

# **Consolidated report of**

## **MILESTONE MEDICAL INC. and its SUBSIDIARY**

### **For the Year Ended December 31, 2018**

***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, 2019

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

To Our Valued Shareholders,

2018 was an eventful year for Milestone Medical. Our next-generation DPS Dynamic Pressure Sensing technology® regulates flow rate and monitors pressure at the tip of a needle. This allows for precise identification of the location of the needle within tissue, thereby making drug delivery safer, easier, and more effective. The CompuFlo® Epidural System, provides anesthesiologists and other health care providers for the first time, objective visual and audible in-tissue pressure feedback that allows clinicians to accurately identify the epidural space in real-time.

In February and March 2018, 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 and assist on moving the business forward on an accelerated track. With these key hires in place, we began the next phase of our strategy, which involves building out our distribution channels. Specifically, we are pursuing a decentralized sales strategy employing regional distributors with strong physician relationships within their respective territories and clinical specialties.

During the year we expanded our network to nine independent distributors covering key markets across the U.S., including the Pacific Northwest, Southeast, Southwest, Midwest, Northwest and Mid-Atlantic regions. We believe our rapid progress illustrates the positive response and growing market demand as we educate distributors and leading anesthesiologists on the clinical benefits of the CompuFlo Epidural System. We look forward to further expanding our coverage and working closely with our new distributors.

We also presented the CompuFlo Epidural System at Euroanaesthesia 2018, the European Anesthesiology Congress, which was held in Copenhagen from June 2-4, 2018. In addition, three abstracts were presented during a scientific poster session highlighting the instrument's ability to objectively identify the epidural space in real time. Euroanaesthesia is Europe's largest annual event showcasing the latest and the most relevant knowledge with medical experts active in the field of anesthesia, perioperative medicine, intensive care, emergency medicine and pain treatment. This international event gathers thousands of delegates and exhibitors from over 80 countries with upwards of six thousand delegates from around the world.

We also presented the CompuFlo Epidural System at The Society for Obstetric Anesthesia and Perinatology (SOAP) 50th Annual Meeting that was held in Miami from May 9-13. We were quite pleased with the favorable response the CompuFlo Epidural System generated at the SOAP meeting.

We also had our technology featured in a prominent peer-reviewed scientific journal - Anesthesiology Research and Practice, a peer-reviewed journal that provides a forum for health care professionals engaged in perioperative medicine, critical care, and pain management. The CompuFlo Epidural System was selected to objectively measure and evaluate the integrity of a third-party epidural simulator. We also had a clinical study that was published in the International Journal of Obstetric Anesthesia that found the CompuFlo Epidural System to be successful in objectively identifying the epidural space - even in difficult patients. The preliminary findings suggest that CompuFlo Epidural System could assist the physician in training when performing epidural insertion, which we believe further validates that the instrument is able to safely and effectively identify the epidural space, giving providers a proven alternative to the loss-of-resistance syringe.

In January of 2019, results of a four hundred patient clinical trial by researchers from the University of Miami, University of Texas and Northwestern University, and two prominent California-based pain clinics were

published-ahead-of-print in the top ranked journal, *Anesthesia & Analgesia* (the official Journal of the International Anesthesia Research Society). The controlled study compared the effectiveness of the CompuFlo Epidural System in labor and delivery and chronic pain management, where loss of resistance and fluoroscopy are the current standards of care. CompuFlo was found to be ninety-nine percent successful in objectively identifying the epidural space — even in challenging patients with a higher body mass index.

Performance of epidural anesthesia depends on successful identification of the epidural space. While fluoroscopy is associated with high success, it exposes patients to radiation and requires appropriate radiological equipment. Loss of resistance is subjective and consequently associated with higher failure rates and accidental dural punctures that require further treatment and interventions such as epidural blood patches.

The data from this pivotal study confirms that CompuFlo is a safe and highly effective alternative to current standards of care. The instrument avoids patient radiation exposure when compared to fluoroscopy and demonstrated greater accuracy when compared to loss of resistance. The clinical trial also found:

- CompuFlo’s procedure time was the same as the current standard of care
- Labor and delivery epidurals performed with CompuFlo resulted in no accidental dural punctures, compared to four dural punctures with loss of resistance

In summary, we have been successful in commencing the first phase of our commercial launch of our CompuFlo Epidural Instrument. We continue to gain traction in the scientific community by having the results of our trials published in leading industry journals which aids in driving market awareness and provides further validation for our technology.

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**

## **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, 2018, the Company believes that it does not have sufficient cash on hand and liquidity 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 additional financing is achieved. The Company will continue to manage its cash position while taking strategic steps to finalize supportive clinical studies and market the product and 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 the financial statements, Friedman LLP, which audited the annual consolidated financial statements, was selected by the Audit Committee effective May 30, 2018 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, 2018 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:	<a href="mailto:jdagostino@milestonescientific.com">jdagostino@milestonescientific.com</a>
Main website address:	<a href="http://www.medicalmilestone.com">www.medicalmilestone.com</a>

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%
<b>TOTAL</b>	<b>22,000,000</b>	<b>100.00%</b>

Source: The Issuer

The company reported on ESPI report 6/2016 published on June 17, 2016 that Milestone Scientific initiated a share exchanged program pursuant to which would exchange one share of common stock for every two outstanding shares of Milestone Medical common stock. Through the report date, Milestone Scientific Inc. acquired 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**

<b>NAME OF DIRECTOR</b>	<b>CURRENT AGE</b>	<b>DIRECTOR SINCE</b>	<b>END OF TERM</b>
<b>Zhu Yun</b>	53	Sep-13	Next Annual Meeting of Shareholders
<b>Martin S. Siegel</b>	74	Sep-14	Next Annual Meeting of Shareholders

*\* On May 30, 2018 the Annual General Meeting of Shareholders adopted the resolution on the appointment of two 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 was not 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, 2018 the Issuer employed three (3) 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 Medical Device Trainer. The Company has contracted with one Business Development Consultant for business activities in Europe and the Middle East in 2018. Milestone Medical has three fulltime employees as of December 31, 2018; an Executive VP of Global Marketing and Sales, a Vice President of USA Sales, and a Director of Marketing. These three 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:

31.12.2018: 1EUR = 1.1455 USD

31.12.2017: 1EUR = 1.1979 USD

**Table 4 Selected consolidated financial data of the balance sheet of Milestone Medical as of December 31, 2018 with comparable consolidated data for year 2017.**

Selected consolidated financial data from the balance sheet	USD		EUR	
	31.12.2018	31.12.2017	31.12.2018	31.12.2017
Total Assets	1,378,208	2,005,513	1,203,150	1,674,191
Cash	1,037	19,272	905	16,088
Prepaid expenses and other current assets	31,963	57,154	27,903	47,712
Inventory	234,427	500,313	204,650	417,658
Accounts receivable	-	-	-	-
Advance to contractors	44,148	44,148	38,540	36,855
Equipment, net depreciation	16,633	34,626	14,520	28,906
Intangible assets	1,050,000	1,350,000	916,630	1,126,972
Current Liabilities	11,798,627	9,425,303	10,299,980	7,868,188
Common Stock	2,200	2,200	1,921	1,837
Accumulated paid-in-capital	6,931,861	6,931,861	6,051,385	5,786,678
Accumulated deficit during the development stage	(17,354,480)	(14,353,851)	(15,150,135)	(11,982,512)
Stockholder's Deficit	(10,420,419)	(7,419,790)	(9,096,830)	(6,193,998)

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:

01.01.2018 to 31.12.2018: 1EUR = 1.1815 USD

01.01.2017 to 31.12.2017: 1EUR = 1.1300 USD

**Table 5 Selected consolidated financial data of the statement of operations of Milestone Medical Inc. from January 1, 2018 to December 31, 2018 with comparable consolidated data for year 2017.**

Selected consolidated financial data from Statement of Operations	USD		EUR	
	31.12.2018	31.12.2017	31.12.2018	31.12.2017
Revenue	119,800	2,000	101,397	1,770
Cost of Goods	269,252	220,183	227,890	194,852
Gross Profit	(149,452)	(218,183)	(126,493)	(193,082)
Depreciation	324,493	176,949	274,645	156,592
Research and development expenses	92,489	124,820	78,281	110,460
Other expenses	2,344,794	2,019,191	1,984,591	1,786,895
Total Expenses	2,761,776	2,320,960	2,337,517	2,053,947
Interest Expense	93,401	92,936	79,053	82,244
Net loss before income tax	(3,004,629)	(2,632,079)	(2,543,063)	(2,329,273)
Income tax benefit	(4,000)	(1,500)	(3,386)	(1,327)
Net Loss	(3,000,629)	(2,630,579)	(2,539,678)	(2,327,946)

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, 2018 and 2017

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2018 and 2017, and the related consolidated statements of operations, statements of changes in stockholders’ deficit, and cash flows for each of the years in the two-year period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### **The Company’s Ability to Continue as a 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 in regard to 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.

### **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 the purpose of 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.

/s/Friedman LLP

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

East Hanover, New Jersey  
March 21, 2019

Milestone Medical Inc. And Subsidiary  
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
<u>ASSETS</u>		
Cash and cash equivalents	\$ 1,037	\$ 19,272
Inventories, net	234,427	500,313
Advances on contracts	44,148	44,148
Prepaid expenses and other current assets	31,963	57,154
Total current assets	311,575	620,887
Equipment, net	16,633	34,626
Intangible asset, net	1,050,000	1,350,000
Total assets	\$ 1,378,208	\$ 2,005,513
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Accounts payable	\$ 113,380	\$ 56,978
Accrued expenses and other payables	660,500	445,258
Advances from Milestone Scientific Inc.	8,224,747	6,123,067
Due to Milestone Scientific, Inc.	2,800,000	2,800,000
Total current liabilities	11,798,627	9,425,303
<u>COMMITMENTS AND CONTINGENCIES</u>		
Stockholders' Deficit		
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at December 31, 2018 and December 31, 2017	2,200	2,200
Additional paid-in capital	6,931,861	6,931,861
Accumulated deficit	(17,354,480)	(14,353,851)
Total stockholders' deficit	(10,420,419)	(7,419,790)
Total liabilities and stockholders' deficit	\$ 1,378,208	\$ 2,005,513
See Notes to Consolidated Financial Statements		

Milestone Medical Inc. And Subsidiary  
Consolidated Statements of Operations  
For the Years Ended December 31, 2018 and 2017

	2018	2017
Product sales, net	\$ 119,800	\$ 2,000
Cost of products sold	269,252	220,183
Gross profit	(149,452)	(218,183)
Selling, general and administrative expenses	2,344,794	1,948,964
Depreciation and amortization	324,493	176,949
Shared services	-	70,227
Research and development expenses	92,489	124,820
Total operating expenses	2,761,776	2,320,960
Loss from operations	(2,911,228)	(2,539,143)
Interest expense	(93,401)	(92,936)
Loss before income tax	(3,004,629)	(2,632,079)
Income tax benefit	(4,000)	(1,500)
Net loss	\$ (3,000,629)	\$ (2,630,579)

See Notes to Consolidated Financial Statements

Milestone Medical Inc. And Subsidiary  
Consolidated Statements of Changes in Stockholders' Deficit  
For the Years Ended December 31, 2018 and 2017

	<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balance, January 1, 2017	<u>22,000</u>	<u>2,200</u>	<u>6,861,634</u>	<u>(11,723,272)</u>	<u>(4,859,438)</u>
Contributed Capital- Milestone Scientific Inc. Shared Services Expenses			70,227		70,227
Net loss				<u>(2,630,579)</u>	<u>(2,630,579)</u>
Balance, December 31, 2017	<u>22,000</u>	<u>2,200</u>	<u>6,931,861</u>	<u>(14,353,851)</u>	<u>(7,419,790)</u>
Net loss				<u>(3,000,629)</u>	<u>(3,000,629)</u>
Balance, December 31, 2018	<u>22,000</u>	<u>\$ 2,200</u>	<u>\$ 6,931,861</u>	<u>\$ (17,354,480)</u>	<u>\$ (10,420,419)</u>

See Notes to Consolidated Financial Statements



Milestone Medical Inc. And Subsidiary  
Consolidated Statements of Cash Flows  
For the Years Ended December 31, 2018 and 2017

	2018	2017
Cash flows from operating activities:		
Net loss	\$ (3,000,629)	\$ (2,630,579)
Adjustments to reconcile net cash (used in) operating activities:		
Depreciation and amortization expense	324,493	176,949
Contributed capital - Milestone Scientific, Inc. shared services expense	-	70,227
Increase in inventories allowance	234,350	219,834
Changes in operating assets and liabilities:		
Decrease in inventories	31,536	21,246
Decrease (increase) to prepaid expenses and other current assets	25,191	(3,617)
Increase (decrease) in accounts payable and accrued expenses	271,641	(113,172)
Net cash used in operating activities	<u>(2,113,418)</u>	<u>(2,259,112)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(6,497)	-
Net cash used in investing activities	<u>(6,497)</u>	<u>-</u>
Cash flows from financing activities:		
Related party advances	2,101,680	2,265,197
Net cash provided by investing activities	<u>2,101,680</u>	<u>2,265,197</u>
Net (decrease) increase in cash and cash equivalents	(18,235)	6,085
Cash and cash equivalents at beginning of period	19,272	13,187
Cash and cash equivalents at end of period	<u>\$ 1,037</u>	<u>\$ 19,272</u>

See Notes to Consolidated Financial Statements

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For twelve months ended December 31, 2018 and 2017**

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**NOTE 1 – ORGANIZATION AND BUSINESS:**

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

In September 2014, the Company established a special purpose Polish company called Milestone Medical Poland Sp. z.o.o. The purpose of which is for the application and acceptance of Polish Government Grants for research and development of current and future improvement to the epidural and intra-articular instruments. Milestone Medical Poland Sp. z.o.o., is seventy – five percent owned by the Company. Through December 31, 2018, 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™ (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 510K original application filed with FDA lapsed in January 2019. The Company intends to resubmit an application for a 510k to the FDA in 2019.

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 the Epidural instruments in the United States and throughout the world.

In January 2019, the Company filed on the ESPI 1/2019 a report that announced New Clinical Trial Findings for the CompuFlo® Epidural Instrument. The pivotal study confers that the CompuFlo® Epidural instrument is a highly effective alternative to standards of care. The instrument avoids patient radiation exposure when compared to fluoroscopy and demonstrated greater accuracy when compared to loss of resistance.

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

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The Company has evaluated whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued. Milestone Medical Inc. has incurred significant operating losses since its inception. At December 31, 2018 Milestone Medical

Inc. had cash of approximately \$1,000 and a negative working capital of approximately \$11.5 million compared to negative working capital of approximately \$8.8 million at December 31, 2017. As of December 31, 2018, Milestone Medical Inc. 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, throughout the world and obtain regulatory approval of Intra-Articular instrument.

Additional financing is necessary to fund the commercialization of the Epidural instrument and continue the Intra-Articular regulatory process. To this end, the Company and Milestone Scientific, Inc. are 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. If the Company and Milestone Scientific, Inc. are unsuccessful in obtaining additional financing on a timely basis there would most likely be a material adverse effect on the Company.

The financial statements do not include any adjustments relating to the recoverability and classification of assets carrying amounts or the amounts and classification of liabilities that might result should the Company be unable to continue as a going concern.

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

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#### **Basis of Presentation**

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

#### **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 GAAP which 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 the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

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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 years ended December 31, 2018 and 2017 was approximately \$24,000 and \$27,000, respectively. The costs of maintenance and repairs are charged to operations as incurred.

**Revenue Recognition**

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To perform revenue recognition for arrangements, the Company performs the following five steps:

- i. identification of the promised goods or services in the contract;
- ii. determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;
- iii. measurement of the transaction price, including the constraint on variable consideration;
- iv. allocation of the transaction price to the performance obligations based on estimated selling prices; and
- v. recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606.

The Company derives its revenues from the sale of its products, primarily medical instruments, handpieces, and other related products. The Company expects to sell its products through a global distribution network that includes non-exclusive distribution agreements with third parties.

Revenue from product sales are recognized upon transfer of control of a product to a customer, generally upon date of shipment. For certain arrangements where the shipping terms are FOB destination, revenue is recognized upon delivery. The Company has no obligation on product sales for any installation, set-up or maintenance, these being the responsibility of the buyer. Milestone Medical's only obligation after sale is the normal commercial warranty against manufacturing defects if the alleged defective unit is returned within the warranty period.

We generally do not accept non-defective returns from our customers. Product returns under warranty are accepted, evaluated and repaired or replaced in accordance with the Company's warranty policy. Returns not within the warranty policy are evaluated and the customer is charged for repair.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

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**Financing and Payment**

Our payment terms differ by geography and customer, but payment is generally required within 90 days from the date of shipment or delivery.

**Costs to Obtain or Fulfill a Customer Contract**

Sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in selling, general and administrative expense in the consolidated statements of operations.

Shipping and handling costs, if any, are paid by or billed to customers at the time of shipment. Domestic and international shipments are FOB warehouse; therefore, no costs are incurred by Milestone Medical. The Company accounts for any shipping and handling activities related to contracts with customers as fulfillment costs which are included in cost of products sold in the consolidated statements of operations.

**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. Intangibles are amortized utilizing the straight-line method which resulted in amortization expense for the years ended December 31, 2018 and 2017 of \$300,000 and \$150,000, respectively.

Long-lived tangible assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company's impairment review process is based upon an estimate of future undiscounted cash flow. Factors the Company considers that could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results,
- significant changes in the manner of our use of the acquired assets or the strategy for our overall business
- significant negative industry or economic trends
- significant technological changes, which would render the technology obsolete

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs. . During the year, the Company assessed the intangible for impairment because the marketing and sales efforts relating to the Epidural instrument have not met the original expectations following the 2017 approval . The Company's impairment assessment is based on several factors including projected cash flows from the Epidural instruments. Based on this analysis , no impairment was deemed necessary as of December 31, 2018 .

**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.

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**NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued):**

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**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, 2018 and 2017, 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 for 2015, 2016, and 2017 years are subject to audit by federal and state jurisdictions.

**Recent Accounting Pronouncements**

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 determined that the adoption of this ASU will have an immaterial effect 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 Medical determined that, the adoption of this ASU will have an immaterial effect on its financial position, results of operations and cash flows.

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**NOTE 4 - INVENTORY:**

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Inventory as of December 31, 2018 and 2017 consist of the following:

	December 31	
	2018	2017
Inventories consist of the following:		
Epidural instruments	\$ 188,133	\$ 240,918
Intra-articular instruments, net reserve	-	234,367
Component parts and other materials	46,294	25,028
Total	\$ 234,427	\$ 500,313

The reserve against Intra-articular instrusment was approximately \$454,000 and \$220,000 for the years ended December 31, 2018 and 2017, respectively.

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**NOTE 5 - JOINT VENTURE AGREEMENT:**

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

Milestone Scientific, Inc. 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.'s 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.

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**NOTE 6 - RELATED PARTY TRANSACTIONS:**

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On December 31, 2014, Milestone Scientific Inc. executed a \$2 million line of credit agreement to provide bridge financing to the Company through April 15, 2016. Borrowings under the line bear interest at a rate of 3.25%, the prime rate at the inception of the agreement. In September 2015, the company requested and received approval from the Board of Directors of Milestone Scientific Inc. to increase the limit of the line of credit to a maximum of \$2.5 million. In January 2016, the credit agreement increased to \$3 million. As of December 31, 2018, and 2017, Milestone Scientific, Inc. has advanced \$2.8 million to Milestone Medical under this line of credit which is classified as Due to Milestone Scientific Inc. on the accompany Consolidated Balance Sheets. All other terms in the line of credit agreement remain unchanged. However, Milestone Scientific Inc. has not demanded payment of the line of credit. 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 Medical purchased this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs will receive additional payments of 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, 2018 and 2017, was approximately \$0 and \$70,000, respectively.

As of December 31, 2018, and 2017, the Company owes approximately \$8.2 million and \$6.1 million, respectively, to Milestone Scientific, Inc. for expenses paid on the Company's behalf. These advances are non-interest bearing and due on demand.

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**NOTE 6 - RELATED PARTY TRANSACTIONS:**

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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, 2018, 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, 2018.

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, "Consulting Agreement" 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 December 19, 2017 Mr. Osser suspended 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 Consulting Agreement will continue once he is no longer Interim Chief Executive Officer.

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**NOTE 7 - CONCENTRATIONS:**

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The Company has informal arrangements for the manufacture of its products, the epidural and intra-articular instruments are manufactured by Tricor Systems, Inc. pursuant to specific purchase orders. There are no open purchase orders for the manufacture of instruments as of December 31, 2018. The Company sub-contracts its research and development to a vendor, which accounted for 65%, and 100% of research and development expenses incurred for twelve months ended December 31, 2018 and 2017, 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.

For the twelve months ended December 31, 2018, an aggregate of approximately 86% of net product sales were to three customers/distributors, 28%, 28% and 30% respectively

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**NOTE 8 - COMMITMENTS AND CONTINGENCIES:**

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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, 2018 and 2017, we expensed approximately \$0 and \$50,000 respectively relating to this agreement.

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

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**NOTE 9 – SUBSEQUENT EVENT:**

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After December 31, 2018 Milestone Scientific Inc., has advanced Milestone Medical approximately \$245,000 to continue the commercialization process for the epidural instrument and other expenses necessary for the day to day operations of Milestone Medical. Milestone Scientific Inc. is not legally obligated to loan or advance additional funds to the Issuer. See Note 2.

## **6. REPORT ON MILESTONE MEDICAL INC. AND SUBSIDIARY'S ACTIVITIES IN YEAR 2018**

In October 2018, Milestone Medical signed a Distributor Agreement in the USA. This agreement provides that this Distributor will purchase and hold an inventory of the CompuFlo® Epidural instrument and disposables for sale. At this time there have been no minimum purchase established with the Distributor. The Distributor identified above purchased five (5) CompuFlo® Epidural instruments and disposables after executing the Agreement.

For the twelve months ended December 31, 2018 the Issuer and its Subsidiary have generated a net loss of \$3,000,630. This loss was due to research and development costs of \$92,489 and to a high level of general and administrative and other expenses, which amounted to \$2,344,794

On May 30, 2018 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 2018. Friedman LLP was approved and recommended as independent auditor by the Audit Committee of the Board.

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

The Issuer, in 2018, continued in the process of commercializing the company. However, there are several risk areas that are identifiable:

1. Instrument commercialization delays; the intra articular instruments has passed this risk feature with the instruments finalized by the third-party developer, the Company has not submitted for regulatory clearance in the USA due to lack of funding. 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; in the USA for the Intra Articular instrument; 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 and in the USA in 2018. 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 continuing to explore 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 approximately \$627,000 in the year ended December 31, 2018 from \$2.0 million in the year ended December 31, 2017. At the end of year 2018, the balance sheet in total was lower by approximately 31% in comparison to year 2017.

During years 2018 and 2017 the assets' structure was similar. In 2018 nearly 76% 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 2018 compared to 2017 was a net intangible asset value, a decrease of \$300,000 for amortization of this assets. The cash balance of \$1,037 is a critical issue for the Company moving into 2019 and an additional inventory write down of \$234,350. 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)

	2018	2017
<b><u>Current Assets</u></b>	<b><u>311,575</u></b>	<b><u>620,887</u></b>
Cash	1,037	19,272
Accounts receivable	0	0
Prepaid expenses and other current assets	31,963	57,154
Inventory	234,427	500,313
Advances to contractors	44,148	44,148
<u>Equipment, net depreciation</u>	16,633	34,626
<u>Intangible Assets</u>	1,050,000	1,350,000
<b>TOTAL ASSETS</b>	<b>1,378,208</b>	<b>2,005,513</b>

Source: The Issuer

During 2018, 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, 2018 and 2017, 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 \$11.8 million in year ended December 31, 2018 and approximately \$9.4 million in the year ended December 31, 2017. 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)**

	2018	2017
<b><u>Current Liabilities</u></b>	<b><u>11,798,627</u></b>	<b><u>9,425,303</u></b>
Accounts payable and accrued expenses	773,880	502,236
<b><u>Commitments and Contingencies</u></b>	<b><u>11,024,747</u></b>	<b><u>8,923,067</u></b>
<b>TOTAL LIABILITIES</b>	<b>11,798,627</b>	<b>9,425,303</b>

Source: The Issuer

The \$11,798,627, and \$9,425,303 at December 31, 2018 and 2017 includes \$2.8 million of advances on a line of credit established by Milestone Scientific Inc in both years, and approximately \$8.2 million and \$6.1 million for 2018 and 2017, 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)**

	2018	2017
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at December 31, 2018 and December 31, 2017	2,200	2,200
Additional paid in capital	6,931,861	6,931,861
Accumulated deficit during the development stage	(17,354,480)	(14,353,851)
<b>TOTAL SHAREHOLDERS' DEFICIT</b>	<b>(10,420,419)</b>	<b>(7,419,790)</b>

Source: The Issuer

### **Liquidity analysis**

All liquidity ratios decreased in the year ended December 31, 2018 compared to the year ended December 31, 2017. As of December 31, 2018, 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 2018 was primarily caused by a significant increase in total current liabilities (approximately \$11,798,627 in 2018 from approximately \$9,425,303 in 2017) due to an increase in research and development costs, general and administrative cost, marketing expenses and trade show. The decrease in the value of all liquidity ratios were significant in 2018 compared to 2017 as described above due to the increase in current liabilities for the Issuer in 2018.

As of December 31, 2018, 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 are progressing 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**

	2018	2017
Current ratio (CR)	0.03	0.07
Quick ratio (QR)	0.00	0.00
Cash ratio	0.00	0.00

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 – 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 continue to be reduced in 2019. 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 during 2019. Most of the cost associated with this application will be internal personnel cost but some third party follow up and review expenses are expected to increase.

**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 \$92,000 in research and development for the two instruments in 2018, a reduction of approximately \$32,000 over 2017. 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 2018 and 2017. 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.

In October 2018, Milestone Medical signed a Distributor Agreement in the USA. This agreement provides that this Distributor will purchase and hold an inventory of the CompuFlo® Epidural instrument and disposables for sale. At this time there have been no minimum purchase established with the Distributor. The Distributor identified in the previous sentence purchased five (5) CompuFlo® Epidural instruments and disposables after executing the Agreement.

**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 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 2019.

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.

**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 was approximately \$94,000 and Chief Financial Officer was approximately \$35,000 in 2018. The Officers of the Company were paid through charges amounting to; Chief Executive Officer \$124,313, and Chief Financial Officer \$62,545 in 2017.

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

### **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

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, 2018 and 2017, and the related consolidated statements of operations, statements of changes in stockholders’ deficit, and cash flows for each of the years in the two-year period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

#### **The Company’s Ability to Continue as a 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 in regard to 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.

#### **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 the purpose of 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.

/s/Friedman LLP

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

East Hanover, New Jersey  
March 21, 2019

Milestone Medical, Inc.

Annual Report for Year 2018

## 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	
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 2018, 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 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 delayed 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 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.	YES	
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="http://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.	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 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 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.	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 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	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	<p>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.</p>	YES	
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Leonard Osser  
Interim Chief Executive Officer

Joseph D’Agostino  
Chief Financial Officer