (“Beijing 3H”), a People’s Republic of China (“PRC”) Company. At inception, Milestone Scientific, Inc. contributed an exclusive worldwide royalty-free license for the development and commercialization of intra-articular and epidural drug delivery instruments, utilizing its patented CompuFlo technology. Additionally, Beijing 3H, a shareholder of Milestone Scientific, Inc. contributed \$1.5 million to the Company.

In September 2014, the Company established a special purpose Polish company called Milestone Medical Poland Sp. z.o.o. The purpose of which is for the application and acceptance of Polish Government Grants for research and development of current and future improvement to the epidural and intra-articular instruments. Milestone Medical Poland S.P. z.o.o., is seventy – five percent owned by the Company. As of December 31, 2015, Milestone Medical Poland S.P. z.o.o. has not received any grants from the Polish Government.

As of December 31, 2015, the Company has not yet obtained U.S. Food and Drug Administration (“FDA”) regulatory clearance. However as of September 2014, the company did receive European Union (CE) clearance to market the instruments in the European Market. The Company is now awaiting final regulatory marketing clearance in the U.S. by the FDA. In 2014, the Company began to commercially market the instruments with the commitment to purchase 500 instruments (250 epidural and 250 intra-articular instruments) from the instrument manufacturer. All 500 instruments were delivered by September 30, 2015. In the interim of receiving final FDA approval, introductory meetings are being held with medical device distributors within the foreign market. The first two instruments (epidural) were shipped to a Polish distributor in June 2015, an Italian distributor was shipped five epidural instruments in September 2015. Once the Company’s planned principal operations commence, its focus will be on marketing its two instruments throughout the world.

Although the Company’s instruments have progressed beyond the development stage, additional equity financing will be necessary to fund final regulatory approval and commercialization of the medical instruments. To this end, the Company is currently in the process of pursuing an additional equity financing through a public offering in Poland, in 2016.

In December 2015, the company obtained approval of a Prospectus filed with the regulatory authority in Poland to raise \$4 million of capital, and to uplist the Company to the Warsaw Stock Exchange from the New Connect Market (Alternative Trading System). The company eventually cancelled the offering launched in 2015, but is expecting to continue its capital raising activities in 2016.

Milestone Medical Inc has incurred significant operating losses since its inception as a development company. Milestone Medical Inc had negative cash flows from operating activities for the twelve months ending December 31, 2015 of approximately \$3,496,000. At December 31, 2015 Milestone Medical Inc had cash of \$1,222 and a negative working capital of approximately \$3,296,000 as compared to positive working capital of \$620,000 at December 31, 2014. The working capital decreased by \$2,676,000 as compared to December 31, 2014. The change in working capital is primarily due to a decrease in cash, increase in accounts receivable and inventories, decrease in advances on contract and a significant increase in current liabilities. Milestone Medical’s management continues to examine all areas of the business to manage its cash flow. Milestone Medical Inc is actively pursuing the generation of positive cash flows from operating activities through an increase in revenue based upon management’s assessment of present contracts for delivery of epidural and intra-articular instruments to both customers in EU countries and for obtaining FDA clearance in the United States.

As of December 31, 2015, Milestone Medical Inc believes that it does not have sufficient cash reserves or collections of accounts receivable to meet all of its anticipated obligations for the next twelve months. Milestone Medical Inc will continue to manage its cash position while taking strategic steps to finalize the clinical studies and to expand its business in the medical business sectors.

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

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**Basis of Presentation**

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

**Basis of Consolidation**

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

**Cash and Cash Equivalents**

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

**Accounts Receivable**

Milestone Medical Inc. records accounts receivable at estimated net realizable value, and closely monitors the extension of credit to its customers while maintaining allowances, if necessary, for potential credit losses. On a periodic basis, Milestone Medical Inc. evaluates its accounts receivable and establishes an allowance for doubtful accounts, based on a history of past write-offs and collections and current credit conditions. Management has provided a reserve that it believes is sufficient to record accounts receivable at net realizable value as of December 31, 2015, and 2014 respectively.

**Inventory**

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

**Use of Estimates**

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

**Advances to Contractors**

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

**Equipment**

Equipment (molds for pre-production and commercialized instruments) is recorded at cost, less accumulated depreciation. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets, which is five years. The depreciation expense was approximately \$57,000 and \$17,000 year ended December 31, 2015 and December 31, 2014, respectively. The costs of maintenance and repairs are charged to operations as incurred.

**Revenue Recognition**

Revenue from product sales is recognized net of discounts and allowances to domestic 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 is 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's estimated useful life will be based on the average remaining life of the underlying patents. Currently the remaining useful life of the patents is approximately 9.5 years. The Company assesses the intangible asset for impairment at each reporting period or sooner if there are indicators that trigger an earlier assessment. The Company's impairment assessment is based on several factors including the progress made in developing the two medical instruments, the results from the research performed by the vendor, the Company's ability to use its technical capabilities to forecast the outcome of the research being performed and more recently feedback received from professionals as the Company applies for FDA clearance. CE clearance was received in September 2014. All these factors indicate that the technology continues to be feasible to be used in the two instruments being developed. Accordingly, no impairment has been recorded in these financial statements for the periods being reported.

### **Research and Development**

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

### **Income Taxes**

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

### **Services Provided by Stockholder**

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

### **Accounting for Uncertain Tax Positions**

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

At December 31, 2015, no significant income tax uncertainties have been included in the Company's financial statements. The Company's policy is to recognize interest and penalties on unrecognized tax benefits in income tax expense in the statement of operations. Tax returns since inception are subject to audit by federal and state jurisdictions.



### Recent Accounting Pronouncements

In May 2014, the 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. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

In June 2014, the FASB issued guidance for stock compensation which requires that a performance target that affects vesting of share-based payments and that could be achieved after the requisite service period be treated as a performance condition that affects vesting and as such, should not be reflected in estimating the grant-date fair value of the award. The guidance is effective for annual and interim periods beginning after December 15, 2015. This standard is not expected to have a material effect on the Company's financial position, results of operations or cash flows.

In July 2015, the FASB issued guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The guidance is effective for reporting periods beginning after December 15, 2016. The guidance should be applied prospectively, with earlier application permitted. We will adopt the guidance as of January 1, 2016, on a prospective basis. The adoption of this new guidance is not expected to have a material impact on our financial statements.

In November 2015, the Financial Accounting Standards Board ("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. As of December 31, 2015 and 2014, there are no deferred tax assets or liabilities recorded.

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on its results of operations, financial position, or cash flows.

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### NOTE 3 - JOINT VENTURE AGREEMENT:

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Pursuant to the Joint Venture Agreement, Milestone Scientific, Inc. contributed an exclusive worldwide royalty-free license for the development and commercialization of intra-articular and epidural drug delivery instruments, utilizing its patented CompuFlo technology and a group of individual investors contributed \$1.5 million to the Company. At inception, the Company reviewed this transaction to assess the technological feasibility of the products being developed. Based on the following factors, the Company believed the technology was feasible from inception.

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

Milestone Scientific, Inc. was authorized by the Joint Venture Agreement to manage and oversee the development of the two medical instruments for the Company. In connection with this, Milestone Scientific, Inc. entered into an



agreement with a vendor to develop the two instruments. Milestone Scientific, Inc. personnel monitored the development of the instruments with the third party vendors on a periodic basis thus ensuring that the instruments are being developed according to medical standards.

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

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**NOTE 4 - 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. Borrowers under the line bear interest is being charged at a rate of 3.25%, the prime rate at the inception of the agreement. In September 2015, the company requested and received approval from the Board of Directors of Milestone Scientific Inc. to increase the limit of the line of credit to a maximum of \$2.5 million (an increase of \$500,000). As of December 31, 2015, Milestone Scientific, Inc. has advanced \$2,500,000 to Milestone Medical. In January 2016, the credit agreement was increased by \$300,000 to \$2.8 million. All other terms in the line of credit agreement remain unchanged. Milestone Scientific Inc is not legally obligated to provide any funding to Milestone Medical Inc.

The shared expenses relate to the management, financial, engineering and accounting services provided by the staff of Milestone Scientific Inc. These expenses relate to the costs incurred related to obtaining CE and FDA approval and represent additional contributions from Milestone Scientific. The shared expenses for the years ended December 31, 2015 and 2014 were approximately \$150,000 and \$395,000 respectively.

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

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**NOTE 5 - PROVISION FOR INCOME TAXES:**

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The Company has loss carry-forwards which can be used to offset future taxable income. The loss carry-forwards, which will begin to expire through 2035, total approximately \$8,000,000 and \$4,200,000 at December 31, 2015 and 2014, respectively, for federal and state income taxes. Additionally, the Company has tax credits which can be used to offset future federal tax liabilities. Such tax credits amounted to approximately \$215,000 and \$136,000 at December 31, 2015 and 2014, respectively. However, management does not believe any of the benefits attributed to the loss carry-forwards or tax credits to be currently realizable and has recorded a full valuation allowance of approximately \$3,400,000 and \$1,814,000 at December 31, 2015 and 2014, respectively. Accordingly, the financial statements do not reflect a current and/or deferred asset or benefit

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**NOTE 6 - CONCENTRATIONS:**

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The Company sub-contracts its research and development to a vendor which accounted for 20% and 21% of total expenses incurred for the year ended December 31, 2015, and 2014, respectively. If the vendor or the Company terminated the current arrangement, additional expenses may be incurred for further research and development to occur. As of December 31, 2015, distributors in Italy and Poland represented 56%, and 32% of revenue, respectively. As of December 31, 2015, there are no known circumstances which would lead to termination by either party.

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**NOTE 7 - COMMITMENTS AND OTHERS:**

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In July 2013, Milestone Scientific, Inc. (as an agent for Milestone Medical Inc.), entered a strategic partnership with the largest provider of specialty sales and distribution solutions for healthcare in the United States. During the three year strategic partnership, the distributor will hold the exclusive rights to market, resell, label and distribute Milestone's CompuFlo injection technology for use in epidural applications for childbirth and other pain management



needs in hospitals in the U.S. This agreement was terminated in June 2015, due to a delay in receiving FDA clearance on the epidural instrument.

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**NOTE 8 - SUBSEQUENT EVENT**

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

## **6. REPORT ON MILESTONE MEDICAL INC. AND SUBSIDIARY'S ACTIVITIES IN YEAR 2015**

During the year ending December 31, 2015, Milestone Medical Inc. ("Issuer") and Milestone Scientific Inc. ("Controlling Entity") continued the process of obtaining regulatory clearance for the two medical instruments (Epidural and Intra-Articular Injections Systems) in the United States of America (USA). The regulatory approval process for the USA (FDA), is moving forward. As of December 31, 2015 the Issuer is in the process of clinical studies at several premier sites in the USA. Successful completion of the studies is a necessary step in obtaining FDA clearance to market the instrument in the USA. The Issuer received CE clearance for both instruments in September 2014. The Company employed three full time employees in 2015; President, a Director of Sales and Business Development and an instrument trainer (the Director of Sales and instrument trainer are open as of December 31, 2015). Currently the Company has one full time employee, the President. The President is supported by a Business Development Consultant for the European and Middle Eastern markets. Additionally the President is supported by a full time Senior Brand Manager and the staff of Milestone Scientific Inc. Additionally, the Company is continuing its efforts to identify and meet with potential distributors for both instruments throughout the world. The Issuer's President and the Business Development Consultant are actively pursuing distribution partners. As a result of the above activities performed by the Issuer, the Issuer during the second quarter of 2015 signed a Memorandum of Understanding with Fidia Farmaceutici SpA ("Fidia"), a specialty pharmaceutical company based in Italy, for the co-development and manufacture of a custom intra-articular drug delivery instrument for Fidia's hyaluronic acid formulations. Additionally, during the second quarter of 2015 the Company reported on EBI report no. 25/2015 published on June 10, 2015 that a medical distributor in Italy, Moss S.P.A. agreed to a three year agreement that included minimum purchases of the epidural instrument and disposals for the Italian market.

In the second quarter of 2015, the Issuer also commenced the first shipments of its CompuFlo™ Epidural Instrument to distributors and key opinion leaders in Europe. Since receiving CE Mark marketing clearance for the Issuer epidural instrument, the Issuer has been in negotiations with distributors in a number of countries in Europe and the Middle East and, as previously announced, signed an exclusive agreement with TRIMED Sp.z.o.o. ("Trimed"), one of the largest distributors of diagnostic equipment in Poland. Trimed has purchased a small number of instruments, initially for internal use and training purposes as it ramps up for a formal launch later this year.

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

For the year ended, December 31, 2015, the Issuer has generated a net loss of approximately \$4,040,000. This loss was caused mainly due to a high level of general and administrative expenses, which amounted to approximately \$3,039,000. These expenses were incurred due to the continued process of clinical studies in the USA and the market and commercialization of the instruments in Europe.

### **6.1. Description of basic exposures and risks**

The Issuer, in 2015, emerged as a Commercial company with revenue. However, there are several risk areas that are identifiable:

1. Instrument commercialization delays; the two instruments have passed this risk feature with the instruments finalized by the third party developer and the instruments submitted for regulatory approval; the (FDA); additionally, the Issuer is moving forward in Europe for distribution partners in several countries for the epidural and intra-articular instruments;
2. The instruments will not receive regulatory approval; the core software included in each instrument has already received approval in the USA (FDA) for a dental instrument. Therefore, management believes that this risk has been significantly mitigated. Additionally, the European Union has gain marketing clearance to both instruments (CE) in September 2014;
3. The instruments will not attract medical device distributors to sell the instruments; the distributor agreements have been signed in Italy and Poland. Therefore management believes that this risk has been mitigated.

4. The Issuer may not be able to obtain financing or raise capital to continue in existence; The Issuer is exploring several means of additional loans, a capital raise, or other financing alternatives. In the meantime, Milestone Scientific Inc. is supporting the expenses of the Issuer on a limited basis until alternative financing is available.

In all, the Issuer has identified the business risks as noted above and attempted to mitigate these risks.

## 6.2. Characteristic of the structure of assets and liabilities of the consolidated balance sheet, also from the perspective of liquidity of the Company and Subsidiary

The value of the Issuer's total assets for the period covered by the consolidated financial information decreased from approximately \$3.2 million in year ended December 31, 2014 to \$2.6 million in year ended December 31, 2015. At the end of year 2015, the balance sheet in total was lower by approximately 16% in comparison to year 2014.

During years 2015 and 2014 the assets' structure has changed significantly. In 2015 nearly 57% of total assets were intangible assets, primarily for royalty – free license to use Milestone Scientific's patented CompuFlo Technology. These rights were valued initially at \$1.5 million for the remaining 50% ownership interest in the Company (the valuation was made by Tinari Economics Group, an independent valuation company, which certified that the valuation and analysis was completed in accordance with the National Association of Certified Valuators and Analysts Professional Standards). The second major decrease in the asset in 2015 compared to 2014 was a decrease of over \$1 million in cash as a result of our operations. The cash balance of \$1,222 is a critical issue for the Company moving into 2016.

**Table 6: The structure of the Company's assets for each of historical financial year (in US Dollars)**

	Year ended December 31, 2015	Year ended December 31, 2014
<b>Current Assets</b>	<b><u>1,018,419</u></b>	<b><u>1,582,415</u></b>
Cash	1,222	1,080,035
Accounts receivable	45,075	-
Prepaid expenses and other current assets	42,637	86,906
Inventory	885,961	45,244
Advances to contractors	43,524	370,230
<u>Equipment, net of accumulated depreciation</u>	119,006	93,737
<b>Intangible Assets</b>	<b>1,500,000</b>	<b>1,500,000</b>
<b>TOTAL ASSETS</b>	<b><u>2,637,425</u></b>	<b><u>3,176,152</u></b>

Source: the Issuer

During 2015, the main source of the Issuer's financing was borrowing from Milestone Scientific Inc. not equity. In November 2013, the Issuer raised \$2,363,206 in net proceeds (gross funding was \$3 million) through a private placement offering. The offering resulted in the issuance of 2 million shares of common stock at \$1.50(4.65 PLN) per share in a private placement in Poland. As a result of the offering and the receipt of the net proceeds, the Issuer believed it would have sufficient cash flow to continue on its plan for the commercialization of the medical instruments. However delays and additional costs in obtaining FDA clearance required a second capital raise in November and December 2015. However due to a slow-down in the capital markets in late 2015, the Issuer delayed the capital raise until 2016 and cancelled the offering. The Issuer intends to slow its' cost structure until the next capital raise.

In years ended December 31, 2015 and 2014, the Issuer had no long-term debt or any other long-term liabilities. The Company had only current liabilities (accounts payable, accrued expenses, line of credit and advances for Milestone Scientific Inc. in the amount of approximately \$4,300,000 in year ended December 31, 2015 and approximately \$963,000 in the year ended December 31, 2014. The substantial increase in current liabilities is primarily due to the

costs related to the delay in finalizing the clinical studies in the USA and the resulting delay in obtaining FDA clearance.

Below the Company presents the structure of the Company's liabilities and stockholders' equity.

**Table 7: The structure of the Company's liabilities (in US Dollars)**

	Year ended December 31, 2015	Year ended December 31, 2014
<b><u>Current Liabilities</u></b>	<b><u>4,314,104</u></b>	<b><u>962,655</u></b>
Accounts payable and accrued expenses	815,651	462,655
<b><u>Commitments and Contingencies</u></b>	<b><u>3,498,453</u></b>	<b><u>500,000</u></b>
<b>TOTAL LIABILITIES</b>	<b>4,314,104</b>	<b>962,655</b>

Source: the Issuer

The \$3,498,453 includes \$2.5 million of advances on a line of credit established by Milestone Scientific Inc, and \$998,453 of other advances prior to the line of credit began established.

**Table 8: The structure of the Company's stockholders' equity on basis of historical financial information (in US Dollars)**

1. Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at December 31, 2015 and December 31, 2014	2,200	2,200
2. Additional paid in capital	6,693,000	6,543,138
3. Accumulated deficit during the development stage	(8,371,879)	(4,331,841)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>(1,676,679)</b>	<b>2,213,497</b>

Source: the Issuer

**Liquidity analysis**

All liquidity ratios decreased in year ended December 31, 2015 in comparison to year ended December 31, 2014. As of December 31, 2014, the Issuer had lower level of total current liabilities and more cash that resulted in a higher liquidity ratio. The reduction in the liquidity ratios in 2015 was primarily caused by a significant increase in total current liabilities (from approximately \$963,000 in 2014 to approximately \$4,300,000 in 2015) due to an increase in research and development costs, general and administrative cost for clinical studies, marketing expenses and shared services expenses incurred and not paid by year end and the fact that the Company received \$500,000 from a related party in error in December 2014 - such amount is included in cash and accounts payable and accrued expenses at December 31, 2014. The \$500,000 was returned to the affiliate in January 2015. Also, cash decreased by approximately \$1,079,000. The decrease in the value of all liquidity ratios were significant in 2015 compared to 2014. As described above due to the increase net loss for the Issuer in 2015.

**Table 9: Basic liquidity ratios of the Company**

	Year ended December 31, 2015	Year ended December 31, 2014
Current ratio (CR)	0.24	1.64
Quick ratio (QR)	0.23	1.55
Cash ratio	0.00	1.12

Source: the Issuer

The algorithm of above ratios' calculation was:

Current ratio (CR)	=	Total current assets/Total current liabilities
Quick ratio (QR)	=	(Total current assets – Prepaid expenses and other current assets)/Total current liabilities
Cash ratio	=	Cash and cash equivalents/Total current liabilities

**6.3. Major circumstances or events that significantly affect the activities and financial results of the Company’s group during the financial year, or that may affect them in the coming year.**

In December 2015, the Issuer obtained approval of a Prospectus filed with the regulatory authority in Poland to raise an additional \$4.0 million of capital, and to uplist the Issuer to the Warsaw Stock Exchange from the New Connect Market (Alternative Trading System). The Issuer is expecting to continue its capital raising activities, as the financial conditions improve in Poland.

**6.4. Description of the structure of main equity deposits or main capital investments made within the Company’s group during the financial year.**

The Issuer has expensed approximately \$791,397 in research and development for the two instruments in 2015. With the CE clearance to market both instruments in the European Union (“EU”) beginning September 2014, our investment in both instruments was realized in a limited number of instrument sales in 2015. The Issuer plans to expand its marketing efforts in the CE authorized countries in Europe and the Middle East in 2016.

**6.5. Description of organization of the Company’s group and indication of unites being consolidated as well as description of organizational changes in the Company’s group.**

Up to the date of this report completion, the Company does have a special purpose subsidiary, the purpose of which 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 Company presents some basic information about its subsidiary:

**Table 10: General information about subsidiary of the Company**

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.

**6.6. Description of the development policy of the Company’s group.**

The Company continues to work on obtaining FDA approval for both instruments in the United States. This process is moving steadily forward. Currently, clinical studies are being processed at five major medical facilities in the USA. Over 340 patients have completed the process. The remaining patients of approximately 60 are expected to complete the study in the first and second quarter of 2016.

**6.7. Description of material off-balance sheet items in terms of the entity, subject and value.**

There are no off - balance sheet investment or liabilities for Milestone Medical Inc.

**6.8 Remuneration to Directors and Officers**



The Issuer does not pay any remuneration for their service provided. The Officers of the Company were paid through charges amounting to; Chief Executive Officer \$150,600 President \$ 204,187, and Chief Financial Officer \$55,957 in 2015.

**7. REPORT WITH THE OPINION ON AUDIT OF ANNUAL CONSOLIDATED FINANCIAL STATEMENTS**

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM





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bakertilly.com

## INDEPENDENT AUDITORS' REPORT

To the Shareholders and Board of Directors  
Milestone Medical, Inc.  
Livingston, New Jersey

We have audited the accompanying consolidated balance sheets of Milestone Medical, Inc. and Subsidiary (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, changes in stockholders' (deficit) equity, and cash flows for the years then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of the Company's internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Milestone Medical, Inc. as of December 31, 2015 and 2014 and the results of their consolidated operations and cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

*Baker Tilly Virchow Krause, LLP*

New York, New York  
April 15, 2016

## 8. APPLICATION OF CORPORATE GOVERNANCE RULES

According to the paragraph 6.3 of the Exhibit 3 to the Alternative Trading System Rules “Current and Periodical Information in the Alternative Trading System on the NewConnect Market”, Board of Directors of Milestone Medical include its statement on compliance with "Best Practices of Companies Listed on the NewConnect" contained in Annex 1 of Resolution No. 795/2008 of the Management Board of the Stock Exchange in Warsaw SA of 31 October 2008 and its subsequent amendments in whole year 2015.

**Statement of Milestone Medical Inc. (“the Company”) on  
Compliance by the Company with "Best Practices of Companies Listed on the NewConnect"  
Contained in Annex 1 of Resolution No. 795/2008 of the Management Board of the Stock Exchange in Warsaw  
SA of 31 October 2008 and its subsequent amendments.**

No	RULE	YES/NO/NOT APPLICABLE	COMMENTS
1.	The Company should pursue a transparent and effective information policy, using both traditional methods and modern technologies, Ensuring fast, secure and convenient access to information. The Company using the fullest extent of these methods should ensure adequate communication with investors and analysts, line broadcasts of General Meetings over the Internet, record meetings and publish it on a website.	YES	The Issuer shall apply this practice with an exception of broadcast and publication of General Meetings over the Internet, since in the opinion of the Company's use of this practice will not bring benefits compared to the projected costs of such proceedings.
2.	The Company should ensure effective access to information necessary to assess the company’s situation and outlook as well as its operations.	YES	
3.	The Company should maintain a corporate website and publish:		
	3.1 Basic information about the Company and its business (home page);	YES	
	3.2. Description of the Issuer’s business including indication of the Issuer’s business segment generating the highest revenue;	YES	In 2015 and currently, the Issuer began to generate revenue. Additionally the Company has only one business segment.
	3.3 Description of the issuer’s market including indication of the Issuer’s market position;	YES	The Issuer applies this practice with an exception of indication of the Company’s market position.
	3.4 Professional CVs of the members of the company’s governing bodies;	YES	
	3.5. Information known to the Management Board based on a statement by a member of the Supervisory Board on any relationship of a member of the Supervisory Board with a shareholder who holds shares representing not less than 5% of all votes at the Company’s General Meeting;	NOT APPLICABLE	The Company has no Supervisory Board, all important relations between the Issuer and members of the Issuer’s Board of Directors and Executive Officers and the Company’s significant shareholders are indicated in the Issuer’s Information Document in Chapter 4.11.1 and 4.11.2
3.6 Corporate documents of the Company;	NO	During 2015, the Company didn’t place	

			such documents
	3.7. Outline of the Company's strategic plans;	YES	Strategic plans of the Company were placed in Chapter 4.12.11 of Information Document
	3.8. Published financial forecasts for the current financial year including their assumptions and adjustments of such targets (if targets are published by the Issuer);	NO	The Issuer did not publish financial forecasts. When the Company decides to publish financial forecasts, it will apply this practice.
	3.9. The issuer's shareholding structure including indication of the main shareholders and free-float shares;	YES	
	3.10 Personal and contact data for the Company's officer responsible for investor relations and media contacts;	YES	
	3.11. [deleted]	-	
	3.12. Published current and periodic reports;	YES	On Milestone Medical website there is a direct link to website of GPWInfoStrefa.pl, where all reports are published
	3.13. Dates of planned publication of periodic financial reports, General Meetings, meetings with investors and analysts and press conferences;	YES	
	3.14. Information on corporate events such as payment of the dividend, or other events leading to the acquisition or limitation of rights of a shareholder, including the deadlines and principles of such operations. Such information should be published within a timeframe enabling investors to make investment decisions;	NOT APPLICABLE	In future, the Company will disclose if applicable
	3.15. [deleted]	-	
	3.16. Shareholders' questions on issues on the agenda submitted before and during a General Meeting together with answers to those questions;	NOT APPLICABLE	Yes, if will be applicable
	3.17. Information about the reasons for cancellation of a General Meeting, change of its date or agenda together with grounds;	NOT APPLICABLE	Yes, if will be applicable
	3.18. Information about breaks in a General Meeting and the grounds of those breaks;	NOT APPLICABLE	Yes, if will be applicable
	3.19. Information about the entity which signed an Authorized Adviser Service Agreement with the Company, including the name, the website address, telephone numbers and e-mail addresses of the Adviser;	YES	
	3.20. Information about the entity acting as animator of the Issuer's shares;	YES	
	3.21. Information document (issue prospectus) of the Company published within the last 12 months;	YES	
	3.22. [deleted]	-	
	Information presented on the website should be provided in a way enabling easy access to such information. The Issuer should update information presented on the website. If new significant information is available or information presented on the website changes significantly, it should be updated immediately.	YES	The Company has sometimes delays in immediate actualization of its corporate website but the Issuer is making great efforts to make such actualization on timely basis.
4.	The Company should publish its corporate website in Polish or in	YES	

	English, at the Issuer's discretion. Current and periodic reports should be published on the website in the same language in which they are published according to regulations applicable to the Issuer.		
5.	The Company should pursue an information policy with a particular emphasis on the needs of individual investors. For this purpose, in addition to its corporate website, the Company should use its individual investor relations section on the website <a href="http://www.gpwinfostrefa.pl">www.gpwinfostrefa.pl</a>	YES	
6.	The Issuer should maintain ongoing contacts with representatives of the Authorized Adviser in order to enable it to properly perform its obligations towards the issuer. The Company should appoint a person responsible for contacts with the Authorized Adviser.	YES	
7.	If an event occurs in the Company which, in the opinion of the Issuer, has material significance to the performance of obligations by the Authorized Adviser, the Issuer should immediately inform the Authorized Adviser thereof.	YES	
8.	The Issuer should give the Authorized Adviser access to all documents and information necessary to perform the obligations of an Authorized Adviser. In the annual report the Issuer should publish:	YES	
9.	9.1. information about the total amount of remuneration of all members of the Management Board and the Supervisory Board	YES	The Issuer applies this practice with an exception of Supervisory Board since the Company does not have a Supervisory Board.
	9.2. information about the fee paid by the Issuer to the Authorized Adviser in respect of all services provided to the Issuer.	NO	The remuneration is regulated by an Agreement with Authorized Adviser and is confidential information. The Issuer cannot publish such data without Authorized Adviser permission.
10.	A General Meeting should be attended by members of the Management Board and the Supervisory Board who can answer questions asked at the General Meeting.	YES	The Issuer applies this practice with an exception of Supervisory Board since the Company does not have a Supervisory Board.
11.	The Issuer in cooperation with the Authorized Adviser should organize meetings with investors, analysts and the media open to the public at least 2 times per year.	YES	The Issuer organized at least 2 such meetings in year 2015.
12.	A resolution of the General Meeting concerning an issue of shares with subscription rights should specify the issue price or the mechanism setting it or obligate the competent body to set it before the date of subscription rights within a timeframe enabling an investment decision.	NOT APPLICABLE	Yes, if will be applicable
13.	Resolutions of the General Meeting should allow for a sufficient period of time between decisions causing specific corporate events and the date of setting the rights of shareholders pursuant to such events.	NOT APPLICABLE	Yes, if will be applicable

13a.	If the Management Board of the Issuer is notified by a shareholder who holds at least a half of the share capital or at least a half of all votes in the Company that the Issuer has convened an extraordinary General Meeting pursuant to Article 399 § 3 of the Code of Commercial Partnership and Companies, the Management Board of the Issuer shall immediately organizing and conducting a General Meeting. This principle shall also apply where the registration court authorizes shareholders to convene an extraordinary General Meeting pursuant to Article 400 § 3 of the Code of Commercial Partnership and Companies.	NOT APPLICABLE	Provisions of the Commercial Code do not apply to the Issuer.
14.	The date of setting the right to dividend and the date of dividend payment should be set so to ensure the shortest possible period between them, in each case not longer than 15 business days. A longer period between these dates requires detailed grounds.	NOT APPLICABLE	Yes, if will be applicable
15.	A resolution of the General Meeting concerning a conditional dividend payment may only contain such conditions whose potential fulfillment must take place before the date of setting the right to dividend.	NOT APPLICABLE	Yes, if will be applicable
16.	The Issuer should publish monthly reports within 14 days after the end of each month. Monthly reports should include at least the following: <ul style="list-style-type: none"> <li>• environment which, in the opinion of the Issuer, could in future have significant effects to the financial standing and the financial results of the Issuer;</li> <li>• list of all information published by the Issuer in the form of current reports in the reporting period;</li> <li>• information about achievement of the goals of an issue if they were achieved at least partly in the reporting period;</li> <li>• dates important to investors including events planned in the coming month concerning the Issuer and important from the perspective of investor rights, including in particular dates of publication of periodic reports, planned General Meetings, opening of subscriptions, meetings with investors or analysts and expected dates of publication of analytical report</li> </ul>	NO	At the moment, this principle is not applied by the Issuer. Due to the fact that the report published current and periodic provide shareholders and investors with access to a complete and sufficient information giving a complete picture of the situation, the Management Board of the Issuer does not see the need at the moment of publication of monthly reports.
16a.	If the Issuer is in breach of the reporting obligation set out in Exhibit 3 to the Alternative Trading System Rules (“Current and Periodical Information in Alternative Trading System on the NewConnect Market”), the Issuer shall immediately publish information explaining the situation pursuant to the procedure applicable to providing current reports on the NewConnect market.	YES	

Leonard A. Osser,  
Chief Executive Officer

Joseph D’Agostino  
Chief Financial Officer