

# **Consolidated report of**

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

**For the Year Ended December 31, 2020**

***Report includes:***

1. General information about Milestone Medical, Inc. (“Issuer”) and Milestone Medical Poland Sp. Z o.o. (the Subsidiary), collectively the Company or Milestone Medical.
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 19, 2021

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

To Our Valued Shareholders,

With COVID-19 infections declining in certain regions, and several hospitals re-opening to outside vendors, we have made significant progress over the past year advancing our commercial efforts around the CompuFlo® Epidural Instrument and CathCheck™ System. Specifically, we have added several new distributors, and hospitals are purchasing our disposables with prospects of increased business in the coming years.

Most notably, in first three months of 2021, we began selling CompuFlo Epidural and CathCheck disposables to three premier medical centers: Regional Medical Center (RMC), a premier regional healthcare system in South Carolina; the University of Texas Medical Branch at Galveston (UTMB), an institution of the University of Texas System and agency of the State of Texas; and nationally recognized Medical University of South Carolina (MUSC); and one leading hospital, University Hospital of Würzburg in Germany. The purchase orders received from these three leading U.S. medical centers and one leading European hospital further reinforces our confidence in the outlook for both CathCheck and CompuFlo and the value proposition to other healthcare systems across Europe and North America as we strive to become the new standard of care in epidural procedures.

Additionally, we entered into an agreement with Bitmedical AG to distribute the CompuFlo Epidural Instrument and CathCheck System, as well as related disposables, in Switzerland and Austria. Bitmedical is a premier distributor of medical devices and equipment within Switzerland and Austria, supporting many of the leading global manufacturers in these markets. Penetrating the sizeable Austrian and Swiss markets is an important step forward in our commercial launch of the CompuFlo Epidural System in Europe.

In October 2020 we were awarded a group purchasing agreement for CompuFlo and CathCheck with Premier, a leading group purchasing organization, with approximately 4,100 U.S. hospitals and 200,000 other providers within their network.

As we are constantly evolving our injection and drug delivery systems, we recently received two Notices of Allowance for a key patent from the U.S. Patent and Trademark Office and Notice of Allowance from the European Patent Office (EPO).

The first patent relates to the disposable component of Milestone's CompuFlo Instrument and covers the unique interactions of the disposable assembly and a micro-chip security verification feature embedded in the disposables, which provides numerous clinical and safety benefits for the patient and practitioner. Ensuring the use of only authorized disposable components is critical to CompuFlo's performance and safety, as well as the long-term financial success of our Company.

The second patent relates to our new CompuPulse System, which integrates the CompuWave™ technology with a manual syringe. This new technology provides an efficient and low-cost alternative for procedures where a manual syringe may suffice, while still providing the ability to verify needle and subsequent catheter placement, which opens up a number of exciting new markets and applications for our technology.

The third patent from the European Patent Office (EPO) combines minimum intensity of nerve stimulation (MIS) and real-time injection pressure (IP) monitoring utilizing Milestone's CompuFlo® instrument and associated DPS Dynamic Pressure Sensing Technology® to optimize needle tip location in ultrasound-guided peripheral nerve block (PNB) procedures; thus helping to reduce the risk of needle injury during PNB procedures.

The results of our clinical trials have also been published in leading industry journals, which aids in driving market awareness and further validation for our technology. Importantly, the CompuFlo Epidural System is fully validated in terms of safety, efficacy, and economics. Similarly, the CathCheck technology has the potential to transform the monitoring of catheter placement following an epidural procedure by confirming the placement of a catheter within 2 minutes, versus 20-40 minutes using conventional methods. For these reasons, we are further encouraged that our technology will become the new standard of care in labor and delivery anesthesia in the U.S.

In summary, we have been successful in commencing the first phase of a commercial rollout of the CompuFlo Epidural Instrument. A key element of our sales strategy focuses on the disposable components of our system, which we believe will contribute to high margins and recurring revenue. Overall, the response from both hospitals and physicians has been positive and we are in a few trials across the country that have the potential to convert to additional commercial orders. Our sales pipeline is more robust than ever, and we look forward to finalizing additional agreements with several premier hospitals soon.

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 Milestone Medical, Inc. and Subsidiary ("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's financial results and that the report on the Company is presented in a fair view of the Company, including a description of basic exposures and risks.

As of December 31, 2020, 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 the Company declares that, the authorized entity to audit the consolidated financial statements, Friedman LLP was selected by the Audit Committee effective November 4, 2020 in accordance with legal regulations and that this entity and certified auditors, who audited these financial statements met conditions to express their 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, 2020 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

Joseph D'Agostino – Chief Financial Officer

## 1. General information

**Table 1 General Information about the Issuer**

<b>THE ISSUER</b>	<b>MILESTONE MEDICAL INC.</b>
	<b>(Earlier: Milestone Scientific Research and Development, Inc.)</b>
<b>Registered office/Office:</b>	425 Eagle Rock Avenue, Roseland, NJ 07068, USA
<b>Telephone number:</b>	011-973-535-2717
<b>Facsimile number:</b>	011-973-535-2829
<b>E-mail:</b>	<a href="mailto:jdagostino@milestonescientific.com">jdagostino@milestonescientific.com</a>
<b>Main website address:</b>	<a href="http://www.medicalmilestone.com">www.medicalmilestone.com</a>

Source: The Issuer

\*Milestone Medical, Inc. moved its office to Roseland, New Jersey in January 2020.

### 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.**

<b>Name of Shareholder</b>	<b>Number of owned shares/votes</b>	<b>Shareholding/votes at General Meeting of Shareholders [%]</b>
<b>MILESTONE SCIENTIFIC, INC.</b>	21,633,084	98.33%
<b>OTHERS (&lt;5%)</b>	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.

### 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>	55	Sep-13	Next Annual Meeting of Shareholders
<b>Martin S. Siegel</b>	76	Sep-14	Next Annual Meeting of Shareholders

\* On November 4, 2020, 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.

Source: The Issuer

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

On December 31, 2020, the Issuer employed four (4) full time employees and four (4) persons allocated from the parent company (Milestone Scientific Inc.) converted into full-time equivalents (“FTEs”). These employees will promote direct market support for Milestone Medical and assist on moving the medical business forward.

#### 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:

31.12.2020: 1EUR = 1.1228 USD

31.12.2019: 1EUR = 1.1227 USD

Selected consolidated financial data from the Balance Sheets	USD		EUR	
	31.12.2020	31.12.2019	31.12.2020	31.12.2019
Total assets	923,658	590,727	822,638	526,167
Cash	22,119	8,773	19,700	7,814
Prepaid expenses and other current assets	123,769	82,814	110,232	73,763
Inventories, net	455,365	215,151	405,562	191,637
Accounts receivable	-	2,600	-	2,316
Advance to contractors	314,116	273,149	279,761	243,298
Equipment, net depreciation	8,289	8,240	7,382	7,339
Current liabilities	17,945,911	14,505,850	15,983,177	12,920,504
Common stock	2,200	2,200	1,959	1,960
Accumulated paid-in-capital	7,258,833	6,931,861	6,464,939	6,174,277
Accumulated deficit	(24,283,286)	(20,849,184)	(21,627,437)	(18,570,575)
Stockholder's deficit	(17,022,253)	(13,915,123)	(15,160,539)	(12,394,338)

**Table 4 Selected consolidated financial data of the balance sheet of Milestone Medical, Inc. as of December 31, 2020 with comparable consolidated data for year 2019.**

*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:

01.01.2020 to 31.12.2020: 1EUR = 1.1414 USD

01.01.2019 to 31.12.2019: 1EUR = 1.1199 USD

Selected consolidated financial data from Statements of Operations	USD		EUR	
	31.12.2020	31.12.2019	31.12.2020	31.12.2019
Revenue	15,800	37,600	13,843	33,574
Cost of goods	51,010	25,899	44,691	23,126
Gross (loss) profit	(35,210)	11,701	(30,848)	10,448
Depreciation & amortization	5,694	308,393	4,989	275,375
Research and development expenses	303,944	189,923	266,291	169,589
Other expenses	2,993,564	2,913,487	2,622,712	2,601,560
Total operating expenses	3,303,202	3,411,803	2,893,992	3,046,525
Interest expense	95,690	94,091	83,836	84,017
Net loss before income tax	(3,434,102)	(3,494,193)	(3,008,675)	(3,120,094)
Provision (benefit) for income taxes	-	511	-	456
Net loss	(3,434,102)	(3,494,704)	(3,008,675)	(3,120,550)

**Table 5 Selected consolidated financial data of the statement of operations of Milestone Medical Inc. from January 1, 2020 to December 31, 2020 with comparable consolidated data for year 2019.**

*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, 2020 and 2019

<u>Table of Contents</u>	<u>Page</u>
Report of Independent Registered Public Accounting Firm	10
Consolidated Financial Statements:	
Consolidated Balance Sheets	11
Consolidated Statements of Operations	12
Consolidated Statement of Changes in Stockholders' Deficit	13
Consolidated Statements of Cash Flows	14
Notes to Consolidated Financial Statements	15-24

## 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, 2020 and 2019, 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, 2020 and 2019, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020 and 2019, 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.

### Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

## ***Inventories and Valuation of Related Estimates and Obsolescence***

### *Critical Audit Matter Description*

Certain inventory requires management to make significant assumptions and subjective judgments about the net realizability of product inventory for which the products have been approved by appropriate regulatory agencies, but which also represent new technology with unproven market acceptance. These assumptions include future usage and those required to develop sales forecasts based on studies and analysis without the benefit of historical experience. Given the subjectivity of estimating these key assumptions, performing audit procedures to evaluate whether inventory was appropriately recorded at December 31, 2020 required a high degree of auditor judgment and an increased extent of effort.

### *How We Addressed the Matter in Our Audit*

The following are the most relevant procedures we performed to address this critical audit matter:

- Testing whether the data used to determine if inventory is obsolete was complete and accurate and sufficiently precise.
- Evaluating whether the expected customer demand used was reasonable, considering the Company's current and past marketing efforts and their market studies in developing the estimate of future demand, the estimated useful life of the inventory, current economic and competitive conditions that could impact the forecasts, and the timing of the introduction and development of new or enhanced products.
- Evaluating the reasonableness of management's assumption related to the risk of technological or competitive obsolescence for products involved considering the technological or competitive obsolescence experiences during the product life cycle of existing products used in other business lines.

*/s/ Friedman LLP*

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

East Hanover, New Jersey  
March 19, 2021

Milestone Medical, Inc. and Subsidiary  
Consolidated Balance Sheets  
As of December 31,

	2020	2019
<u>ASSETS</u>		
Cash and cash equivalents	\$ 22,119	\$ 8,773
Accounts receivable	-	2,600
Inventories, net	455,365	215,151
Advances to contractors	314,116	273,149
Prepaid expenses and other current assets	123,769	82,814
Total current assets	915,369	582,487
Equipment, net	8,289	8,240
Total assets	\$ 923,658	\$ 590,727
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Accounts payable	\$ 96,088	\$ 291,956
Accrued expenses and other payables	322,810	251,868
Accrued interest payable- related party	494,136	402,889
Advances from related party	14,232,877	10,759,137
Due to related party	2,800,000	2,800,000
Total current liabilities	17,945,911	14,505,850
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, 2020 and December 31, 2019	2,200	2,200
Additional paid-in capital	7,258,833	6,931,861
Accumulated deficit	(24,283,286)	(20,849,184)
Total stockholders' deficit	(17,022,253)	(13,915,123)
Total liabilities and stockholders' deficit	\$ 923,658	\$ 590,727

See Notes to Consolidated Financial Statements

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

	2020	2019
Product sales, net	\$ 15,800	\$ 37,600
Cost of products sold	51,010	25,899
Gross (loss) profit	(35,210)	11,701
Selling, general and administrative expenses	2,993,564	2,163,487
Research and development expenses	303,944	189,923
Depreciation and amortization	5,694	308,393
Impairment of intangible assets	-	750,000
Total operating expenses	3,303,202	3,411,803
Loss from operations	(3,338,412)	(3,400,102)
Interest expense	(95,690)	(94,091)
Loss before income tax	(3,434,102)	(3,494,193)
Provision (benefit) for income taxes	-	511
Net loss	\$ (3,434,102)	\$ (3,494,704)

See Notes to Consolidated Financial Statements

Milestone Medical, Inc. and Subsidiary  
Consolidated Statements of Changes in Stockholders' Deficit  
For the Years Ended December 31, 2020 and 2019

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, January 1, 2019	22,000,000	\$ 2,200	\$ 6,931,861	\$ (17,354,480)	\$ (10,420,419)
Net loss				(3,494,704)	(3,494,704)
Balance, December 31, 2019	<u>22,000,000</u>	<u>\$ 2,200</u>	<u>\$ 6,931,861</u>	<u>\$ (20,849,184)</u>	<u>\$ (13,915,123)</u>
Stock Compensation from Parent			326,972		326,972
Net loss				(3,434,102)	(3,434,102)
Balance, December 31, 2020	<u>22,000,000</u>	<u>\$ 2,200</u>	<u>\$ 7,258,833</u>	<u>\$ (24,283,286)</u>	<u>\$ (17,022,253)</u>

See Notes to Consolidated Financial Statements

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

	2020	2019
Cash flows from operating activities:		
Net loss	\$ (3,434,102)	\$ (3,494,704)
Adjustments to reconcile net cash (used in) operating activities:		
Depreciation and amortization expense	5,694	308,393
Stock Compensation from Parent	326,972	-
Write off of advances to contractors	43,499	-
Impairment of long-lived assets	-	750,000
Changes in operating assets and liabilities:		
Decrease (increase) in accounts receivable	2,600	(2,600)
(Increase) decrease in inventories	(240,214)	19,276
(Increase) in advances to contractors	(84,466)	(229,001)
(Increase) to prepaid expenses and other current assets	(40,955)	(50,851)
(Decrease) increase in in accounts payable and accrued expenses	(124,926)	81,834
Increase in accrued interest - related party	91,247	90,999
Net cash used in operating activities	<u>\$ (3,454,651)</u>	<u>\$ (2,526,654)</u>
Cash flows from investing activities:		
Purchases of equipment	(5,743)	-
Net cash used in investing activities	<u>\$ (5,743)</u>	<u>\$ -</u>
Cash flows from financing activities:		
Advances from related party	3,473,740	2,534,390
Net cash provided by financing activities	<u>\$ 3,473,740</u>	<u>\$ 2,534,390</u>
Net increase in cash and cash equivalents	13,346	7,736
Cash and cash equivalents at beginning of period	8,773	1,037
Cash and cash equivalents at end of period	<u>\$ 22,119</u>	<u>\$ 8,773</u>

See Notes to Consolidated Financial Statements

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For twelve months ended December 31, 2020 and 2019.**

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**NOTE 1 – ORGANIZATION AND BUSINESS:**

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In March 2011, Milestone Medical, Inc. and subsidiary (the “Company” or “Milestone Medical”) 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. (the “Parent Company”) 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, Milestone Medical received Conformité Européenne (CE) clearance to distribute its epidural and intra-articular devices in the European Community (EU). We have entered into a limited number of distributor arrangements in Europe and the Middle East for the CompuFlo Epidural System. Our distribution strategy is initially aimed at having key opinion leaders (KOLs) use and accept the device and initiates their own studies. Milestone Medical is continuing to pursue distributors for the instrument in the EU community.

During 2016, Milestone Scientific filed for 510(k) marketing clearance with the U.S. Food and Drug Administration (FDA) for both intra-articular and epidural injections with the CompuFlo System. In June 2017, the FDA approved the CompuFlo System for epidural injections. Beginning in 2020 Milestone Medical began the process of building an internal sales force to market our epidural instrument to medical schools, hospitals and individual anesthesiologists within the United States and other international markets. Milestone Medical’s immediate focus is on marketing its epidural device throughout the United States and Europe.

In December 2016, we received notification from the FDA that based upon the 510(k)-application submitted for intra-articular injections, we did not adequately document that the device met the equivalency standard required for 510(k) clearances. Following consultation with the FDA’s Office of Device Evaluation, we filed a new 510(k) application for the device in June 2018. In November 2018, the FDA provided Milestone Scientific with a list of questions on the intra-articular 510(k) application filed in June 2018. Due to the delay in responding to FDA questions, Milestone Scientific will be required to file a new 510(k) application. Milestone Scientific did not complete this process in 2019, due to a lack of funding. In 2020 the Parent Company raised approximately \$19 million (in two capital raises) and is in the process of evaluating the use of these funds to improve existing devices, develop new instruments, including the continued regulatory process for the intra-articular instrument.

In October 2018, Milestone Medical signed a Distributor Agreement in the U.S. This agreement provides that this Distributor will purchase and hold an inventory of the CompuFlo Epidural System and disposables for sale. At this time there have been no minimum purchase established with the Distributor. This Distributor purchased five CompuFlo Epidural Systems and disposables after executing the Agreement.

In April 2019, Milestone Scientific entered an Agreement with American 3B Scientific, a leading supplier of didactic material for education, for the development and sale of a CompuFlo® Epidural Training Instrument. This instructional instrument utilizes the pressure sensing technology and will be utilized as a training instrument to improve epidural placement success. The first sale of this new medical instrument occurred in May 2019, for three instruments and three disposable kits.

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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 has incurred significant operating losses since its inception. On December 31, 2020, cash on hand was \$22,119 with negative working capital of approximately \$17 million. As of December 31, 2020, the Company 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 will continue to manage its cash position while taking strategic steps to commercialize the Epidural instrument in the USA and throughout the world.

During the second quarter of 2020 the Parent Company raised gross proceeds of approximately \$19.7 million from the sale of common stock and warrants. Milestone Scientific, Inc intends to advance additional funds to the Company for manufacturing, marketing, sales, and distribution of its CompuFlo® Epidural System and for the development of new products and new product uses. However, Milestone Scientific, Inc. is under no obligation to advance any or all of such funds and may be required to utilize some or all of the funds to support Milestone Scientific Inc.'s other working capital requirements and for general corporate purposes.

If Milestone Scientific, Inc. is unable to advance appropriate amounts of funding and Milestone Medical is unable to obtain other sources of funding, there will 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.

**Inventories**

Inventories principally consist of finished goods and component parts stated at the lower of cost (first-in, first-out method) or net realizable value. Inventory quantities on hand are reviewed on a quarterly basis and a provision for excess, slow moving, defective, and obsolete inventory is recorded if required based on past and expected future sales, potential technological obsolescence, and product expiration requirements. The valuation allowance creates a new cost basis for the inventory, and it is not subsequently marked up.

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

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through a reduction in the valuation allowance based on any changes in the underlying facts and circumstances. The valuation allowance is only reduced if or when the underlying inventory is sold or destroyed. For the years ended, December 31, 2020 and 2019, inventory was recorded net of a valuation allowance for slow moving inventory of approximately \$450,000. See Note 4.

**Use of Estimates**

The preparation of financial statements in conformity with 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 the financial statements and reported amounts of revenues and expenses during the reporting period. The most significant estimates relate to inventory realization, cash flow assumptions regarding going concern considerations and valuation allowances on deferred tax assets. Actual results could differ from estimates.

**Advances to Contractors**

The advances to contractors represent funding to a subcontractor for parts required for epidural instrument manufacturing and repairs. For the years ended, December 31, 2020 and 2019 advances to contractors was \$314,116 and \$273,149, respectively.

**Equipment, net**

Equipment, net 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, 2020 and 2019 was approximately \$5,700 and \$8,400, 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 assess revenue recognition for its customer 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; 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;
- 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.

The Company derives its revenues from the sale of its products, primarily medical instruments, handpieces/disposables, and other related products. The Company sells its products primarily through medical facilities and a global distribution network. Revenue from product sales is 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.

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

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The Company has no obligation on product sales for any installation, set-up, or maintenance, these being the responsibility of the buyer. The Company's only obligation after sale, except for specific contracts and arrangements that provide for customer right to return provisions, 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.

*Sales Returns*

The Company records allowances for product returns as a reduction of revenue at the time the product sales are recorded. Several factors are considered in determining whether an allowance for product returns is required, including the customers' return rights, the Company's historical experience with returns and the amount of product in the distribution channel not consumed by end users and subject to return.

The Company relies on historical return rates to estimate returns. In the future, if any of these factors and/or the history of product returns change, an adjustment to the allowance for product returns may be required.

*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 be 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 condensed consolidated statements of operations.

*Disaggregated Revenue Information*

	2020	2019
Product sales, net		
Domestic		
Epidural devices-trainer	\$ -	\$ 10,800
Handpieces/disposables-EPI	2,000	2,900
Total	<u>\$ 2,000</u>	<u>\$ 13,700</u>
International		
Epidural devices	\$ -	\$ 8,000
Epidural devices-trainer	7,600	-
Handpieces/disposables-EPI	6,200	15,500
Accessories	-	400
Total	<u>\$ 13,800</u>	<u>\$ 23,900</u>
Total Product sales	<u>\$ 15,800</u>	<u>\$ 37,600</u>

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

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**Intangible Asset**

The Company amortizes the intangible asset contributed which is comprised of platform technology over its estimated useful life of 5 years. In the fourth quarter of 2019, the marketing and sales efforts relating to the Epidural instrument had not met the expectations as forecasted for the year. Based on forecasts, the Company did not expect to realize the carrying value of the asset before the estimated useful life expired and, as a result, recorded an impairment charge of \$750,000 in the fourth quarter of 2019. There was \$0 and \$300,000 of amortization expense in the years ended December 31, 2020, and 2019, respectively.

**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.

The Company and its Parent Company file a federal income tax return on a consolidated basis. State Income Taxes are filed on a separate company tax return. Income taxes are calculated on a separate return basis in accordance with a tax sharing agreement between Milestone Scientific, Inc., and its consolidated affiliates. For the years ended December 31, 2020 and 2019, the Company recorded a de minimis State tax provision(benefit). The Federal benefits in 2020 and 2019 has been completely offset by a valuation allowance.

Deferred tax assets and liabilities are recognized as temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities. The Company currently does not recognize certain deferred tax assets because they file a consolidated tax return with Milestone Scientific, Inc, and does not have the legal ability to utilize the deferred tax assets.

On December 31, 2020 and 2019, we had no uncertain tax positions that required recognition in the consolidated 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 2017, 2018, and 2019 years are subject to audit by federal and state jurisdictions.

**Stock-Based Compensation**

Share-based payments to employees and third parties for services are recognized in the Statements of Operations over the service period, as an operating expense, based on the grant-date fair values. The compensation has been allocated to Milestone Medical for officers of Milestone Scientific Inc. that have provided services to Milestone Medical and were issued stock options of Milestone Scientific Inc.

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

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**Recent Accounting Pronouncements**

In September 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-13, “Financial Instruments - Credit Losses” (Topic 326). The ASU sets forth a “current expected credit loss” (CECL) model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable supportable forecasts. This replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. In February 2020, the FASB issued ASU 2020-02, “Financial Instruments - Credit Losses” (Topic 326), which amends the effective date of the original pronouncement for smaller reporting companies. ASU 2016-13 and its amendments will be effective for the Company for interim and annual periods in fiscal years beginning after December 15, 2022. The Company is currently assessing the impact of the adoption of this standard on its financial statements.

In December 2019, FASB issued ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes”, which clarifies for the accounting treatment for the accounting tax aspects relating, in part, to the intra-period allocations and foreign subsidiaries. ASU 2019-12 is effective for all entities with fiscal years beginning after December 15, 2020. The adoption of this standard is not expected to have a material effect on financial statement presentation.

In August 2020, FASB issued ASU 2020-06, “Debt—Debt with Conversion and Other Options” (Subtopic 470-20) and “Derivatives and Hedging—Contracts in Entity’s Own Equity” (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity, which, generally, provides guidance for accounting regarding derivatives relating to entities common stock and earnings per share. ASU 2020-06 is effective for all entities with fiscal years beginning after December 15, 2021, including interim periods therein. The adoption of this standard is not expected to have a material effect on financial statement presentation.

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**NOTE 4 - INVENTORIES:**

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Inventories, net as of December 31, 2020 and 2019 consist of the following:

	<u>December 31, 2020</u>	<u>December 31, 2019</u>
Inventories consists of the following:		
Epidural instruments	\$ 162,767	\$ 139,090
Epidural instruments - trainer	1,626	4,879
Intra-articular instruments, net	-	-
Epidural instrument- disposables	35,934	-
Component parts and other materials	253,793	69,892
Component parts and other materials - trainer	1,245	1,290
Total	<u>\$ 455,365</u>	<u>\$ 215,151</u>

There is a full reserve for all Intra-articular instrument which was approximately \$450,000 for the years ended December 31, 2020 and 2019.

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**NOTE 5 - RELATED PARTY TRANSACTIONS:**

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On December 31, 2014, Milestone Scientific, Inc. executed a \$2 million line of credit agreement to provide bridge financing to the Company through April 15, 2016. Borrowings under the line bear interest at a rate of 3.25%, the prime rate at the inception of the agreement. In September 2015, the company requested and received approval from the Board of Directors of Milestone Scientific, Inc. to increase the limit of the line of credit to a maximum of \$2.5 million. In January 2016, the credit agreement was again increased to \$3 million hold.

As of December 31, 2020, and 2019, \$2.8 million is outstanding as due to - related party on the accompany Consolidated Balance Sheets. Additionally, as of December 31, 2020 and 2019, the Company owes accrued interest on the line of credit of approximately \$494,000 and \$403,000, which is reported as accrued interest payable- related party. Interest is payable based on availability of funds. No interest has been paid to the Parent Company since the inception of the loan. As of the financial report issuance date, Milestone Scientific, Inc. has not demanded payment of the line of credit.

Also, as of December 31, 2020, and 2019, the Company owes approximately \$14.2 million and \$10.8 million, respectively, to Milestone Scientific, Inc. for expenses paid on the Company's behalf. These advances are non-interest bearing and due on demand. As of the financial report issuance date, Milestone Scientific, Inc. has not demanded payment of the advances.

The technology underlying the CompuFlo®, and an improvement to the controls for CompuDent® were developed by the Director of Clinical Affairs and assigned to the Parent Company. Milestone Medical purchased a license to this technology pursuant to an agreement dated January 1, 2005. The Director of Clinical Affairs will receive payments of 5% of the total sales of the Company's products until the expiration of the last patent carried by Milestone Scientific, Inc. The Director of Clinical Affairs' royalty fee was approximately \$790 and \$1,800 for the years ended December 31, 2020 and 2019, respectively.

In July 2017, Leonard 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 December 19, 2017, Mr. Osser placed on hold his consulting agreement with Milestone Medical to rejoin Milestone Medical Inc. as Interim Chief Executive Officer and will not receive or earn any compensation under the consulting agreement until he is no longer Interim Chief Executive Officer.

In December 2020, the Company signed an Agent Agreement (Agreement) with Milestone Scientific Inc. to facilitate sales of medical instrument and disposables to a General Purchasing Organization (GPO) in the USA. The Agreement requires the Company to pay a five (5) percent commission on all sales to this GPO, to Milestone Scientific Inc. The GPO services a significant number of hospitals and other medical facilities in the USA and requires that the Parent Company be financially responsible to the delivery and efficacy of the instrument and the related disposables. In 2020, there were no commissions due under this agreement.

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**NOTE 6 – CONCENTRATIONS AND SUPPLY UNCERTAINTIES:**

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The Company has informal arrangements for the manufacture of its products. The epidural, epidural trainer, and intra-articular instruments are manufactured by Tricor Systems, Inc., a United States based Company, pursuant to specific purchase orders.

The Company sub-contracts its research and development (R&D) to multiple vendors, for the year ended December 31, 2020 and three vendors made up 61% of total R&D cost. For the year ended December 31, 2019, one vendor made up 92% of total R&D cost.

The handpieces with no needles are supplied by several independent contractors in the United States, which are manufactured in China. In December 2019, and through the date of financial statement issuance, the outbreak of the Wuhan Coronavirus (COVID-19), and the continuing spread of the illness in China and other parts of the world, did not result in a disruption in the supply chain of raw materials. If the outbreak of the Wuhan Coronavirus continues to expand (Pandemic), the possibility of factory quarantines and imposing shipping and travel restrictions, could interfere with our delivery of parts and other components required to produce our medical instruments and disposable kits, and could adversely impact our financial condition and results of operations. As of the date of this report, the Chinese factories that we depend on for the delivery of parts and components to produce our medical instruments and disposable kits are operational.

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. Accordingly, the termination or interruption 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.

For the twelve months ended December 31, 2020, an aggregate of approximately 100% of net product sales were to three customers/distributors, 49%, 38% and 13%, respectively. For the twelve months ended December 31, 2019, an aggregate of approximately 93% of net product sales were to three customers/distributors, 41%, 30% and 22%, respectively.

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**NOTE 7 – STOCK BASED COMPENSATION:**

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Stock-based compensation cost is measured at the grant date on the fair value of the award. Generally, compensation expense is recognized over the vesting period. For the years ended December 31, 2020 and 2019, the Company recorded stock compensation expense of approximately \$327,000 and \$-, respectively. The compensation has been allocated to Milestone Medical for officers of Milestone Scientific Inc. that have provided services to Milestone Medical and were issued stock options of Milestone Scientific Inc. The Company had approximately \$519,000 and \$-, of unrecognized compensation cost related to non-vested options, for the years ended December 31, 2020 and 2019 respectively, which Milestone Medical expects to recognize these costs over a weighted average period of 2.98 years and 0 years, respectively.

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**NOTE 8 - COMMITMENTS :**

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As of December 31, 2020, we have an open purchase order of \$607,735 for Epidural instruments and have advanced \$314,116 against this purchase commitment.

See Note 5 for Related Party Commitments.

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**NOTE 9 – INCOME TAX :**

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Milestone Medical, Inc. and its Parent Company file a federal income tax return on a consolidated basis. State Income Taxes are filed on a separate company tax return. Income taxes are calculated on a separate return basis in accordance with a tax sharing agreement between Milestone Scientific and its consolidated affiliates. For the years ended December 31, 2020 and 2019, Milestone Medical, Inc. recorded a Federal and State tax provision and benefit of approximately \$0 and \$511, respectively.

Deferred tax assets and liabilities are recognized as temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities. The Company currently does not recognize any deferred tax assets because they file a consolidated tax return with Milestone Scientific, Inc, and does not have the legal ability to utilize the deferred tax asset.

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**NOTE 10 – SUBSEQUENT EVENTS:**

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After December 31, 2020, Milestone Scientific Inc. has advanced Milestone Medical approximately \$150,000 to support the commercialization process for the epidural instrument and other expenses necessary for the day-to-day operations of the Company.

## 6. REPORT ON MILESTONE MEDICAL INC. AND SUBSIDIARY'S ACTIVITIES IN YEAR 2020

The Company intends to continue to work with the medical education market with the introduction of the CompuFlo® Epidural Trainer (CompuFlo Trainer), an instructional instrument that uses pressure sensing technology to improve epidural placement success. The COVID -19 Pandemic has reduced our access to this segment of the Medical business since earlier this year. The company has signed an agreement to distribute the CompuFlo Trainer with American 3B Scientific, a leading supplier of didactic material for medical education. 3B's customers include universities, schools, ministries or authorities of health and education, hospitals, practitioners, educational and medical distributors, and medical students. The CompuFlo Epidural Trainer is for training purposes only and not intended for clinical use. The Company will continue to address sales effort on the medical education space with medical schools and skill labs with the introduction of the Epidural Trainer instrument. The training institutions will also be a main customer target for our direct sales team, that was further expanded on in the USA in 2020.

The Company added three Territory Sales Managers (in the USA) in 2020 and in 2021, the Company added a Sales Director to focus on the USA Market for Hospitals and Medical Centers. Unfortunately, the COVID-19 Pandemic has significantly reduced the effectiveness of the new additions to staff, by severely limiting access of these individuals to potential users of the CompuFlo Epidural instrument.

On September 9, the Company provided on ESPI/21/2020 a business update regarding the commercial roll-out of its CompuFlo® Epidural System and CathCheck™ technology. With COVID-19 infections declining in certain regions, and several hospitals re-opening to outside vendors, the Board of Directors of the Company is advancing sales efforts around the CompuFlo® Epidural System and CathCheck™ technology. To support the hospitals in performing procedures during the pandemic, the Board of Directors of the Issuer decided to make the CompuFlo instrument more readily available to hospitals by lending the instrument to the hospital, in exchange for a commitment to purchase a minimum number of disposables. This offering is limited to the first hospitals that sign up for this program. At the same time, the Company is partnering with anesthesiologists, to approach the purchasing departments of the hospitals together. The Board of Directors of the Company believes that the current strategy allows the Issuer to streamline the Value Analysis Team (VAT) approval process, and thereby shorten the sales cycle. The response thus far has been encouraging, and the Company is increasing new trials in major hospitals over the coming weeks. The Board of Directors of the Company looks forward to finalizing agreements with several premier hospitals soon as the sales pipeline is more robust than ever.

For the twelve months ended December 31, 2020 the Issuer and its Subsidiary have generated a net loss of \$3,420,474. This loss was due to research and development costs of \$303,944, interest expense of \$95,690 and to a high level of general and administrative and other expenses, which amounted to \$2,979,936.

On April 15, 2020, the company reported on ESPI/12/2020 Milestone announced that it has validated the new "Quick Start," which has been implemented into the CompuFlo® Epidural System. The Quick Start feature simplifies and provides an alternative pathway to reduce the procedure preparation time for the CompuFlo® instrument prior to the procedure.

The Issuer also announced on April 17, 2020 on ESPI/13/2020 the first major study to clearly validate the cost benefits of CompuFlo within labor and delivery versus the traditional loss of resistance technique using the hypodermic syringe. This study has become be an important tool as we present the value proposition of our instrument to hospitals across the country, indicating an average cost saving of \$504 per hospital stay related to a lower rate of accidental dural puncture complications with our instrument.

The Company has made technical improvements to its products, which the Issuer believes will support the commercial efforts going forward. On April 21, 2020, the Company reported on ESPI/14/2020 Milestone announced that it has validated and integrated the new CathCheck™ feature into the CompuFlo® Epidural System. Using CathCheck™, physicians and nurses can monitor the placement of a catheter to determine the presence or absence of a pulsatile waveform (heartbeat) providing new information that can be used to determine if the catheter is in place or has become dislodged from the epidural space. This can be performed within seconds by measuring the pulsatile waveform within the epidural space. This capability saves time and money and provides better patient care. In fact, a major university hospital familiar with CompuFlo was attracted to new CathCheck technology, given its ability to minimize contact between the patient and provider, which is especially important during the COVID-19 pandemic.

On May 13, 2020, the Company announced on ESPI/15/2020 that a study was published in the Open Journal of Anesthesiology validating the efficacy of the CompuFlo® CathCheck™ System to confirm the correct placement and positioning of an epidural catheter for use during and after an epidural procedure. This is another validation that the CathCheck™ feature will help to significantly reduce time and cost for the institution by providing a more reliable way to re-check the catheter throughout the day to ensure that the catheter has not been displaced.

On October 13, 2020, Milestone Medical, Inc. announced a Group Purchasing Agreement with Premier, a leading healthcare improvement company, utilizing an alliance of approximately 4,100 U.S. hospitals and 200,000 other providers, to transform healthcare. The Agreement is effective November 1, 2020, and allows Premier members, at their discretion, to take advantage of special pricing and terms pre-negotiated by Premier for the CompuFlo® Epidural System and CathCheck™. The Agreement expires on February 28, 2022.

The Company was in the process of attending Medical device trade shows and attending introductory meetings with medical device distributors within the United States, Europe, and other International markets. COVID-19 was reported to have surfaced in Wuhan, China in December 2019, and now that it has spread to other countries throughout the world, it could adversely impact our operations or those of our third-party partners. Effects of COVID-19 have dramatically reduced our direct marketing capabilities at Hospitals and Medical Centers in the USA and worldwide during 2020.

Due to the Coronavirus Pandemic, such trade shows have been cancelled through 2020. The Company is now in the process of re-energizing its direct sales efforts with select hospitals and end user meetings as the Pandemic surge has slowed in the USA. The Company's focus will be on marketing the Epidural medical instruments in the United States.

Beginning in September 2020, selective states in the USA have opened their facilities to elective medical procedures and to allow non-employee Sales Representative to enter their facilities. The Vice President of Sales and Territory Sales Managers have started to reengage with targeted medical customers. However, this process is slow and subject to change based on the future impact of a COVID-19 resurgence.

The extent to which the Coronavirus impacts our operations or those of our third-party partners will depend on future developments, which are still highly uncertain and cannot be predicted with confidence. The continued possible spread and/or resurgence of the virus could negatively impact the manufacture, supply, distribution, marketing efforts, and sale of our products and our financial results.

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

The Issuer, in 2020, 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 need approval of 510(k) prior to commercialization. The IA instruments are finalized by the third-party developer, but 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 instruments; and the Issuer is moving forward for direct sales opportunities with medical facilities and, potential 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 for both instruments (CE) in the European Union during September 2014; and FDA clearance for the Epidural Instrument in June 2017. Thus Management believes that upon resubmission of the IA instrument it will receive approval because of the epidural and dental precedent.
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 2019 (for the epidural trainer) and other potential distribution outside the USA in the future. Additionally, the Company is expanding direct sales policy with key medical facilities in the USA and intentional, to provide additional points of contact. 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 increased to approximately \$924,000 for the year ended December 31, 2020 from \$591,000 for the year ended December 31, 2019.

The cash balance of \$22,119 is a critical issue for the Company moving into 2021. 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)**

	2020	2019
<b>Current Assets</b>	<b>915,369</b>	<b>582,487</b>
Cash	22,119	8,773
Accounts receivable	-	2,600
Prepaid expenses and other current assets	123,769	82,814
Inventory	455,365	215,151
Advances to contractors	314,116	273,149
Equipment, net depreciation	8,289	8,240
<b>TOTAL ASSETS</b>	<b>923,658</b>	<b>590,727</b>

Source: The Issuer

During 2020, the main source of the Issuer's financing was borrowing from Milestone Scientific, Inc. The Issuer intends to slow its cost structure for instrument development. However, the Company will expend funds for marketing and sales of the medical instruments in the USA and in Europe in 2021. For the years ended December 31, 2020 and 2019, the Issuer had no long-term debt or any other long-term liabilities. The Company had current liabilities (accounts payable, accrued expenses, line of credit and advances from Milestone Scientific, Inc.) in the amount of approximately \$17.9 million for the year ended December 31, 2020 and approximately \$14.5 million for the year ended December 31, 2019. The substantial increase in current liabilities of approximately \$3.4 million, is due to loss from operations in 2020, financed by the parent company, Milestone Scientific, Inc. 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)**

	2020	2019
<b>Current Liabilities</b>	<b>17,945,911</b>	<b>14,505,850</b>
Accounts payable and accrued expenses	418,898	543,824
Accrued interest due Milestone Scientific, Inc.	494,136	402,889
Payable to Milestone Scientific, Inc.	17,032,877	13,559,137
<b>TOTAL LIABILITIES</b>	<b>17,945,911</b>	<b>14,505,850</b>

Source: The Issuer

The \$17,945,911 and \$14,505,850 on December 31, 2020 and 2019 includes \$2.8 million of advances on a line of credit established by Milestone Scientific Inc in both years, and approximately \$14.7 million and \$11.2 million for 2020 and 2019, respectively, of other advances and accrued interest.

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

	2020	2019
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at December 31, 2020 and December 31, 2019	2,200	2,200
Additional paid in capital	7,258,833	6,931,861
Accumulated deficit	(24,283,286)	(20,849,184)
<b>TOTAL SHAREHOLDERS' DEFICIT</b>	<b>(17,022,253)</b>	<b>(13,915,123)</b>

Source: The Issuer

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

	<b>2020</b>	<b>2019</b>
Current ratio (CR)	0.05	0.04
Quick ratio (QR)	0.00	0.00
Cash ratio	0.00	0.00

Source: The Issuer

The algorithm of above ratios' calculation was:

$$\begin{aligned} \text{Current ratio (CR)} &= \text{Total current assets/Total current liabilities} \\ \text{Quick ratio (QR)} &= \frac{\text{(Total current assets – Inventory-Prepaid expenses and other current assets- customer advances)}}{\text{Total current liabilities}} \\ \text{Cash ratio} &= \text{Cash and cash equivalents/Total current liabilities} \end{aligned}$$

### **Liquidity analysis**

As of December 31, 2020, the Issuer had higher levels of total current liabilities and a low amount of cash. The increase in the liquidity ratios in 2020 was primarily caused by a more significant rise in total current assets than total current liabilities.

As of December 31, 2020, 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 CompuFlo Epidural instrument progressed beyond the development stage, additional equity financing is necessary to fund the commercialization of the medical instruments. To this end, Milestone Scientific, Inc., the Parent Company, raised gross proceeds of approximately \$19.7 million from the sale of Milestone Scientific common stock and warrants. Milestone Scientific, Inc intends to advance additional funds to the Company for manufacturing, marketing, sales, and distribution of its CompuFlo® Epidural System and development of new products and new product uses as well as to help mitigate the risks related to COVID-19. However, Milestone Scientific, Inc. is under no obligation to advance any or all of such funds and may be required to utilize some or all of the funds to support Milestone Scientific Inc.'s other working capital requirements and for general corporate purposes.

### **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.**

Although the CompuFlo Epidural instrument obtained FDA clearance in the United States (June 2017), the development costs is expected to increase for specific instrument enhancements during 2020. These enhancements do not require a new 510(k). The FDA clearance provided 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 510(k)-application process has been delayed due to the Covid-19 Pandemic.

**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 \$304,000 in research and development for the Epidural instruments in 2020, an increase of approximately \$114,000 over 2019. The increase was due to specific instrument enhancements. The Issuer plans to expand its marketing efforts including attending virtual medical device trade conferences in the USA (major focus) and CE authorized countries in Europe and the Middle East in 2020.

**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**

<b>SUBSIDIARY</b>	<b>MILESTONE MEDICAL POLAND SP. Z.O.O.</b>
Registered office/Office:	Place 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 510(k) original application filed with FDA lapsed in January 2019. Following consultation with the FDA Office of Device Evaluation, we intended to file a new 510(k) application for the device in 2020. Due to the COVID-19 Pandemic, this process is currently under review.

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.

In January 2020, the company reports on ESPI/4/2020 the receipt of a report by Dr Olivier Choquet, a recognized international expert on peripheral nerve blocks (PNB) and a consultant to Milestone Scientific, Inc., the majority shareholder and licensor of the Issuer, which concludes that the CompuFlo® with Dynamic Pressure Sensing technology® is the only available device capable of precisely measuring, displaying, warning, controlling and recording needle tip pressure in real time to help reduce the risk of needle injury during PNB procedures.

Moreover, in relation to PNB instrument, in February 2020, the Company announced on ESPI 6/2020 that Milestone Scientific, Inc. has received Notice of Allowance from the European Patent Office (EPO) covering its instrument for performing a peripheral nerve block (PNB). This patent award follows a similar patent in United States, and further expands the worldwide intellectual property. This instrument is designed to significantly improve safety, efficiency, and efficacy of PNB procedures. The Board of Directors of the Company believes that PNBs represent an attractive market for the CompuFlo® technology, as PNBs are increasingly utilized in the treatment of trauma and surgical procedures, including orthopedic surgeries as well as for postoperative and nonsurgical analgesia.

In January 2020, the Issuer reported on ESPI 2/2020 that Milestone Scientific, Inc. has received a Notice of Allowance for a key patent from the U.S. Patent and Trademark Office on its CompuWave technology, which is being integrated into the CompuFlo® Epidural System. The Issuer is constantly evolving and innovating the technology. This patent represents a significant achievement for the Company since it extends the IP protection around the CompuFlo instrument for another 20 years and provides not only additional confirmation of placement, but also verification during the procedure that the catheter has not been displaced. The Board of Directors of the Issuer believes that this advanced patented technology further enhances the position of the Company at the forefront of the computerized injection market.

In February 2020, the Company announced an abstract entitled "Confirmation of epidural catheter location by epidural pressure waveform recordings by the CompuFlo® Epidural Instrument (CompuFlo)," has been accepted for presentation at the prestigious Euroanaesthesia 2020 Congress which was to take place May 30 - June 1, 2020 in Barcelona, Spain. Euroanaesthesia is Europe's largest annual event showcasing the latest news and innovations in the field of anaesthesia, perioperative medicine, intensive care, emergency medicine and pain treatment. This international event gathers upwards of six thousand delegates from around the world. The abstract will be presented during scientific poster sessions highlighting how CompuWave technology integrated with the CompuFlo Epidural System combines both objective in-line pressure measurements and the detection of a pulsatile pressure waveform in a single system. However due to the continual spread of COVID-19, The Issuer's presented at the prestigious Euroanaesthesia 2020 Congress in Barcelona held in August 2020.

Moreover, also in February 2020, the Issuer reported on ESPI/7/2020 that new pre-assembled disposable kit for the CompuFlo® Epidural System has received CE Mark approval in Europe through the Company's supplier. The Board of Directors of the Issuer believes that this CE Mark approval overcomes an important hurdle to commercialization in Europe. Based on market feedback, it was evident that anesthesiologists using the epidural instrument preferred to have the disposable kit pre-assembled before packaging to save valuable minutes in the operatory.

The Company also announced on ESPI 9/2020 filed on March 20, 2020 the impact of the COVID-19 pandemic on the commercial rollout of the CompuFlo® Epidural System and Issuer's financial results in 2020. The Company is doing its part to promote and protect the health of the employees and partners by maintaining safe working environments or remote working. On the supply side, the current inventory level for epidural instruments and handpieces are sufficient to cover immediate needs for at least the next two financial quarters. All the suppliers continue to manufacture the instrument and the Company does not anticipate any supply chain disruptions. Going forward, as the social gatherings are currently prohibited, the Company adjusted its commercial rollout strategy by placing the system with key opinion leaders, leading anesthesiologists in the U.S. and Europe, as well as distributors and Group Purchasing Organizations (GPO) utilizing distance communication and training instead of face-to-face meetings and trade shows. However, the Company is aware of the potential for lower demand near-term, as the anesthesiologists and hospitals are currently focusing on fighting the COVID-19 pandemic. Nevertheless, the Company remains confident in the long-term outlook for the business, and the prospects for the CompuFlo Epidural System to become the standard of care in the coming years.

On January 4, 2021, the Company announced on ESPI/1/2021 that as per a purchase order the Company received in late 2020, the Issuer has begun selling CompuFlo® disposables to the University of Texas Medical Branch at Galveston (UTMB), an institution of the University of Texas System and agency of the State of Texas.

On January 11, 2021, the Company announced on ESPI/3/2021 that it entered into an agreement with Bitmedical AG to distribute the CompuFlo Epidural Instrument and CathCheck System, as well as related disposables, in Switzerland and Austria. Bitmedical is a distributor of medical devices and equipment within Switzerland and Austria.

On January 11, 2021, the Company announced on ESPI/3/2021 that it entered into an agreement with Bitmedical AG to distribute the CompuFlo Epidural Instrument and CathCheck System, as well as related disposables, in Switzerland and Austria. Bitmedical is a distributor of medical devices and equipment within Switzerland and Austria.

On January 12, 2021, the Company announced on ESPI/4/2021 that it has commenced sales of CompuFlo Epidural and CathCheck Disposables to Regional Medical Center (RMC), a premier regional healthcare system in South Carolina, United States of America.

On February 23, 2021, the Company announced on ESPI/6/2021 that it has begun selling its CompuFlo® Epidural Instrument and related disposables to the University Hospital of Würzburg, one of the leading national hospitals in Germany.

On February 24, 2021, Milestone Medical, Inc. announced on ESPI/7/2021 that Milestone Scientific Inc., the licensor, and the majority shareholder of the Issuer has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) related to its new CompuPulse System, which integrates the Company's CompuWave™ technology with a manual syringe.

On March 2, 2021, the Company announced on ESPI/8/2021 that it has begun selling CompuFlo® / CathCheck™ disposables to the Medical University of South Carolina (MUSC). MUSC Health owns and operates eight hospitals and provides patient care throughout the state of South Carolina.

On March 10, 2021, the Company announced on ESPI/9/2021 that Milestone Scientific Inc., the licensor and the majority shareholder of Milestone Medical Inc. has received Notice of Allowance from the European Patent Office (EPO) combining minimum intensity of nerve stimulation (MIS) and real-time injection pressure (IP) monitoring utilizing Milestone's CompuFlo® instrument and associated DPS Dynamic Pressure Sensing Technology® to optimize needle tip location in ultrasound-guided peripheral nerve block (PNB) procedures.

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

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

#### **6.8 Remuneration to Directors and Officers**

The Issuer does not pay any remuneration to the directors for their service provided. The Interim Chief Executive Officer was paid approximately \$180,000 and Chief Financial Officer was paid approximately \$50,000 in 2020. The Officers of the Company were paid Interim Chief Executive Officer \$95,000 and Chief Financial Officer \$35,000 in 2019. All payments to the Interim Chief Executive Officer and the Chief Financial Officer were recorded as due to the Company's parent Milestone Scientific, Inc.

## **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, 2020 and 2019, 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, 2020 and 2019, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020 and 2019, 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.

### **Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

## ***Inventories and Valuation of Related Estimates and Obsolescence***

### *Critical Audit Matter Description*

Certain inventory requires management to make significant assumptions and subjective judgments about the net realizability of product inventory for which the products have been approved by appropriate regulatory agencies, but which also represent new technology with unproven market acceptance. These assumptions include future usage and those required to develop sales forecasts based on studies and analysis without the benefit of historical experience. Given the subjectivity of estimating these key assumptions, performing audit procedures to evaluate whether inventory was appropriately recorded at December 31, 2020 required a high degree of auditor judgment and an increased extent of effort.

### *How We Addressed the Matter in Our Audit*

The following are the most relevant procedures we performed to address this critical audit matter:

- Testing whether the data used to determine if inventory is obsolete was complete and accurate and sufficiently precise.
- Evaluating whether the expected customer demand used was reasonable, considering the Company's current and past marketing efforts and their market studies in developing the estimate of future demand, the estimated useful life of the inventory, current economic and competitive conditions that could impact the forecasts, and the timing of the introduction and development of new or enhanced products.
- Evaluating the reasonableness of management's assumption related to the risk of technological or competitive obsolescence for products involved considering the technological or competitive obsolescence experiences during the product life cycle of existing products used in other business lines.

*/s/ Friedman LLP*

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

East Hanover, New Jersey  
March 19, 2021

## 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 2020.

**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 except for 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	The Company has only one business segment generating revenue.
	3.3 Description of the issuer’s market including indication of the Issuer’s market position;	YES	The Issuer applies this practice except for 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 Prospectus in Chapter B.5, B.6, 17.2, 18.3 and 19
3.6 Corporate documents of the Company;	NO	During 2020, the Company did not place such documents	

3.7. Outline of the Company's strategic plans;	YES	Strategic plans of the Company were placed in Chapter 6.1.2 of Prospectus available in the Investor Relations section of the Issuer's website
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	
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.infostrefa.com">www.infostrefa.com</a>	NO	The Company does not use its individual investor relations section on the website <a href="http://www.infostrefa.com">www.infostrefa.com</a> . The Issuer pursues an information policy on Investor Relations section of its corporate website.
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 except for 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 except for 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.	NO	The Issuer is owed approximately 98.3% 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	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

Milestone Medical, Inc.