# Consolidated report of

# MILESTONE MEDICAL INC. and its SUBSIDIARY

# For the Year Ended December 31, 2017

# Report include:

- 1. General information about Milestone Medical Inc ("Issuer") and Milestone Medical Poland Sp. Z o.o. (the Subsidiary).
- 2. Consolidated 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, 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, March 21, 2018

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

To Our Valued Shareholders,

2017 was a transformative year for Milestone Medical. First, we announced that the CompuFlo® Epidural Computer Controlled Anesthesia System received 510(k) clearances from the U.S. Food and Drug Administration (FDA), which is considered globally to be the regulatory gold standard.

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.

Immediately following regulatory approval in the U.S., we announced that the first patient in the U.S was successfully treated with the CompuFlo® Epidural Instrument at the University of Miami Hospital. In fact, the CompuFlo® Epidural System has now been successfully utilized in over 750 epidural procedures, including both labor and delivery, as well as pain management, with zero complications reported. The CompuFlo® Epidural System has been deployed in a variety of settings at leading institutions in the U.S., Europe and South America.

We are now focused on reaching out to the top key opinion leaders (KOL) in the U.S., as we have been doing successfully across Europe. As evidence our KOL strategy is working, our product is now being featured at leading industry conferences. We recently announced that an abstract featuring the CompuFlo® epidural instrument was presented on September 13, 2017 at the 36th Annual European Society of Regional Anesthesia & Pain Therapy (ESRA) Congress 2017, in Lugano, Switzerland. The European Society of Regional Anesthesia & Pain Therapy has a current membership of over 3,500 of the leading anesthesiologists in Europe.

We were pleased to have our technology featured by a leading anesthesiologist at one of the premier industry conferences in Europe. This case report demonstrated the value and effectiveness of CompuFlo® in identifying and locating the epidural space, especially in complicated cases, such as the one in this case report. In this case, the standard loss of resistance technique not only failed to locate the epidural space, but also led to a complication, known as accidental epidural puncture, which caused the patient a severe headache that required a subsequent intervention. As a result, an epidural blood patch was successfully performed using the CompuFlo® instrument to repair the epidural defect. This is clear illustration of the mounting clinical experience with CompuFlo, as it continues to meet new challenges in difficult patients, demonstrating its value as an everyday epidural confirmation solution for all patients.

Shortly afterwards, we announced that Dr. Camila Gonzalez of Clinical Davila, Department of Anesthesiology at the University of Los Andes located in Bogota, Columbia, presented an abstract at the 45th Chilean Congress of Anesthesiology on November 11, 2017, entitled: "Utilization of dynamic pressure sensing in epidural puncture for labor."

The abstract summarizes the results of a new clinical study evaluating the use of Milestone's CompuFlo<sup>TM</sup> Epidural Instrument in 50 labor and delivery patients. Not only was the epidural space correctly identified in 100% of patients, but it was recognized on the first attempt. This represents a significant benefit for the payors, physicians, and most importantly, the patients. There were no cases of accidental puncture of the dura, a common risk factor for traditional epidural procedures using the loss of resistance technique.

Milestone Medical, Inc.

Additionally, in February and March 2018, Milestone Scientific Inc. added two key employees for Milestone Medical Inc. We added an Executive VP of Global Marketing and Sales and a Vice President of USA Sales. These two employees will promote direct market support for Milestone Medical and assist on moving the medical business forward on an accelerated track.

In summary, we have been successful in gaining marketing clearance and commencing the first phase leading up to the commercial launch of our CompuFlo<sup>TM</sup> Epidural Instrument. Following successful completion of the clinical trials, we are now gaining traction with KOLs. We expect to see the results of our trials published in leading industry journals in 2018, which should help drive market awareness and provide further validation. Heading into 2018, we look forward to beginning the launch process of our Intra-Articular Instrument.

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 - Interim 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 were prepared in accordance with accounting principles generally accepted in the United States of America and presents a true and fair view of the Company and its Subsidiary's financial results and that the report on the Company and its Subsidiary's activities are presented in a fair view of the Company and its Subsidiary's situation, including a description of basic exposures and risks.

As of December 31, 2017, the Company believes that it does not have sufficient cash reserves to meet all its anticipated obligations for the next twelve months, which raises substantial doubt regarding the Company's ability to continue as a going concern unless financing is achieved. The Company will continue to manage its cash position while taking strategic steps to finalize the clinical studies and market the products, to expand its business in the medical business sectors.

On behalf of the Board of Directors and management of the Company: Leonard Osser– Interim 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, Friedman LLP, which audited the annual consolidated financial statements, was selected by the Audit Committee effective May 23, 2017 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. Friedman LLP's report on the December 31, 2017 consolidated financial statements, included herein, expresses an unqualified opinion and includes explanatory paragraph referring to the substantial doubt regarding the Company's ability to continue as a going concern.

On behalf of the Board of Directors and management of the Company: Leonard Osser–Interim Chief Executive Officer

#### 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

# 3.1. 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 annual 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.	21,633,084	98.33%
OTHERS (<5%)	366,916	1.67%
TOTAL	22,000,000	100.00%

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 10,689,078 (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. After the exchange, Milestone Scientific will own approximately 98.59% of the shares in Milestone Medical.

#### 3.2. 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. In December 2017, Leonard Osser rejoined the Management of Milestone Medical Inc. as Interim Chief Executive Officer. The intention of the Company is to nominate Mr. Osser to the Board of Directors in 2018. Source: The Issuer

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

On December 31, 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 Vice President of Marketing. The Company has contracted with two Business development consultants for business activities in Europe and the Middle East in 2017. The open position is under review currently. Additionally, in February and March 2018, Milestone Scientific Inc. added two key employees for Milestone Medical Inc. We added an Executive VP of Global Marketing and Sales and a Vice President of USA Sales. These two employees will promote direct market support for Milestone Medical and assist on moving the medical business forward on an accelerated track.

# 4. SELECTED FINANCIAL INFORMATION

# 4.1. Selected financial data from Balance Sheet

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

31.12.2017: 1EUR = 1.1979 USD

31.12.2016: 1EUR = 1.0525 USD

Table 4 Selected consolidated financial data of the balance sheet of Milestone Medical as of December 31, 2017 with comparable consolidated data for year 2016.

Selected consolidated financial data from	US	SD	EUR	
the balance sheet	31.12.2017	31.12.2016	31.12.2017	31.12.2016
Total Assets	2,005,513	2,413,840	1,674,191	2,293,435
Cash	19,272	13,187	16,088	12,529
Prepaid expenses and other current assets	57,154	53,537	47,712	50,867
Inventory	500,313	741,392	417,658	704,410
Accounts receivable	-	-	-	-
Advance on contracts	44,148	44,148	36,854	41,947
Equipment, net	34,626	61,576	28,906	58,505
Intangible asset	1,350,000	1,500,000	1,126,972	1,425,178
Current Liabilities	9,425,303	7,273,278	7,868,188	6,910,478
Common Stock	2,200	2,200	1,837	2,090
Accumulated paid-in-capital	6,931,861	6,861,634	5,786,678	6,519,367
Accumulated deficit during the development stage	(14,353,851)	(11,723,272)	(11,982,512)	(11,138,501)
Stockholder's deficit	(7,419,790)	(4,859,438)	(6,193,998)	(4,617,043)

Source: The Issuer

# 4.2. Selected consolidated financial data from Statement of Operations

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

Table 5 Selected consolidated financial data of the statement of operations of Milestone Medical Inc. from January 1, 2017 to December 31, 2017 with comparable consolidated data for year 2016.

Selected consolidated financial data from	US	SD	EU	JR
Statement of Operations	31.12.2017	31.12.2016	31.12.2017	31.12.2016
Revenue	2,000	21,253	1,770	19,195
Cost of goods	220,183	12,183	194,852	11,003
Gross profit	(218,183)	9,070	(193,082)	8,192
Depreciation & amortization	176,949	62,720	156,592	56,647
Research and development expenses	124,820	509,797	110,460	460,438
Other expenses	2,019,191	2,693,084	1,786,895	2,432,337
Total expenses	2,320,960	3,265,601	2,053,947	2,949,423
Interest expense	92,936	92,861	82,244	83,870
Net loss before income tax	(2,632,079)	(3,349,392)	(2,329,273)	(3,025,101)
Provision from tax	(1,500)	2,000	(1,327)	1,806
Net loss	(2,630,579)	(3,351,392)	(2,327,946)	(3,026,908)

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

# CONSOLIDATED FINANCIAL STATEMENTS

For the Years ended December 31, 2017 and 2016

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To the Board of Directors and Stockholders of Milestone Medical, Inc.

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Milestone Medical, Inc. and subsidiary (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, statement of days in stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

# **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

#### **Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has recurring losses and negative cash flows from operations. These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to obtain financing, there could be a material adverse effect on the Company.

/s/ Friedman LLP

We have served as the Company's auditor since 2016.

East Hanover, New Jersey

March 21, 2018

# MILESTONE MEDICAL INC. AND SUBSIDIARY CONSOLIDATED BALANCE SHEETS

	December 31, 2017		December 31, 2016	
ASSETS				
Current Assets:				
Cash and cash equivalents	\$	19,272	\$	13,187
Inventories net of allowance for slow moving inventory		500,313		741,392
Advances on contracts		44,148		44,148
Prepaid expenses and other current assets		57,154		53,537
Total current assets		620,887		852,264
Equipment net of accumulated depreciation of \$211,989 as of December 31, 2017 and \$185,040 as of December 31, 2016		34,626		61,576
Intangible asset net of accumulated depreciation of \$150,000 as of December 31, 2017 and \$0 as of December 31, 2016		1,350,000		1,500,000
Total assets	\$	2,005,513	\$	2,413,840
LIABILITIES AND STOCKHOLDERS' DEFECIT		, , ,		, , ,
Current Liabilities:				
Accounts payable	\$	56,978	\$	183,095
Accrued expenses and other payables		445,258		432,313
Advances from Milestone Scientific Inc.		6,123,067		3,857,870
Due to Milestone Scientific, Inc.		2,800,000		2,800,000
Total current liabilities		9,425,303		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 December 31, 2017				
and December 31, 2016		2,200		2,200
Additional paid-in capital		6,931,861		6,861,634
Accumulated deficit		(14,353,851)		(11,723,272)
Total deficit		(17,333,031)		(11,123,212)
Total deliet		(7,419,790)		(4,859,438)
Total liabilities and stockholders' deficit	\$	2,005,513	\$	2,413,840

# MILESTONE MEDICAL INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	2017		2016	
Product sales, net	\$	2,000	\$	21,253
Cost of products sold		220,183		12,183
Gross profit		(218,183)		9,070
Selling, general and administrative expenses		1,948,964		2,524,450
Depreciation & amortization		176,949		62,720
Shared services		70,227		168,634
Research and development expenses		124,820		509,797
Total operating expenses		2,320,960		3,265,601
Loss from operations		(2,539,143)		(3,256,531)
Interest expense		(92,936)		(92,861)
Loss before income tax		(2,632,079)		(3,349,392)
Provision from tax		(1,500)		2,000
Net loss	\$	(2,630,579)	\$	(3,351,392)

# MILESTONE MEDICAL INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

Common Stock

	Shares	Ar	nount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, January 1, 2016	22,000	\$	2,200	\$ 6,693,000	\$ (8,371,880)	\$ (1,676,680)
Contributed capital- Milestone Scientific Inc. shared services exp	enses		_	168,634		168,634
Net loss					(3,351,392)	(3,351,392)
Balance, December 31, 2016	22,000	\$	2,200	\$ 6,861,634	\$ (11,723,272)	\$ (4,859,438)
Contributed capital- Milestone Scientific Inc. shared services exp	enses			70,227		70,227
Net loss					(2,630,579)	(2,630,579)
Balance, December 31, 2017	22,000	\$	2,200	\$ 6,931,861	\$ (14,353,851)	\$ (7,419,790)



# MILESTONE MEDICAL INC. AND SUBSIDIARY CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	2017		2016	
Cash flows from operating activities:				
Net loss	\$	(2,630,579)	\$	(3,351,392)
Adjustments to reconcile net cash (used in)				
operating activities:				
Depreciation expense		26,949		62,720
Amortization expense		150,000		-
Contributed capital - Milestone Scientific,				
Inc. shared services expense		70,227		168,634
Increase inventories allowance		219,834		-
Changes in operating assets and liabilities:				
Decrease in accounts receivable		-		45,075
Decrease in inventories		21,246		144,569
Decrease to advances on contracts		-		(624)
Increase to prepaid expenses and other				
current assets		(3,617)		(10,900)
Decrease in accounts payable and				
accrued expenses	_	(113,172)		(200,243)
Net cash (used in) operating activities		(2,259,112)	-	(3,142,161)
Cash flows from investing activities:				
Purchases of property and equipment				(5,290)
Net cash (used in) investing activities				(5,290)
Cash flows from financing activities:				
Increase due to related parties		2,265,197		2,859,416
Proceeds from line of credit		-		300,000
Net cash provided by investing activities		2,265,197		3,159,416
Net increase in cash and cash equivalents		6,085		11,965
Cash and cash equivalents at beginning of period		13,187		1,222
Cash and cash equivalents at end of period	\$	19,272	\$	13,187
			-	



# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS For twelve months ended December 31, 2017 and 2016

# **NOTE 1 – ORGANIZATION AND BUSINESS:**

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

In September 2014, the Company established a special purpose Polish company called Milestone Medical Poland Sp. z.o.o. The purpose of which is for the application and acceptance of Polish Government Grants for research and development of current and future improvement to the epidural and intra-articular instruments. Milestone Medical Poland Sp. z.o.o., is seventy – five percent owned by the Company. As of December 31, 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 currently.

On June 12, 2017 the company announced that the CompuFlo® Epidural Computer Controlled Anesthesia System has received 510(k) clearances 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) clearances. 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 intends to resubmit an application for a 510k to the FDA in the first half of 2018.

The Company is in the process of attending Medical device trade shows and attending 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 December 31, 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. Because of these exchanges, Milestone Scientific owns approximately 99% of Milestone Medical at December 31, 2017.

In March 2017 on the ESPI 3/2017 report the Company announced it has begun its clinical rollout for the epidural instrument in the Middle East and North Africa (MENA) regions, by initiating clinical evaluations at key hospitals in the United Arab Emirates and in Lebanon. Given the extensive published clinical data supporting successful epidural catheter placement in patients with complex 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, and Florence, 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 December 31, 2017 Milestone Medical Inc. had cash of \$19,272 and a negative working capital of \$8,804,416 as of December 31, 2017 compared to negative working capital of approximately \$6,421,000 at December 31, 2016.

As of December 31, 2017, Milestone Medical Inc. believes that it does not have sufficient cash to meet all its anticipated obligations for the next twelve months from the financial statement release date. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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.

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 and Cash Equivalents**

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

# **Inventory**

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or market. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess slow moving and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence and product expiration requirements.

#### **Use of Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles in the United States (GAAP) requires management to make estimates and assumptions in determining the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of Milestone Medical, Inc.

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the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to the allowance for doubtful accounts, inventory valuation, and cash flow assumptions regarding evaluations for impairment of long-lived assets, going concern considerations, and valuation allowances on deferred tax assets. Actual results could differ from those estimates.

#### Advances to Contractors

The advances to contractors represent funding to a subcontractor, for parts required for both epidural and intra articular instruments for the manufacturing of new instruments and repair parts.

# **Furniture, Fixture and Equipment**

Furniture, fixtures and equipment 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 range from two to seven years. The depreciation expense for the year ended December 31, 2017 and 2016 was \$26,949 and \$62,720, 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, since the shipment terms are FOB warehouse. Milestone Medical recognizes revenue on date of arrival of the goods at the customer's location, where shipments are FOB destination. In all cases the price to the buyer is fixed and the collectability is reasonably assured. Further, Milestone Medical has no obligation on these sales for any post installation, set-up or maintenance, these being the responsibility of the buyer.

# **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 began amortizing the intangible asset contributed when the first medical device supported by the intangible obtained final FDA approval, which occurred in June 2017 when the Epidural instrument received 510k clearance from the FDA. The asset's estimated useful life is 5 years based on the estimated useful life of the underlying patented technology. Intangibles are amortized utilizing the straight-line method over estimated useful of 5 years. Amortization expense was \$150,000 and \$0 for the year ended December 31, 2017 and 2016, respectively.

The Company assesses the intangible asset valuation when there is an indicator of impairment. During the year the Company assessed the intangible for impairment because the marketing efforts relating to the Medical instruments has not been fully realized and the cash flow expected following FDA approval has been delayed as a result. 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, recent feedback received from professionals and projected cash flows from the use of the royalty free right to use CompuFlo technology. No impairment has been recorded as of December 31, 2017 and December 31, 2016.

# **Research and Development**



Research and development costs, which consist principally of new product development costs payable to third parties, are expensed as incurred. Advance payments for the research are amortized to expense either as services are performed or over the relevant service period using the straight-line method.

#### **Income Taxes**

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

At December 31, 2017 and 2016, 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 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 Medical 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 June 2016, the FASB issued a new standard ASU No.2016-13, "Financial Instruments – Credit Losses" (Topic 326).: The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2018. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its financial position, results of operations and cash flows.



In August 2016, the FASB issued a new standard ASU No.2016-15, "Statement Cash Flows "Classification of Certain Cash Receipts and Cash Disbursements" Topic 230). The new standard provides guidance as to the conformity of presentation of certain cash receipts and disbursements. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017. Milestone Medical does not anticipate the adoption of this ASU will have a significant impact on its presentation within the statement of cash flows.

In November 2016, the FASB issued a new standard ASU No.2016-18, "Statement of Cash Flows – Restricted Cash" (Topic 230). The new standard provides guidance as to address the diversity of treatment of restricted cash on the statement of cash flows. It will be effective for all entities for fiscal years and interim periods, beginning after December 15, 2017 and interim periods therein. Milestone Medical does not expect the adoption of this ASU to have a material effect 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 Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

In July 2017, the FASB issued a new standard ASU No.2017-11, "Earnings Per Share" (Topic 260), "Distinguishing Liabilities from Equity" (Topic 480), "Derivatives and Hedging" (Topic 815). The new standard provides guidance relating to equity-linked instruments that include certain features. It will be effective for public entities for fiscal years and interim periods, beginning after December 15, 2018. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

In August 2017, the FASB issued a new standard ASU No.2017-12, "Derivatives and Hedging" (Topic 815). The new standard aligns the entity's risk management activities with the financial reporting for hedging relationships. It will be effective for public entities for fiscal years and interim periods, beginning after December 15, 2018. Milestone Medical is in the process of determining what impact, if any, the adoption of this ASU will have on its presentation within the statement of cash flows.

# **NOTE 4 - INVENTORY:**

Inventory as of December 31, 2017 and 2016 consistent of the following:

	2017	 2016
Inventories consist of the following:		
Epidural Instruments	240,918	276,751
Intra-articular instruments net allowance	234,367	458,310
Component parts and other materials	25,028	6,331
Total	\$ 500,313	\$ 741,392

The reserve against inventory was \$219,834 and \$0 for the years ended December 31, 2017 and 2016, respectively.

# **NOTE 5 - 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

Milestone Medical, Inc.



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 6 - 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 December 31, 2017, and 2016, Milestone Scientific, Inc. has advanced \$2,800,000 to Milestone Medical classified as Due to Milestone Scientific Inc. on the accompany Consolidated Balance Sheets. 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 technology underlying the CompuFlo®, and an improvement to the controls for CompuDent® were developed by the Director of Clinical Affairs and assigned to Milestone Scientific. Milestone Scientific purchased this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs will receive additional payments 5% of the total sales of products using certain other of the technologies until the expiration of the last patent carried by Milestone Scientific 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 twelve months ended December 31, 2017 and 2016 were approximately \$70,227 and \$168,634, respectively.

As of December 31, 2017, and 2016, the Company owes \$6,123,067 and \$3,857,870, respectively, to Milestone Scientific, Inc. for expenses paid on the Company's behalf. These advances are non-interest bearing.

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 December 31, 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. Because of these exchanges, Milestone Scientific owned approximately 99% of Milestone Medical at December 31, 2017.

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

Milestone Medical, Inc.

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consulting agreement, U.S. Asian Consulting Group, LLC, is entitled to receive \$100,000 per year for Mr. Osser's services. For the twelve months ended December 31, 2017, we expensed approximately \$50,000 relating to this agreement. On December 19, 2017 Mr. Osser placed on hold on his consulting agreement (US Asian Consulting Group. LLC) with Milestone Medical to rejoin Milestone Scientific Inc and Milestone Medical. as Interim Chief Executive Officer. Mr. Osser will not receive or earn any compensation under his consulting agreement during his appointed time as Interim CEO and the terms of the agreement will be adjusted once he is no longer Interim Chief Executive Officer.

# **NOTE 7 - 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 December 31, 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 twelve months ended December 31, 2017 and 2016, respectively. The epidural and intra-articular handpiece with needle components 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 because of termination of such a relationship, would adversely affect Milestone Medical.

# **NOTE 8 - 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 twelve months ended December 31, 2017, we expensed approximately \$50,000 relating to this agreement. On the same day Mr. Daniel Goldberger was appointed for the position of Chief Executive Officer of the Company.

On October 5, 2017, Daniel Goldberger had resigned as President and Chief Executive Officer effective October 2, 2017.

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

On December 18, 2017, the "Company" announced the appointment of Leonard Osser as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer, and announced that, to facilitate such appointment, Leslie Bernhard had resigned as the Company's Interim Chief Executive Officer effective immediately.

On December 19, 2017 the Board of Directors appointed Leonard Osser Interim Chief Executive Office, replacing Leslie Bernhard. Mr. Osser will enter into a similar employment contract that he received in 2017 before he resigned his position as CEO of the company. Mr. Osser placed on hold on his consulting agreement (US Asian Consulting Group. LLC) with Milestone Medical to rejoin Milestone Scientific Inc and Milestone Medical. as Interim Chief Executive Officer. Mr. Osser will not receive or earn any compensation under his consulting agreement during his appointed time as Interim CEO and the terms of Milestone Medical, Inc.

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the agreement will be adjusted once he is no longer Interim Chief Executive Officer.

# **NOTE 9 – SUBSEQUENT EVENT:**

After December 31, 2017 Milestone Scientific Inc., has advanced Milestone Medical approximately \$190,000 to continue the commercialization of the epidural and other expenses necessary for the day to day operations of Milestone Medical. Milestone Scientific Inc. is not legally obligated to loan additional funds to the Issuer. As such, the Issuer reduced its cash expenditure in 2018 and will continue to monitor expenses until additional capital has been raised or revenues increase to cover these costs.



# 6. REPORT ON MILESTONE MEDICAL INC. AND SUBSIDIARY'S ACTIVITIES IN YEAR 2017

During the second quarter, ending June 30, 2017 the Issuer and its Parent obtained USA (FDA) regulatory clearance to market the Epidural medical instrument. The resubmission 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, who also holds the same position in Milestone Scientific Inc; however, he provides essentially all his time to the Issuer. Additionally, in February and March 2018, Milestone Scientific Inc. added two key employees for Milestone Medical Inc. We added an Executive VP of Global Marketing and Sales and a Vice President of USA Sales. These two employees will promote direct market support for Milestone Medical and assist on moving the medical business forward on an accelerated track. 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 two contracted Business Development Representatives for Europe and the Middle East are actively pursuing distribution partners. The company added an additional Medical device consultant in March 2017, for the specific focus on our Intra Articular instrument in the European Market. Because of the above activities performed by the Issuer, the Company, during the second quarter 2015, signed a Memorandum of Understanding with Fidia Farmaceutici SpA ("Fidia"), a specialty pharmaceutical company based in Italy, for the co-development and manufacture of a custom intra-articular drug delivery instrument for Fidia's hyaluronic acid formulations. Additionally, during the second quarter of 2015 the Company reported on EBI report no. 25/2015 published on June 10, 2015 that a medical distributor in Italy, Moss S.P.A. agreed to a three-year agreement that included minimum purchases of the epidural instrument and disposals for the Italian market. Currently, Moss S.P.A. is continuing its distribution efforts in Italy with many hospitals. However, Moss S.P.A. has not signed any customer purchase agreements to date. As such Moss S.P.A. has not purchased any instruments under this agreement. In January 2018, the Company terminated its distribution agreement with Moss SpA. Shortly thereafter, the Company signed a new distribution agreement with Movi SpA for the distributing of the epidural instrument in Italy.

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

For the twelve months ended December 31, 2017 the Issuer and its Subsidiary have generated a net loss of \$2,630,579. This loss was due to research and development costs of \$124,820 and to a high level of general and administrative and other expenses, which amounted to \$1,948,964. 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 and will continue to monitor expenses 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 December 31, 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 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 owns 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 98.33% 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.

On December 18, 2017, Milestone Scientific Inc. (the "Company") announced the appointment of Leonard Osser as the Company's Interim Chief Executive Officer, to serve in such role until the appointment of a new Chief Executive Officer, and announced that, to facilitate such appointment, Leslie Bernhard had resigned as the Company's Interim Chief Executive Officer effective immediately. Mr. Osser placed on hold on his consulting agreement (US Asian Consulting Group. LLC) with Milestone Medical to rejoin Milestone Scientific Inc and Milestone Medical. as Interim Chief Executive Officer.

# 6.1. Description of basic exposures and risks

The Issuer, in 2017, emerged as a Commercial company with approval from FDA. 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 clearance in the USA and in Europe. Additionally, the Issuer is moving forward in Europe for distribution partners in several countries for the epidural and intra-articular instruments; and the Issuer is moving forward for distribution partners in the USA for Epidural.
- 2. The instruments will not receive regulatory approval; the core software included in each instrument has already received approval in the USA (FDA) and in Europe (CE) for a dental instrument. Therefore, management believes that this risk has been significantly mitigated. Additionally, the Company has gained marketing clearance to both instruments (CE) in the European Union during September 2014; and FDA clearance for the Epidural Instrument in June 2017.
- 3. The instruments will not attract medical device distributors to sell the instruments; the distributor agreement have been signed in Italy. 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 to approximately \$2.0 million in year ended December 31, 2017 from \$2.4 million in year ended December 31, 2016. At the end of year 2017, the balance sheet in total was lower by approximately 14% in comparison to year 2016.

During years 2017 and 2016 the assets' structure was similar. In 2017 nearly 67% 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 major decrease in the asset in 2017 compared to 2016 was a net intangible asset value, a decrease of \$150,000 for amortization of this assets. The cash balance of \$19,272 is a critical issue for the Company moving into 2018. As noted earlier in the report, Milestone Scientific Inc. is supporting the expenses of the Issuer on a limited basis until alternate financing is available.

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

	Year ended December 31, 2017	Year ended December 31, 2016
<u>Current Assets</u>	<u>620,887</u>	<u>852,264</u>
Cash	19,272	13,187
Accounts receivable	0	0
Prepaid expenses and other current assets	57,154	53,537
Inventory	500,313	741,392
Advances to contractors	44,148	44,148
Equipment, net depreciation	34,626	61,576
Intangible Assets	1,350,000	1,500,000
TOTAL ASSETS	2,005,513	2,413,840

Source: The Issuer

During 2017, the main source of the Issuer's financing was borrowing from Milestone Scientific Inc. 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. Because of the offering and the receipt of the net proceeds, the Issuer believed it would have sufficient cash flow to continue 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. Due to a slow-down in the capital markets in late 2015 and 2016, the Issuer delayed the capital raise until 2016 and finally the anticipated offering was cancelled. The Issuer intends to slow its' cost structure until the next capital raise,



or until alternative financing is available. In years ended December 31, 2017 and 2016, 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 \$9.4 million in year ended December 31, 2017 and approximately \$7.3 million in the year ended December 31, 2016. 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 for the epidural instrument. 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)

<u>Current Liabilities</u>	9,425,303	<u>7,273,278</u>
Accounts payable and accrued expenses	502,236	615,408
Commitments and Contingencies	<u>8,923,067</u>	<u>6,657,870</u>
TOTAL LIABILITIES	9,425,303	7,273,278

Source: The Issuer

The \$9,425,303, and \$7,273,278 at December 31, 2017 and 2016 includes \$2.8 million of advances on a line of credit established by Milestone Scientific Inc in both years, and \$6,123,067 and \$3,857,870 for 2017 and 2016 respectively of other advances before and after to the line of credit was established.

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

	Year ended December 31, 2017	Year ended December 31, 2016
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at December 31, 2017 and December 31, 2016	2,200	2,200
Additional paid in capital	6,931,861	6,861,634
Accumulated deficit during the development stage	(14,353,851)	(11,723,272)
TOTAL SHAREHOLDERS' EQUITY	(7,419,790)	(4,859,438)

Source: The Issuer

# Liquidity analysis

All liquidity ratios decreased in year ended December 31, 2017 in comparison to year ended December 31, 2016. As of December 31, 2017, the Issuer had a higher level of total current liabilities and a low amount of cash that resulted in a lower liquidity ratio. The reduction in the liquidity ratios in 2017 was primarily caused by a significant increase in total current liabilities (from approximately \$7,273,278 in 2016 to approximately \$9,425,303 in 2017) due to an increase in research and development costs, general and administrative cost for clinical studies, marketing expenses and shared services expenses. The decrease in the value of all liquidity ratios were significant in 2017 compared to 2016 as described above due to the increase current liabilities for the Issuer in 2017.

As of December 31, 2017, Milestone Medical Inc. believes that it does not have sufficient cash to meet all its anticipated obligations for the next twelve months from the financial statement release date. These factors raise substantial doubt about the Company's ability to continue as a going concern.



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.

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.

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

	Year ended December 31, 2017	Year ended December 31, 2016
Current ratio (CR)	0.07	0.12
Quick ratio (QR)	0.00	0.00
Cash ratio	0.00	0.00

Source: The Issuer

Milestone Medical, Inc.

The algorithm of above ratios' calculation was:

Current ratio (CR) = Total current assets/Total current liabilities

Quick ratio (QR) = (Total current assets – Inventory-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.

Now that the CompuFlo Epidural instrument has obtained FDA clearance in the United States (June 2017), the development costs will be reduced in 2018. The FDA clearance will provide the Company with the opportunity to establish distribution in the USA. At the same time, the Company and its parent are looking to establish additional financing opportunity for the Epidural instrument sales.

The intra-articular instrument will begin the 510K application process later this year/. Most of the cost associated with this application will be internal personnel cost and some low level 3<sup>rd</sup> party review expense.

# 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 \$124,000 in research and development for the two instruments in 2017, a reduction of \$385,000 over 2016. The FDA clearance of the CompuFlo Epidural instrument was a significant factor in this cost reduction. 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 2016 and 2015. The Issuer plans to expand its marketing efforts including attending medical device trade conferences in the USA and CE authorized countries in Europe and the Middle East in 2018.

# 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

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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.		
Registerd 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	75 managant		
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 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 up list from NewConnect Market (Alternative Trading System) to the Main Market of the Warsaw Stock Exchange, in the fourth quarter of 2015.

On June 12, 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) clearances. 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 has received a follow up response from the FDA, based on supplemental information provided in 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) applications for the Compu-Flo Intra Articular instrument will be processed in the first half of 2018.

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.

# 6.7. 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.

Milestone Medical, Inc.

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# **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 \$124,313, and Chief Financial Officer \$62,545 in 2017. The Officers of the Company were paid through charges amounting to; Chief Executive Officer \$137,160, and Chief Financial Officer \$61,373 in 2016.



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

To the Board of Directors and Stockholders of Milestone Medical, Inc.

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Milestone Medical, Inc. and subsidiary (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, statement of days in stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

# **Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has recurring losses and negative cash flows from operations. These conditions, among others, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. If the Company is unable to obtain financing, there could be a material adverse effect on the Company.

/s/ Friedman LLP

We have served as the Company's auditor since 2016.

East Hanover, New Jersey



#### 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 2016.

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	
	The Company should maintain a corporate website and publish:  3.1 Basic information about the Company and its business (home page);	YES	
3.	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 2017, 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	NO	The Issuer did not publish financial forecasts. When the Company decides to publish



targets (if targets are published by the Issuer);		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 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 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 actualizati of its corporate website, but the Issuer is making great efforts to make such actualization on timely basis.
The Company should publish its corporate website in Polish or in 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	YES	



	regulations applicable to the Issuer.		
5.	The Company should pursue an information policy with an 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="https://www.gpwinfostrefa.pl">www.gpwinfostrefa.pl</a>	YES	
6.	The Issuer should maintain ongoing contacts with representatives of the Authorized Adviser 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	
	9.1. 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.	9.2. Information about the fee paid by the Issuer to the Authorized Advisor 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 is owed approximately 99% by a Parent Company
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 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	NOT APPLICABLE	Provisions of the Commercial Code do not apply to the Issuer.



	Companies, the Management Board of the Issuer shall immediately be 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.		
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:  • 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;  • list of all information published by the Issuer in the form of current reports in the reporting period;  • information about achievement of the goals of an issue if they were achieved at least partly in the reporting period;  • dates important to investors including events planned in the coming month concerning the Issuer and important from the perspective of investor rights, including 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	NO	Now, this principle is not applied by the Issuer. Since 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 now 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 Osser Interim Chief Executive Officer

Joseph D'Agostino Chief Financial Officer