

# **Consolidated report of**

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

### **1<sup>st</sup> quarter (January 1, 2021 to March 31, 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, May 17, 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

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.

## 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 |

\* 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

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

On March 31, 2021, the Issuer employed three(3) 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. Milestone Scientific Inc. regrets to announce the passing of Mr. Eric Gilbert on March 23, 2021. Mr. Gilbert was the Vice President US Sales and Marketing.

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. The Company has hired an executive search firm to assist in the identification and selection of a new Chief Financial Officer. The Company believes its current financial and accounting team will be sufficient to support ongoing operations and financial reporting. Mr. D’Agostino will continue as an advisor to the Company.

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.

On May 14, 2021, the Company announced on EBI/4/2021 the appointment of Scott Kahn as Chief Financial Officer, effective May 24, 2021. Mr. Kahn will succeed Joseph D’Agostino who retired from the Company as announced on April 13, 2021.

**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 of March 31, 2021 and December 31, 2020 and for three months ended March 31, 2021 and 2020**  
**(unaudited)**

| <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)

|   | March 31, 2021 | December 31, 2020 |
|---|----------------|-------------------|
| <u>ASSETS</u>   |                |                   |
| Cash and cash equivalents   | \$ 40,892      | \$ 22,119         |
| Accounts receivable   | 26,750         | -                 |
| Inventories, net  | 615,577        | 455,365           |
| Advances to contractors   | 248,637        | 314,116           |
| Prepaid expenses and other current assets   | 81,526         | 123,769           |
| Total current assets  | 1,013,382      | 915,369           |
| Equipment, net  | 5,804          | 8,289             |
| Total assets  | \$ 1,019,186   | \$ 923,658        |
| <u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>  |                |                   |
| Accounts payable  | \$ 68,231      | \$ 96,088         |
| Accrued expenses and other payables   | 432,404        | 322,810           |
| Accrued interest payable- related party   | 516,574        | 494,136           |
| Advances from related party   | 15,077,163     | 14,232,877        |
| Due to related party  | 2,800,000      | 2,800,000         |
| Total current liabilities   | 18,894,372     | 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 March 31, 2021 and December 31, 2020 | 2,200          | 2,200             |
| Additional paid-in capital  | 7,325,323      | 7,258,833         |
| Accumulated deficit   | (25,202,709)   | (24,283,286)      |
| Total stockholders' deficit   | (17,875,186)   | (17,022,253)      |
| Total liabilities and stockholders' deficit   | \$ 1,019,186   | \$ 923,658        |
| See Notes to Condensed Consolidated Financial Statements  |                |                   |

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

|  | Three months ended<br>March 31, 2021 | Three months ended<br>March 31, 2020 |
|--|--------------------------------------|--------------------------------------|
| Product sales, net                           | \$ 71,050                            | \$ 7,800                             |
| Cost of products sold                        | 28,438                               | 3,509                                |
| Gross profit                                 | 42,612                               | 4,291                                |
| Selling, general and administrative expenses | 918,032                              | 562,278                              |
| Research and development expenses            | 16,444                               | 107,480                              |
| Depreciation and amortization                | 3,851                                | 3,712                                |
| Total operating expenses                     | 938,327                              | 673,470                              |
| Loss from operations                         | (895,715)                            | (669,179)                            |
| Interest expense                             | (23,708)                             | (23,794)                             |
| Loss before income tax                       | (919,423)                            | (692,973)                            |
| Provision for income taxes                   | -                                    | -                                    |
| Net loss                                     | \$ (919,423)                         | \$ (692,973)                         |

See Notes to Condensed Consolidated Financial Statements

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

|                                | Common<br>Stock Shares | Common<br>Stock Amount | Additional<br>Paid in Capital | Accumulated<br>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> |
|                                | Common<br>Stock Shares | Common<br>Stock Amount | Additional<br>Paid in Capital | Accumulated<br>Deficit | Total                  |
| Balance, January 1, 2020       | 22,000,000             | \$ 2,200               | \$ 6,931,861                  | \$ (20,849,184)        | \$ (13,915,123)        |
| Net loss                       |                        |                        |                               | (692,973)              | \$ (692,973)           |
| Balance, March 31, 2020        | <u>22,000,000</u>      | <u>\$ 2,200</u>        | <u>\$ 6,931,861</u>           | <u>\$ (21,542,157)</u> | <u>\$ (14,608,096)</u> |

See Notes to Condensed Consolidated Financial Statements

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

|   | Three months<br>ended<br>March 31, 2021 | Three months<br>ended<br>March 31, 2020 |
|---|---|---|
| Cash flows from operating activities:                             |   |   |
| Net loss  | \$ (919,423)                            | \$ (692,973)                            |
| Adjustments to reconcile net cash (used in) operating activities: |   |   |
| Depreciation and amortization expense                             | 3,851                                   | 3,712                                   |
| Stock Compensation from Parent                                    | 66,490                                  | -                                       |
| Changes in operating assets and liabilities:                      |   |   |
| Increase in accounts receivable                                   | (26,750)                                | (1,320)                                 |
| (Increase) decrease in inventories                                | (160,212)                               | 1,700                                   |
| Decrease (increase) in advances to contractors                    | 65,479                                  | (7,098)                                 |
| Decrease to prepaid expenses and other current assets             | 42,243                                  | 9,747                                   |
| Increase in accounts payable and accrued expenses                 | 81,737                                  | 22,687                                  |
| Increase (decrease) in accrued interest related party             | 22,438                                  | (68,490)                                |
| Net cash used in operating activities                             | \$ (824,147)                            | \$ (732,035)                            |
| Cash flows from investing activities:                             |   |   |
| Purchases of equipment  | (1,366)                                 | (3,372)                                 |
| Net cash used in investing activities                             | \$ (1,366)                              | \$ (3,372)                              |
| Cash flows from financing activities:                             |   |   |
| Advances from related party                                       | 844,286                                 | 730,380                                 |
| Net cash provided by financing activities                         | \$ 844,286                              | \$ 730,380                              |
| Net increase (decrease) in cash and cash equivalents              | 18,773                                  | (5,027)                                 |
| Cash and cash equivalents at beginning of period                  | 22,119                                  | 8,773                                   |
| Cash and cash equivalents at end of period                        | \$ 40,892                               | \$ 3,746                                |

See Notes to Condensed Consolidated Financial Statements



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**For three months ended March 31, 2021 and 2020**

---

**NOTE 1 – ORGANIZATION AND BUSINESS:**

---

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 March 31, 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 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.

---

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

---

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 March 31, 2021, cash on hand was \$40,892 with negative working capital of approximately \$17.9 million.

---

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

---

As of March 31, 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.

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. 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.

---

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

---

**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.

**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.

**Reclassifications**

Certain reclassification has been made to the 2020 financial statements to conform to the condensed consolidated 2021 financial statement presentation. These reclassifications had no effect on net loss or cash flows as previously reported.

**Cash and Cash Equivalents**

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

---

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

---

**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 March 31, 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 March 31, 2021 and December 31, 2020 advances to contractors was \$248,637 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 months ended March 31, 2021 and 2020 was approximately \$3,800 and \$3,700, 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.

---

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

---

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 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.

---

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

---

## Disaggregated Revenue Information

|                                     | For the Three Months Ended March 31, |                 |
|-------------------------------------|--------------------------------------|-----------------|
|                                     | 2021                                 | 2020            |
| <b>Domestic: US</b>                 |                                      |                 |
| EPI-Instruments                     | \$ -                                 | \$ -            |
| Handpieces-EPI                      | 4,250                                | -               |
| Handpieces-CathCheck                | 3,900                                | -               |
| Accessories                         | -                                    | -               |
| <b>Grand Total</b>                  | <b>\$ 8,150</b>                      | <b>\$ -</b>     |
| <b>International: Rest of World</b> |                                      |                 |
| EPI-Instruments                     | \$ 42,500                            | \$ -            |
| Handpieces-EPI                      | 11,800                               | 7,600           |
| Handpieces-CathCheck                | 8,600                                | -               |
| Accessories                         | -                                    | 200             |
| <b>Grand Total</b>                  | <b>\$ 62,900</b>                     | <b>\$ 7,800</b> |
| <b>Total Product Sales</b>          | <b>\$ 71,050</b>                     | <b>\$ 7,800</b> |

**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 March 31, 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.

---

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

---

**Recent Accounting Pronouncements**

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 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 has not had a material effect on financial statement presentation.

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 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.

In June 2016, the Financial Accounting Standards Board (“FASB”) issued a new standard ASU No. 2016-13, “Financial Instruments – Credit Losses” (Topic 326), and subsequently amended. 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. The adoption of this standard is not expected to have a material effect on financial statement presentation.

---

**NOTE 4 - INVENTORIES:**

---

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

|   | <u>March 31, 2021</u> | <u>December 31, 2020</u> |
|---|-----------------------|--------------------------|
| Inventories consists of the following:        |                       |                          |
| Epidural instruments                          | \$ 328,376            | \$ 162,767               |
| Epidural instruments - trainer                | 1,626                 | 1,626                    |
| Intra-articular instruments, net reserve      | -                     | -                        |
| Epidural instruments disposables              | 15,753                | 35,934                   |
| Component parts and other materials           | 268,591               | 253,793                  |
| Component parts and other materials - trainer | 1,231                 | 1,245                    |
| Total   | <u>\$ 615,577</u>     | <u>\$ 455,365</u>        |

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

---

**NOTE 5 - RELATED PARTY TRANSACTIONS:**

---

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

As of March 31, 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 March 31, 2021 and December 31, 2020, the Company owes accrued interest on the line of credit of approximately \$517,000 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 March 31, 2021, and December 31, 2020, the Company owes approximately \$15.1 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 March 31, 2021 commission under this agreement was approximately \$500. In 2020, there were no commissions due under this agreement.

#### Director of Clinical Affairs

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 \$3,700 and \$400 for the three months ended March 31, 2021 and 2020, respectively.

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.

---

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

---

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 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, the possibility of factory quarantines and imposing shipping and travel restrictions, could interfere with our delivery of parts and other

---

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

---

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 three months ended March 31, 2021 85% of net product sales were to three customers/distributors, 36%, 29% and 20%, respectively. For the three months ended March 31, 2020 100% of net product sales were to one customer.

---

**NOTE 7 – STOCK BASED COMPENSATION:**

---

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 three months ended March 31, 2021, and 2020 the Company recorded stock compensation expense of approximately \$66,000 and zero, 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 \$509,000 of unrecognized compensation cost related to non-vested options, as of March 31, 2021 which Milestone Medical expects to recognize these costs over a weighted average period of 2.75 years

---

**NOTE 8 - COMMITMENTS :**

---

As of March 31, 2021, the Company has an open purchase order of \$430,693 for Epidural instruments and have advanced \$169,088 against this purchase commitment.

As of March 31, 2021, the Company has an open purchase order of \$59,663 for Epidural and CathCheck disposables kits and have advanced \$44,810 against this purchase commitment.  
See Note 5 for Related Party transactions.

---

**NOTE 9 – SUBSEQUENT EVENTS:**

---

After March 31, 2021, Milestone Scientific Inc. has advanced Milestone Medical approximately \$100,000 to support the commercialization process for the epidural instrument and other expenses necessary for the day-to-day operations of the Company.

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 has announced his intention to resign as Interim Chief Executive Officer of the Company effective May 19, 2021.



### **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 first 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 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 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 January 21, 2021, the Company announced on ESPI/5/2021 that that Milestone Scientific Inc., the licensor, and the majority shareholder of Milestone Medical Inc. has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for a patent relating to the disposable component of Milestone’s CompuFlo® Instrument. The patent 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.

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. 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.

## **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 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 notably, in first three months of 2021, the Company 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 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.

A key element of the sales strategy focuses on the disposable components of its system, which the Issuer believes will contribute to high margins and recurring revenue. The Company is also expanding its medical sales force, and now that new protocols are in place at hospitals, the Issuer is better able to enter the hospitals and has commenced a number of new pilot programs. 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 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 (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 minutes by measuring the pulsatile waveform within the epidural space. This capability saves time and money and provides better patient care.

The Company also 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.

As the Company is constantly evolving our injection and drug delivery systems, it 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 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 two medical instruments 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 two 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                                      |

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.

Leonard Osser  
Interim Chief Executive Officer