

# **Consolidated report of**

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

### **2<sup>nd</sup> quarter (April 1, 2021 to June 30, 2021)**

***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, August 16, 2021

## 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:kharcum@milestonescientific.com">kharcum@milestonescientific.com</a>
<b>Main website address:</b>	<a href="http://www.medicalmilestone.com">www.medicalmilestone.com</a>

Source: The Issuer

### 1.1 Shareholding structure

In the table below shares issued are outstanding for computing the ownership percentage of shareholders holding at least 5% of votes at the General Meeting of Shareholders, applicable percentages are based on 22,000,000 shares outstanding on the date of this 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

## 1.2 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>	54	Sep-13	Next Annual Meeting of Shareholders
<b>Martin S. Siegel</b>	76	Sep-14	Next Annual Meeting of Shareholders

Source: The Issuer

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

On June 30, 2021, the Issuer employed ten (10) full time employees and eight (8) persons allocated from the parent company (Milestone Scientific Inc.) converted into full-time equivalents (“FTEs”). The Company has expanded its medical sales team in part, to more hospitals re-opening their facilities to outside sales representatives, as well as the safety and economic value proposition of our system. Previously, we had made the strategic decision to await the recovery of the pandemic prior to investing heavily in salesforce expansion, which allowed us to preserve capital. However, we are now aggressively building our sales and marketing organization to capitalize on these opportunities.

On April 13, 2021, the Company announced on ESPI/11/2021 the retirement of Joseph D’Agostino, the Company’s Chief Financial Officer. Mr. D’Agostino, age 70, has been instrumental in overseeing treasury and cash management, strategic planning, information technology, internal controls, Sarbanes-Oxley compliance, operations, and financial and tax accounting.

On May 14, 2021, the Company announced on EBI/3/2021 the appointment of Jan Adriaan (Arjan) Haverhals as Chief Executive Officer of the Company, effective May 19, 2021. Mr. Haverhals will succeed Leonard Osser at Milestone Scientific Inc. and the Company.

Also on May 14, 2021, the Board of Directors announced on EBI/4/2021 the appointment of Scott Kahn as the Chief Financial Officer of the Company, effective May 24, 2021. On July 7, 2021, the Company announced on EBI/7/2021 that Scott Kahn, the Company’s Chief Financial Officer, and the Company have reached a mutual decision to part ways on July 2, 2021.

On July 27, 2021 the Company announced on EBI/8/2021 the appointment of Chet Trechock as Vice President of Sales starting from June 23, 2021. The Company believes having such a strategic sales leader with a proven track record in both medical devices and in the field of epidural drug delivery will help accelerate our growth and support our expansion initiatives to market our instruments and consumables nationwide more aggressively.

**2. Condensed Consolidated quarterly financial statements prepared according to the accounting rules applicable to the Issuer and its Subsidiary together with information on accounting rules (policy) applied to the preparation of report**

**Milestone Medical, Inc. and Subsidiary**

**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

As June 30, 2021, and December 31, 2020 and  
for the three and six months ended June 30, 2021 and 2020 (audited)

<b><u>Table of Contents</u></b>	<b><u>Page</u></b>
Condensed Consolidated Financial Statements:	
Condensed Consolidated Balance Sheets	5
Condensed Consolidated Statements of Operations	6
Condensed Consolidated Statement of Changes in Stockholders' Deficit	7
Condensed Consolidated Statements of Cash Flows	8
Notes to Condensed Consolidated Financial Statements	9-17

Milestone Medical, Inc. and Subsidiary  
Condensed Consolidated Balance Sheets  
(unaudited)

	June 30, 2021	December 31, 2020
<u>ASSETS</u>		
Cash and cash equivalents	\$ 128,706	\$ 22,119
Inventories, net	655,841	455,365
Advances to contractors	333,542	314,116
Prepaid expenses and other current assets	69,133	123,769
Total current assets	1,187,222	915,369
Equipment, net	9,755	8,289
Total assets	\$ 1,196,977	\$ 923,658
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Accounts payable	\$ 69,677	\$ 96,088
Accrued expenses and other payables	510,152	322,810
Accrued interest payable- related party	539,262	494,136
Advances from related party	16,247,669	14,232,877
Due to related party	2,800,000	2,800,000
Total current liabilities	20,166,760	17,945,911
Commitments and contingencies		
Stockholders' deficit		
Common stock, par value \$.0001; authorized 50,000,000 shares; 22,000,000 shares issued and outstanding at June 30, 2021 and December 31, 2020	2,200	2,200
Additional paid-in capital	7,389,683	7,258,833
Accumulated deficit	(26,361,666)	(24,283,286)
Total stockholders' deficit	(18,969,783)	(17,022,253)
Total liabilities and stockholders' deficit	\$ 1,196,977	\$ 923,658

See Notes to Consolidated Financial Statements  
See Notes to Condensed Consolidated Financial Statements

Milestone Medical, Inc. And Subsidiary  
Condensed Consolidated Statements of Operations  
(Unaudited)

	Three months ended June 30, 2021	Three months ended June 30, 2020	Six months ended June 30, 2021	Six months ended June 30, 2020
Product sales, net	\$ 21,000	\$ 2,000	\$ 92,050	\$ 9,800
Cost of products sold	9,871	1,237	38,309	4,746
Gross profit	<u>11,129</u>	<u>763</u>	<u>53,741</u>	<u>5,054</u>
Selling, general and administrative expenses	1,113,921	706,426	2,031,953	1,269,339
Research and development expenses	31,044	108,144	47,488	215,624
Depreciation and amortization	1,164	621	5,015	4,333
Total operating expenses	<u>1,146,129</u>	<u>815,191</u>	<u>2,084,456</u>	<u>1,489,296</u>
Loss from operations	(1,135,000)	(814,428)	(2,030,715)	(1,484,242)
Interest expense	<u>(23,957)</u>	<u>(23,649)</u>	<u>(47,665)</u>	<u>(47,443)</u>
Loss before income tax	<u>(1,158,957)</u>	<u>(838,077)</u>	<u>(2,078,380)</u>	<u>(1,531,685)</u>
Provision for income taxes	-	-	-	-
Net loss	<u>\$ (1,158,957)</u>	<u>\$ (838,077)</u>	<u>\$ (2,078,380)</u>	<u>\$ (1,531,685)</u>

See Notes to Condensed Consolidated Financial Statements

Milestone Medical, Inc. and Subsidiary  
Condensed Consolidated Statements of Changes in Stockholders' Deficit  
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, January 1, 2021	22,000,000	\$ 2,200	\$ 7,258,833	\$ (24,283,286)	\$ (17,022,253)
Stock Compensation from Parent	-	-	66,490	-	66,490
Net loss	-	-	-	(919,423)	(919,423)
Balance, March 31, 2021	<u>22,000,000</u>	<u>\$ 2,200</u>	<u>\$ 7,325,323</u>	<u>\$ (25,202,709)</u>	<u>\$ (17,875,186)</u>
Stock Compensation from Parent	-	-	64,360	-	64,360
Net loss	-	-	-	(1,158,957)	(1,158,957)
Balance, June 30, 2021	<u>22,000,000</u>	<u>\$ 2,200</u>	<u>\$ 7,389,683</u>	<u>\$ (26,361,666)</u>	<u>\$ (18,969,783)</u>
	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, January 1, 2020	22,000,000	\$ 2,200	\$ 6,931,861	\$ (20,849,184)	\$ (13,915,123)
Net loss	-	-	-	(693,608)	\$ (693,608)
Balance, March 31, 2020	<u>22,000,000</u>	<u>\$ 2,200</u>	<u>\$ 6,931,861</u>	<u>\$ (21,542,792)</u>	<u>\$ (14,608,731)</u>
Net loss	-	-	-	(838,077)	(838,077)
Balance, June 30, 2020	<u>22,000,000</u>	<u>\$ 2,200</u>	<u>\$ 6,931,861</u>	<u>\$ (22,380,869)</u>	<u>\$ (15,446,808)</u>

See Notes to Condensed Consolidated Financial Statements

Milestone Medical, Inc. and Subsidiary  
Condensed Consolidated Statements of Cash Flows  
(Unaudited)

	Six Months ended June 30, 2021	Six Months ended June 30, 2020
Cash flows from operating activities:		
Net loss	\$ (2,078,380)	\$ (1,531,685)
Adjustments to reconcile net cash (used in) operating activities:		
Depreciation and amortization expense	5,015	4,333
Stock Compensation from Parent	130,850	-
Changes in operating assets and liabilities:		
Increase in accounts receivable	-	600
Increase in inventories	(200,476)	(41,311)
Increase in advances to contractors	(19,426)	(68,585)
Decrease to prepaid expenses and other current assets	54,636	39,347
Increase (decrease) in accounts payable in accounts payable and accrued expenses	160,931	(63,693)
Increase in accrued interest related party	45,126	45,374
Net cash used in operating activities	<u>\$ (1,901,724)</u>	<u>\$ (1,615,620)</u>
Cash flows from investing activities:		
Purchases of equipment	(6,481)	(4,935)
Net cash used in investing activities	<u>\$ (6,481)</u>	<u>\$ (4,935)</u>
Cash flows from financing activities:		
Advances from related party	2,014,792	1,638,392
Net cash provided by financing activities	<u>\$ 2,014,792</u>	<u>\$ 1,638,392</u>
Net increase in cash and cash equivalents	106,587	17,837
Cash and cash equivalents at beginning of period	22,119	8,773
Cash and cash equivalents at end of period	<u>\$ 128,706</u>	<u>\$ 26,610</u>

See Notes to Condensed Consolidated Financial Statements

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For three and six months ended June 30, 2021 and 2020**

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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.

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. As of June 30, 2021, the Company has decided not to proceed with securing the FDA approval for the intra-articular instrument at this time. Milestone Medical’s immediate focus is on marketing its epidural device throughout the United States and Europe.

In 2020 the Parent Company raised approximately \$19.7 million (in two capital raises) and is in the process of evaluating the use of these funds to improve existing devices, develop new instruments, and establish distribution channels for existing products.

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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 condensed consolidated financial statements are issued. Milestone Medical has incurred significant operating losses since its inception. On June 30, 2021, cash on hand was approximately \$129,000 with negative working capital of approximately \$19.0 million.

As of June 30, 2021, 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.

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 marketing, sales, and distribution of its CompuFlo® Epidural System. If Milestone Scientific, Inc. does not or is not able 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.

The coronavirus (COVID-19) adversely impacted our operations and those of our third-party partners. As a result of the reduced hours and closings of dental offices throughout the country and the rest of the world due to the continuing spread of COVID-19, revenues for the three and six months ended June 30, 2020, were adversely affected. Business interruptions, including any interruptions resulting from COVID-19 could significantly disrupt our operations and could have a material adverse impact on our business during 2021. All of our employees are located in the U.S.

In addition to our employees, we rely on (i) distributors, agents, and third-party logistics providers in connection with product sales and distribution and (ii) raw material and component suppliers in the U.S., Europe, and China. If we, or any of these third-party partners encounter any disruptions to our or their respective operations or facilities, or if we or any of these third-party partners were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute, pandemic or other public health crises, or other unforeseen disruption, then we or they may be prevented or delayed from effectively operating our or their business, respectively.

In addition, it is uncertain as to what effect the continuing spread of COVID-19 (such as the Delta variant) will have on our commercialization efforts of our CompuFlo Epidural and CathCheck system as medical devices. Such future developments could have a material adverse effect on our financial results and our ability to conduct business as expected.

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

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#### **Basis of Presentation**

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

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments (consisting of normal recurring entries) necessary to fairly present such interim results. Interim results are not necessarily indicative of the results of operations which may be expected for a full year or any subsequent period. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020, included in Milestone Medical's Annual Report filed on March 19, 2021.

## **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 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. As of June 30, 2021, and December 31, 2020, 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's for parts required for epidural instrument manufacturing and disposable kits. On June 30, 2021 and December 31, 2020 advances to contractors was \$333,542 and \$314,116, 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 three and six months ended June 30, 2021 was approximately \$1,200 and \$5,015, respectively. The depreciation expense for the three and six months ended June 30, 2020 was approximately \$620 and \$4,300, 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;
- iii. measurement of the transaction price, including the constraint on variable consideration;
- iv. allocation of the transaction price to the performance obligations based on estimated selling prices; and
- v. recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a
- vi. distinct good or service to the customer and is the unit of account in ASC 606. The Company derives its revenues from the sale of its products, primarily medical instruments, handpieces/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.

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 shipping point; 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

	Three Months Ended June 30,	
	2021	2020
<b>Domestic: US</b>		
Instruments	\$ -	\$ -
Handpieces	-	2,000
Total Domestic US	<u>\$ -</u>	<u>\$ 2,000</u>
<b>International: Rest of World</b>		
Instruments	\$ 15,500	\$ -
Handpieces	5,500	-
Total International	<u>\$ 21,000</u>	<u>\$ -</u>
<b>Total Product Sales</b>	<u><b>\$ 21,000</b></u>	<u><b>\$ 2,000</b></u>

	Six Months Ended June 30,	
	2021	2020
<b>Domestic: US</b>		
Instruments	\$ -	\$ -
Handpieces	8,150	2,000
Total Domestic US	<u>\$ 8,150</u>	<u>\$ 2,000</u>
<b>International: Rest of World</b>		
Instruments	\$ 58,000	\$ 7,600
Handpieces	25,900	200
Total International	<u>\$ 83,900</u>	<u>\$ 7,800</u>
<b>Total Product Sales</b>	<u><b>\$ 92,050</b></u>	<u><b>\$ 9,800</b></u>

## 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.

On June 30, 2021 and 2020, we had no uncertain tax positions that required recognition in the consolidated financial statements. The Company's policy is to recognize interest and penalties 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. The 2020 tax returns have not yet been filed.

## 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.

## **Recent Accounting Pronouncements**

### Recently Adopted Accounting Pronouncements

In December 2019, FASB issued ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes”, which clarifies the accounting treatment for the accounting tax aspects relating, in part, to the intraperiod 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 as of January 1, 2021, did not have a material effect on the Company’s unaudited condensed consolidated financial statement presentation.

### Recently Issued Accounting Pronouncements

In June 2016, the FASB issued a new standard ASU No.2016-13, “Financial Instruments – Credit Losses” (Topic 326). The new standard is intended to replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. It will be effective for all smaller reporting entities for fiscal years and interim periods, beginning after December 15, 2022.

In January 2020, FASB issued ASU 2020-01, “Investments—Equity Securities (Topic 321), Investments—Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)”, which, generally, provides guidance for investments in entities accounted for under the equity method of accounting. ASU 2020-01 is effective for all entities with fiscal years beginning after December 15, 2021, including interim periods therein. The Company is analyzing the impact of the adoption of this standard; however, the adoption is not expected to have a material effect on the Company’s unaudited condensed consolidated 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 Company is analyzing the impact of the adoption of this standard; however, the adoption of this standard is not expected to have a material effect on the Company’s unaudited condensed consolidated financial statement.

In May 2021, FASB issued ASU 2021-04, Earnings Per Share (topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718) and Derivatives and Hedging – Contracts in an Entity’s Own Equity (Subtopic 815-40) – Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, which provides guidance of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share (EPS) effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU are effective January 1, 2022, including interim periods. Early adoption is permitted. The Company will apply the amendments prospectively to modifications or exchanges occurring on or after January 1, 2022. The Company will evaluate the impact of ASU 2021-04 on any future changes to the terms and conditions of its warrants.

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**NOTE 4 - INVENTORIES:**

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Inventories, net as of June 30, 2021, and December 31, 2020 consist of the following:

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Inventories consists of the following:		
Epidural instruments	\$ 425,590	\$ 162,767
Epidural instruments - Trainer	1,626	1,626
Intra-articular instruments, net reserve	-	-
Epidural instruments Disposables	118,657	35,934
Component parts and other materials	108,737	253,793
Component parts and other materials - Trainer	1,231	1,245
Total	<u>\$ 655,841</u>	<u>\$ 455,365</u>

There is a full reserve for all Intra-articular instrument which was approximately \$450,000 as of June 30, 2021, and December 31, 2020, respectively.

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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 increased to \$3 million.

As of June 30, 2021, and December 31, 2020, \$2.8 million is outstanding as due to - related party on the accompany Condensed Consolidated Balance Sheets. Additionally, as of June 30, 2021 and December 31, 2020, the Company owes accrued interest on the line of credit of approximately \$539,000 and \$494,000, 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 June 30, 2021, and December 31, 2020, the Company owes approximately \$16.3 million and \$14.2 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.

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. As of June 30, 2021 commission under this agreement was approximately \$500. In 2020, there were no commissions due under this agreement.

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 \$640 and \$4,330 for the three and six months ended June 30, 2021, respectively. The Director of Clinical Affairs' royalty fee was approximately \$100 and \$500 for the three and six months ended June 30, 2020, respectively.

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

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The COVID-19 pandemic materially adversely affected the Company's financial results and business operations. The Company's employees have been and are being affected by the COVID-19 pandemic. The majority of our office and management personnel are working remotely. The health of the Company's workforce is of primary concern and the Company may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the coronavirus. The effectiveness of the on-going vaccination process, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that have been imposed to date, and numerous other uncertainties. Such events may result in business and manufacturing disruption, inventory shortages, delivery delays, and reduced sales and operations, any of which could materially affect our business, financial condition, and results of operations.

Milestone Medical has informal arrangements with third-party manufacturers of the epidural, and intra-articular devices, pursuant to which they manufacture these products under specific purchase orders but without any long-term contract or minimum purchase commitment. Consequently, advances on contracts have been classified as current at June 30, 2021 and December 31, 2020. The termination of the manufacturing relationship with any of these manufacturers could have a material adverse effect on Milestone Scientific's ability to produce and sell its products. Although alternate sources of supply exist, and new manufacturing relationships could be established, Milestone Medical would need to recover its existing tools or have new tools produced. Establishment of new manufacturing relationships could involve significant expense and delay. Any curtailment or interruption of the supply, because of termination of such a relationship, would have a material adverse effect on Milestone Medical's financial condition, business, and results of operations.

For the three months ended June 30, 2021, international net product sales were an aggregate of approximately 100% respectively. For the six months ended June 30, 2021, domestic and international net product sales were an aggregate of approximately 12% and 88% respectively.

For the three months ended June 30, 2020, domestic net product sales were an aggregate of approximately 100%. For the six months ended June 30, 2020, domestic and international net product sales were an aggregate of approximately 20% and 80% respectively.

As of June 30, 2021, the purchase order commitment for epidural instruments was approximately \$328,000 and advances of approximately \$150,000 are reported in advances on contract in the unaudited condensed consolidated balance sheet.

In February 2021, the Company entered a new purchase commitment for the delivery of 1,185 cases of Epidural and CathCheck disposable kits beginning in April 2021. As of June 30, 2021, we have an open purchase order of approximately \$197,000 for 1,185 cases of Epidural and CathCheck disposable kits and have advanced approximately \$172,000, reported in advances on contract in the unaudited condensed consolidated balance sheet.

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**NOTE 7 – STOCK BASED COMPENSATION:**

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Stock based 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. Stock-based compensation cost is measured at the grant date on the fair value of the award. Generally, compensation expense is recognized over the awards vesting period. For the six months ended June 30, 2021 and 2020, Milestone Medical recognized approximately \$64,000 and \$131,000 of total employee compensation cost, respectively. As of June 30, 2021 there was approximately \$3.5 million of total unrecognized compensation cost related to non-vested options. Milestone Scientific expects to recognize these costs over a weighted average period of 4.4 years.

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**NOTE 8 - COMMITMENTS :**

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As of June 30, 2021, the Company entered a new purchase commitment for the delivery of 100 Epidural instruments beginning in September 2021. As of June 30, 2021, the purchase order commitment for epidural instruments was approximately \$329,000 and advances of approximately \$161,000 are reported in advances on contract in the unaudited condensed consolidated balance sheet.

As of June 30, 2021, we have an open purchase order of approximately \$196,000 for 935 cases of Epidural and CathCheck disposable kits and have advanced approximately \$171,000 reported in advances on contract in the unaudited condensed consolidated balance sheet.

On April 6, 2021, Leonard Osser and Milestone Scientific Inc. restructured the U.S. Asian Consulting Group, LLC, agreements originally signed July 10, 2017 with the Company. The Consulting Agreement dated as of July 10, 2017 (the “Consulting Agreement”) between the Company and U.S. Asian Consulting Group, LLC, a company of which Mr. Osser is a principal, the compensation increased by \$100,000 to \$200,000, equally split between a cash amount and an amount in shares of Milestone Scientific Inc. common stock. Compensation under the Consulting Agreement are payable for 9.5 years from the date Mr. Osser steps down as Interim-CEO. Leonard Osser resigned as Interim Chief Executive Officer of the Company effective May 19, 2021. For three months and six months ended June 30, 2021 the Company recorded expense of \$12,500 related to the US Asian Consulting Group, LLC.

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**NOTE 9 – SUBSEQUENT EVENTS:**

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After June 30, 2021, Milestone Scientific Inc. has advanced Milestone Medical approximately \$20,000 to support the commercialization process for the epidural instrument and other expenses necessary for the day-to-day operations of the Company.

On May 12, 2021, the Board of Directors appointed Scott Kahn as the Chief Financial Officer of the Company, effective May 24, 2021. On July 2, 2021, Mr. Kahn and the Company reached a mutual decision to part ways.

### **3. Information on the rules applied to the preparation of the report, including information on the changes in applied account rules (policies)**

Consolidated quarterly report for the second quarter of 2021 was prepared in accordance with the rules indicated in Exhibit 3 to the Alternative Trading System Rules “Current and Periodical Information in the Alternative Trading System on the NewConnect market”. Information on applied accounting rules (policies) are presented in Note 3 to the Financial Statement.

### **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 impact the achieved results.-**

On June 18, 2021, the Company announced on ESPI/13/2021 that the Annual Meeting of Shareholders of the Company shall be held on August 18, 2021, at 9:00 am ET in Roseland, New Jersey, United States of America at the corporate office of the Company, located at 425 Eagle Rock Avenue, Suite 403. The record date for the notice of the meeting, the record date for voting, and the date of the determination of beneficial ownership shall be June 20, 2021.

### **5. A description of the status of implementation of activities and investments of the Issuer and its Subsidiary and the timetable of their implementation**

The CompuFlo Epidural Computer Controlled Anesthesia System (or the CompuFlo Epidural System) is one such platform extension of our DPS Dynamic Pressure Sensing Technology platform, providing anesthesiologists and other healthcare providers the ability, for the first time, to quantitatively determine and document the pressure at the needle tip in real-time for proper needle placement in epidural procedures used for labor/delivery and back pain management. Our proprietary DPS Dynamic Pressure Sensing Technology allows the CompuFlo Epidural System to provide objective visual and audible in-tissue pressure feedback that allows anesthesiologists to identify and confirm placement in the epidural space.

Our CompuFlo Epidural System provides an objective tool that we believe consistently and accurately identifies the epidural space by detecting the difference in pressure between the ligamentum flavum and the intrafilamentary tissue. In studies, the CompuFlo Epidural System with DPS Dynamic Pressure Sensing Technology has been shown to be effective in correctly identifying the epidural space. Knowing the precise location of a needle tip during an epidural injection procedure provides a measure of safety not presently available to doctors using conventional syringes. In the absence of fluoroscopy, identifying the epidural space by relying on the subjective perception of loss of resistance to saline requires a very long education period and learning curve and could result in morbidity and lack of efficacy. During back pain management epidural procedures, where fluoroscopy is commonly used, the CompuFlo Epidural System allows the clinician to locate the epidural space, without using fluoroscopy, thereby protecting the patient and clinician from unnecessary exposure to radiation along with significantly reducing capital and operating costs.

The Company has made significant progress over the past quarter advancing its commercial efforts around the CompuFlo® Epidural Instrument and CathCheck™ System. The Company has added new distributors and begun to penetrate hospitals with our CompuFlo® Epidural Instrument and the Issuer expects this trend to continue as it anticipates adding additional hospitals in 2021.

Most recently, in July 2021, the Company has commenced sales of CompuFlo Epidural and CathCheck disposables to the University of Texas Medical Branch (UTMB) Health Clear Lake Campus Hospital. UTMB is an institution of the University of Texas System and agency of the State of Texas.

This expansion follows successful use of the instrument and disposables at the UTMB Galveston Campus Hospital and is strong validation of the favorable response to Milestone Scientific's technology by leading anesthesiologists.

Most notably, in 2021, the Company began selling CompuFlo Epidural and CathCheck disposables to four premier medical centers: UTMB Health Clear Lake Campus Hospital, Regional Medical Center (RMC), a premier regional healthcare system in South Carolina; the University of Texas Medical Branch at Galveston (UTMB); and nationally recognized Medical University of South Carolina (MUSC); and one hospital, University Hospital of Würzburg in Germany. The purchase orders received from these three 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 it strives to become the new standard of care in epidural procedures.

The Company remains focused on advancing efforts establishing Milestone's platform as the standard-of-care in painless and precise drug delivery, providing for the first time objective visual and audible in-tissue pressure feedback, and continuing to expand platform applications. Commercializing our CompuFlo Epidural System, a transformative device for epidural anesthesia procedures expanding the global footprint of our CompuFlo Epidural System by partnering with distribution companies worldwide.

The Company is witnessing growing interest in CompuFlo® Epidural Instrument and CathCheck™ System among anesthesiologists and hospitals. This interest is due, in part, to more hospitals reopening their facilities to outside sales representatives, as well as the safety and economic value proposition of our system. Previously, the Company made the strategic decision to await the recovery of the pandemic prior to investing heavily in salesforce expansion, which allowed the Company to preserve capital and extend the cash runway. However, the Company is now aggressively building the sales and marketing organization to capitalize on these opportunities. Specifically, the Company has expanded its medical sales force during the second quarter of 2021 to 10 representatives and 7 seasoned sales executives hired in just over the past two months alone, including the appointment of senior industry sales executive Chet Trechock as VP of Sales Medical. Overall, the response from both hospitals and physicians has been positive and the Company is in a number of trials across the country that have the potential to convert to additional commercial orders later this year.

The Company has made technical improvements to its products, which the Issuer believes will support the commercial efforts going forward. The Company 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 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 minutes by measuring the pulsatile waveform within the epidural space. This capability saves time and money and provides better patient care.

As the Company is constantly evolving our injection and drug delivery systems, it has 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 U.S. 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. Ensuring the use of only authorized disposable components is critical to CompuFlo's performance and safety with long-term financial success of the Company. The second U.S. patent relates to new CompuPulse System, which integrates the CompuWave™ technology with a manual syringe. This technology provides 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.

Thru an independent study which validated the cost and safety benefits of CompuFlo within labor and delivery versus the traditional loss of resistance technique using the hypodermic syringe. The study has become be an important tool as the Company is presenting the value proposition of its 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 the instrument.

Given a strong cash runway of its parent, The Issuer believes that the Company is well funded to accelerate the sales and marketing activities around the medical instruments. The Board of Directors of the Company believes that the strength of its balance sheet of its parent provides the substantial runway to advance the development and commercialization of other indications for our proprietary DPS Dynamic Pressure Sensing Technology. The Company believes this technology platform is quite broad with multiple indications in large and underserved markets.

**6. If the Issuer and its Subsidiary took initiatives to develop its activities aimed to implement innovative solutions at the enterprise during the period of the report – information on such activities.**

The Issuer and its Subsidiary continues to consider and where appropriate include innovative initiatives for its medical instrument in the EU community. The Company continues to work and introduce the Epidural instrument in key medical institutions in the United States.

**7. Description of the organization of the group indicating consolidated entities**

Up to the date of this report completion, the Issuer does have a special purpose subsidiary Milestone Medical Poland Sp. z.o.o. The purpose of this company is the application and acceptance of Polish Government Grants for research and development of the current and future improvements to the medical instruments. Below the Issuer presents some basic information about its subsidiary:

**Table 6 General information about Subsidiary of the Issuer**

<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
Percentage share of the Issuer in the total number of votes	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 Condensed Consolidated Financial Statements with this subsidiary according to laws and regulations applicable to the Issuer.

Jan A. Haverhals  
Chief Executive Officer