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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended June 30, 2020**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number: 000-55723**

**GUARDION HEALTH SCIENCES, INC.**

*(Exact name of Registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**47-4428421**

*(I.R.S. Employer  
Identification No.)*

**15150 Avenue of Science, Suite 200  
San Diego, California 92128  
Telephone: 858-605-9055**

*(Address and telephone number of principal executive offices)*

**Not applicable**

*(Former name, former address, and former fiscal year, if changed since last report)*

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or Section 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

|                         |                                     |                           |                                     |
|-------------------------|-------------------------------------|---------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/>            | Accelerated filer         | <input type="checkbox"/>            |
| Non-accelerated filer   | <input checked="" type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
|                         |                                     | Emerging growth company   | <input checked="" type="checkbox"/> |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).  Yes  No

Securities registered pursuant to Section 12(b) of the Act:

| <u>Title of each class</u>                | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|---|--------------------------|--|
| Common Stock, par value \$0.001 per share | GHSI                     | The NASDAQ Stock Market, LLC                     |

As of August 12, 2020, there were 88,327,312 shares of the Company's common stock, par value \$0.001 per share, issued and outstanding.

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## FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for the three-month period ended June 30, 2020 contains “forward-looking statements” within the meaning of the Securities Act of 1933, as amended (the “Securities Act”), and the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects, and other similar matters. These forward-looking statements are based on management’s current expectations and assumptions about future events, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. These statements may be identified by words such as “expects,” “plans,” “projects,” “will,” “may,” “anticipates,” “believes,” “should,” “intends,” “estimates,” and other words of similar meaning.

Actual results could differ materially from those contained in forward-looking statements. Many factors could cause actual results to differ materially from those in forward-looking statements, including those matters discussed below. Readers are urged to read the risk factors set forth in the Company’s recent filings with the U. S. Securities and Exchange Commission (the “SEC”), including the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in other documents the Company files with the SEC from time to time. These filings are available at the SEC’s website ([www.sec.gov](http://www.sec.gov)).

Other unknown or unpredictable factors that could also adversely affect our business, financial condition and results of operations may arise from time to time. Given these risks and uncertainties, the forward-looking statements discussed in this report may not prove to be accurate. Accordingly, you should not place undue reliance on these forward-looking statements, which only reflect the views of the Company’s management as of the date of this report. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results or expectations, except as required by law.

**PART I – FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**Guardion Health Sciences, Inc.  
Condensed Consolidated Balance Sheets**

|  | <b>June 30, 2020</b> | <b>December 31, 2019</b> |
|--|----------------------|--------------------------|
|  | <b>(Unaudited)</b>   |                          |
| <b>Assets</b>  |                      |                          |
| <b>Current assets</b>  |                      |                          |
| Cash   | \$ 11,603,459        | \$ 11,115,502            |
| Accounts receivable  | 34,180               | 78,337                   |
| Inventories  | 1,235,052            | 310,941                  |
| Prepaid expenses   | 274,140              | 362,938                  |
| Equipment held for sale  | 24,500               | -                        |
|  | <b>13,171,331</b>    | <b>11,867,718</b>        |
| <b>Total current assets</b>  | <b>13,171,331</b>    | <b>11,867,718</b>        |
| Deposits   | 11,751               | 11,751                   |
| Property and equipment, net  | 304,534              | 374,638                  |
| Right of use asset, net  | 496,387              | 572,714                  |
| Intangible assets  | 50,000               | 50,000                   |
|  | <b>50,000</b>        | <b>50,000</b>            |
| <b>Total assets</b>  | <b>\$ 14,034,003</b> | <b>\$ 12,876,821</b>     |
| <b>Liabilities and Stockholders' Equity</b>  |                      |                          |
| <b>Current liabilities</b>   |                      |                          |
| Accounts payable   | \$ 332,787           | \$ 70,291                |
| Accrued expenses   | 162,461              | 175,052                  |
| Due to former officer  | 311,458              | -                        |
| Derivative warrant liability   | 19,411               | 13,323                   |
| Lease liability – current  | 157,119              | 151,568                  |
|  | <b>983,236</b>       | <b>410,234</b>           |
| <b>Total current liabilities</b>   | <b>983,236</b>       | <b>410,234</b>           |
| Lease liability – long term  | 355,127              | 434,747                  |
|  | <b>355,127</b>       | <b>434,747</b>           |
| <b>Total liabilities</b>   | <b>1,338,363</b>     | <b>844,981</b>           |
| <b>Commitments and contingencies</b>   |                      |                          |
| <b>Stockholders' Equity</b>  |                      |                          |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding   | -                    | -                        |
| Common stock, \$0.001 par value; 250,000,000 shares authorized; 88,309,962 and 74,982,562 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively | 88,310               | 74,983                   |
| Additional paid-in capital   | 61,173,074           | 57,468,528               |
| Accumulated deficit  | (48,565,744)         | (45,511,671)             |
|  | <b>12,695,640</b>    | <b>12,031,840</b>        |
| <b>Total stockholders' equity</b>  | <b>12,695,640</b>    | <b>12,031,840</b>        |
| <b>Total liabilities and stockholders' equity</b>  | <b>\$ 14,034,003</b> | <b>\$ 12,876,821</b>     |

*See accompanying notes to condensed consolidated financial statements.*

**Guardion Health Sciences, Inc.**  
**Condensed Consolidated Statements of Operations**

|  | Three Months Ended<br>June 30, |                       | Six Months Ended<br>June 30, |                       |
|--|--------------------------------|-----------------------|------------------------------|-----------------------|
|  | 2020<br>(Unaudited)            | 2019<br>(Unaudited)   | 2020<br>(Unaudited)          | 2019<br>(Unaudited)   |
| <b>Revenue</b>   |                                |                       |                              |                       |
| Medical foods and nutraceuticals   | \$ 1,152,894                   | \$ 104,448            | \$ 1,304,028                 | \$ 204,382            |
| Medical devices  | 35,315                         | 150,222               | 126,505                      | 292,826               |
| Other  | 2,700                          | 6,300                 | 6,100                        | 6,300                 |
| <b>Total revenue</b>   | <u>1,190,909</u>               | <u>260,970</u>        | <u>1,436,633</u>             | <u>503,508</u>        |
| <b>Cost of goods sold</b>  |                                |                       |                              |                       |
| Medical foods and nutraceuticals   | 628,205                        | 40,681                | 695,291                      | 78,953                |
| Medical devices  | 15,278                         | 53,816                | 55,920                       | 109,036               |
| Other  | 1,096                          | 2,559                 | 2,477                        | 2,559                 |
| <b>Total cost of goods sold</b>  | <u>644,579</u>                 | <u>97,056</u>         | <u>753,688</u>               | <u>190,548</u>        |
| <b>Gross profit</b>  | <u>546,330</u>                 | <u>163,914</u>        | <u>682,945</u>               | <u>312,960</u>        |
| <b>Operating expenses</b>  |                                |                       |                              |                       |
| Research and development   | 44,581                         | 77,688                | 75,769                       | 106,716               |
| Sales and marketing  | 519,067                        | 409,409               | 1,007,913                    | 764,028               |
| General and administrative   | 1,712,183                      | 2,489,011             | 3,228,698                    | 3,439,633             |
| Costs related to resignation of former officer<br>(including the reversal of previously recognized<br>stock compensation expense of \$1,401,582 and<br>\$965,295 during the three and six months ended<br>June 30, 2020, respectively) | (1,052,223)                    | -                     | (615,936)                    | -                     |
| Impairment loss on equipment held for sale   | 30,948                         | -                     | 30,948                       | -                     |
| <b>Total operating expenses</b>  | <u>1,254,556</u>               | <u>2,976,108</u>      | <u>3,727,392</u>             | <u>4,310,377</u>      |
| <b>Loss from operations</b>  | <u>(708,226)</u>               | <u>(2,812,194)</u>    | <u>(3,044,447)</u>           | <u>(3,997,417)</u>    |
| <b>Other (income) expense:</b>   |                                |                       |                              |                       |
| Interest expense   | 1,790                          | 234,065               | 3,538                        | 251,637               |
| Finance cost upon issuance of warrants   | -                              | 229,921               | -                            | 415,955               |
| Change in fair value of derivative warrants  | (2,856)                        | (227,832)             | 6,088                        | (227,832)             |
| <b>Total other (income) expense</b>  | <u>(1,066)</u>                 | <u>236,154</u>        | <u>9,626</u>                 | <u>439,760</u>        |
| <b>Net loss</b>  | <u>\$ (707,160)</u>            | <u>\$ (3,048,348)</u> | <u>\$ (3,054,073)</u>        | <u>\$ (4,437,177)</u> |
| Net loss per common share – basic and diluted  | <u>\$ (0.01)</u>               | <u>\$ (0.14)</u>      | <u>\$ (0.04)</u>             | <u>\$ (0.21)</u>      |
| Weighted average common shares outstanding –<br>basic and diluted  | <u>86,567,215</u>              | <u>22,537,943</u>     | <u>82,598,791</u>            | <u>21,628,758</u>     |

*See accompanying notes to condensed consolidated financial statements.*

**Guardion Health Sciences, Inc.**  
**Condensed Consolidated Statement of Stockholders' Equity**  
**(Unaudited)**

|   | <u>Common Stock</u>                             |                  | <u>Additional</u>   | <u>Accumulated</u>     | <u>Total</u>         |
|---|---|------------------|---------------------|------------------------|----------------------|
|   | <u>Shares</u>                                   | <u>Amount</u>    | <u>Paid-In</u>      | <u>Deficit</u>         | <u>Stockholders'</u> |
|   | <u>Three and Six Months Ended June 30, 2020</u> |                  |                     |                        |                      |
| <b>Balance at December 31, 2019</b>   | 74,982,562                                      | \$ 74,983        | \$57,468,528        | \$ (45,511,671)        | \$ 12,031,840        |
| Fair value of vested stock options – officer and director                   | -   | -                | 436,287             | -                      | 436,287              |
| Fair value of vested stock options  | -   | -                | 55,281              | -                      | 55,281               |
| Issuance of common stock for services                                       | 25,000  | 25               | 12,300              | -                      | 12,325               |
| Issuance of common stock – warrant exercises                                | 10,382,400                                      | 10,382           | 3,540,399           | -                      | 3,550,781            |
| Net loss  | -   | -                | -                   | (2,346,913)            | (2,346,913)          |
| <b>Balance at March 31, 2020</b>  | <u>85,389,962</u>                               | <u>\$ 85,390</u> | <u>\$61,512,795</u> | <u>\$ (47,858,584)</u> | <u>\$ 13,739,601</u> |
| Fair value of vested stock options – officer and director                   | -   | -                | (1,377,223)         | -                      | (1,377,223)          |
| Fair value of vested stock options  | -   | -                | 41,782              | -                      | 41,782               |
| Issuance of common stock – warrant exercises                                | 2,920,000                                       | 2,920            | 995,720             | -                      | 998,640              |
| Net loss  | -   | -                | -                   | (707,160)              | (707,160)            |
| <b>Balance at June 30, 2020</b>   | <u>88,309,962</u>                               | <u>\$ 88,310</u> | <u>\$61,173,074</u> | <u>\$ (48,565,744)</u> | <u>\$ 12,695,640</u> |
|   | <u>Three and Six Months Ended June 30, 2019</u> |                  |                     |                        |                      |
| <b>Balance at December 31, 2018</b>   | 20,564,328                                      | \$ 20,564        | \$37,798,562        | \$(34,633,363)         | \$ 3,185,763         |
| Fair value of vested stock options  | -   | -                | 56,232              | -                      | 56,232               |
| Issuance of common stock – warrant exercises                                | 292,283   | 293              | 30,957              | -                      | 31,250               |
| Net loss  | -   | -                | -                   | (1,385,099)            | (1,385,099)          |
| <b>Balance at March 31, 2019</b>  | <u>20,856,611</u>                               | <u>\$ 20,857</u> | <u>\$37,885,751</u> | <u>\$(36,018,462)</u>  | <u>\$ 1,888,146</u>  |
| Fair value of vested stock options – officer and director                   | -   | -                | 1,066,159           | -                      | 1,066,159            |
| Fair value of vested stock options  | -   | -                | 62,763              | -                      | 62,763               |
| Fair value of warrants  | -   | -                | 359,683             | -                      | 359,683              |
| Sale of common stock  | 1,250,000                                       | 1,250            | 3,886,750           | -                      | 3,888,000            |
| Issuance of common stock for services                                       | 54,387  | 55               | 123,947             | -                      | 124,002              |
| Issuance of common stock – warrant exercises                                | 463,726   | 463              | 100,162             | -                      | 100,625              |
| Issuance of common stock – conversion of notes payable and related interest | 109,038   | 109              | 250,679             | -                      | 250,788              |
| Net loss  | -   | -                | -                   | (3,052,078)            | (3,052,078)          |
| <b>Balance at June 30, 2019</b>   | <u>22,733,762</u>                               | <u>\$ 22,734</u> | <u>\$43,735,894</u> | <u>\$(39,070,540)</u>  | <u>\$ 4,688,088</u>  |

*See accompanying notes to condensed consolidated financial statements.*

**Guardion Health Sciences, Inc.**  
**Condensed Consolidated Statements of Cash Flows**

|  | Six Months Ended<br>June 30, |                     |
|--|------------------------------|---------------------|
|  | 2020<br>(Unaudited)          | 2019<br>(Unaudited) |
| <b>Operating Activities</b>  |                              |                     |
| Net loss   | \$ (3,054,073)               | \$ (4,437,177)      |
| Adjustments to reconcile net loss to net cash used in operating activities:            |                              |                     |
| Depreciation and amortization  | 46,619                       | 137,128             |
| Impairment loss on equipment held for sale   | 30,948                       | -                   |
| Amortization of debt discount  | -                            | 250,000             |
| Amortization of lease right  | 76,327                       | 61,571              |
| Accrued interest expense included in notes payable                                     | -                            | 788                 |
| Stock-based compensation   | 109,388                      | 242,996             |
| Stock-based compensation – officer and director  | (940,936)                    | 1,066,159           |
| Non-cash financing costs – derivative liability  | -                            | 415,955             |
| Change in fair value of warrants – derivative liability                                | 6,088                        | (227,832)           |
| Changes in operating assets and liabilities:   |                              |                     |
| (Increase) decrease in -   |                              |                     |
| Accounts receivable  | 44,157                       | (7,718)             |
| Inventories  | (607,162)                    | 39,311              |
| Prepaid expenses   | (219,380)                    | (84,533)            |
| Increase (decrease) in -   |                              |                     |
| Accounts payable   | 262,496                      | 156,314             |
| Lease liability  | (74,070)                     | (56,844)            |
| Accrued expenses   | (12,591)                     | (49,814)            |
| Due to former officer  | 311,458                      | -                   |
| Net cash used in operating activities  | <u>(4,020,731)</u>           | <u>(2,493,696)</u>  |
| <b>Investing Activities</b>  |                              |                     |
| Purchase of property and equipment   | <u>(40,733)</u>              | <u>(58,934)</u>     |
| Net cash used in investing activities  | <u>(40,733)</u>              | <u>(58,934)</u>     |
| <b>Financing Activities</b>  |                              |                     |
| Proceeds from initial public offering  | -                            | 3,888,000           |
| Proceeds from issuance of convertible notes  | -                            | 250,000             |
| Proceeds from issuance of promissory notes   | -                            | 100,000             |
| Payments on promissory notes   | -                            | (100,548)           |
| Proceeds from exercise of warrants   | 4,549,421                    | 131,875             |
| Deferred financing costs of IPO  | -                            | (19,000)            |
| Net cash provided by financing activities  | <u>4,549,421</u>             | <u>4,250,327</u>    |
| <b>Cash:</b>   |                              |                     |
| Net increase   | 487,957                      | 1,697,697           |
| Balance at beginning of period   | 11,115,502                   | 670,948             |
| <b>Balance at end of period</b>  | <u>\$ 11,603,459</u>         | <u>\$ 2,368,645</u> |
| <b>Supplemental disclosure of cash flow information:</b>                               |                              |                     |
| Cash paid for:   |                              |                     |
| Interest   | \$ -                         | \$ -                |
| Income taxes   | \$ -                         | \$ -                |
| <b>Non-cash financing activities:</b>  |                              |                     |
| Fair value of warrants issued in connection with convertible notes                     | \$ -                         | \$ 436,034          |
| Recording of lease asset and liability upon adoption of ASU 2016-02                    | \$ -                         | \$ 663,218          |
| Reclass of prepaid costs to inventory  | \$ 308,178                   | \$ -                |
| Reclass of property and equipment to equipment held for sale                           | \$ 55,448                    | \$ -                |
| Reclass of property and equipment to inventory   | \$ 8,771                     | \$ -                |
| Reclass of warrant liability to equity   | \$ -                         | \$ 359,683          |
| Fair value of common stock issued upon conversion of common stock and accrued interest | \$ -                         | \$ 250,788          |
| Reclass of deferred offering cost to equity  | \$ -                         | \$ 270,000          |

*See accompanying notes to condensed consolidated financial statements.*

**Guardion Health Sciences, Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**  
**Six Months Ended June 30, 2020 and 2019**

**1. Organization and Business Operations**

***Organization and Business***

Guardion Health Sciences, Inc. (the “Company”) was formed in December 2009 as a California limited liability company under the name P4L Health Sciences, LLC. On June 30, 2015, the Company converted from a California limited liability company to a Delaware corporation, changing its name from Guardion Health Sciences, LLC to Guardion Health Sciences, Inc.

The Company is a specialty health sciences company (1) that has developed medical foods and medical devices in the ocular health space and (2) that has developed and is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers.

Since inception, the Company has been primarily engaged in research and development, product commercialization and capital raising activities.

***Going Concern and Liquidity***

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of \$3,054,073 and utilized cash in operating activities of \$4,020,731 during the six months ended June 30, 2020. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. As a result, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern within one year of the date that the financial statements are issued.

The Company’s independent registered public accounting firm has also included explanatory language in their opinion accompanying the Company’s audited financial statements for the year ended December 31, 2019, stating there is substantial doubt about the Company’s ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the possible inability of the Company to continue as a going concern.

The Company will continue to incur significant expenses for commercialization activities related to its medical foods, nutraceuticals, the MapcatSF medical device, VectorVision diagnostic equipment, and with respect to efforts to continue to build the Company’s infrastructure. Development and commercialization of medical foods, nutraceuticals and medical devices involves a lengthy and complex process. Additionally, the Company’s long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines. Management is reviewing all of its business segments and operations with the assistance of an outside consulting firm in order to determine its future business strategies and focus. Furthermore, management is reviewing its expense profile, with its consulting firm, in order to increase efficiencies and reduce its cash utilization over the near and long term, while hoping to increase stockholder value.

The Company intends to seek to raise additional debt and/or equity capital to fund future operations, but there can be no assurances that the Company will be able to secure such additional financing in the amounts necessary to fully fund its operating requirements on acceptable terms or at all. If the Company is unable to access sufficient capital resources on a timely basis, the Company may be forced to reduce or discontinue its technology and product development programs and curtail or cease operations.

## ***COVID-19***

The Company is subject to risks and uncertainties as a result of the COVID-19 pandemic. The extent of the impact of the COVID-19 pandemic on the Company's business is highly uncertain and difficult to predict, as the responses that the Company, other businesses and governments are taking continue to evolve. Furthermore, capital markets and economies worldwide have also been negatively impacted by the COVID-19 pandemic, and it is possible that the COVID-19 pandemic could cause a local, national and/or global economic recession. Policymakers around the globe have responded with fiscal policy actions to support the healthcare industry and economy as a whole, but it is presently unknown whether and to what extent further fiscal actions will continue. The magnitude and overall effectiveness of these actions remain uncertain.

The Company believes that sales results have been negatively affected by the closure of medical facilities due to COVID-19 "Stay at Home" orders. The severity of the impact of the COVID-19 pandemic on the Company's business will continue to depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company's customers, service providers and suppliers, all of which are uncertain and cannot be predicted. As of the date of issuance of the Company's financial statements, the extent to which the COVID-19 pandemic may in the future materially impact the Company's financial condition, liquidity or results of operations is uncertain.

## ***NASDAQ Notice***

On September 20, 2019, the Company received a notification letter from the Nasdaq Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common stock was below the minimum \$1.00 per share requirement for continued listing on The Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Nasdaq letter had no immediate effect on the listing of the Company's common stock on the Nasdaq Capital Market.

In accordance with Nasdaq listing rules, the Company was provided an initial period of 180 calendar days, or until March 18, 2020, to regain compliance with the Minimum Bid Price Requirement. The Company was unable to regain compliance with the Minimum Bid Price Requirement during the initial period and was eligible for an additional 180 calendar day compliance period under the NASDAQ listing rules. The Company provided written notice of its intention to cure the deficiency during the additional compliance period, and on March 19, 2020, the Company received a written notification from Nasdaq that the Company had been granted an additional 180 calendar days, or until September 14, 2020, to regain compliance with the Minimum Bid Price Requirement.

The current COVID-19 crisis has created unprecedented turmoil in U.S. and world financial markets and has significantly impacted investor confidence. Given these extraordinary market conditions, Nasdaq has determined to toll the compliance periods for bid price and market value of publicly held shares through June 30, 2020 (the "Price-based Requirements").

Accordingly, since the Company had 152 calendar days remaining in its bid price compliance period as of April 16, 2020, it will, upon reinstatement of the Price-based Requirements, still have 152 calendar days from July 1, 2020, or until November 30, 2020, to regain compliance. The Company can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by evidencing compliance with the Price-based Requirements for a minimum of 10 consecutive trading days.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying condensed consolidated financial statements are unaudited. These unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC. The condensed consolidated balance sheet as of December 31, 2019 included herein was derived from the audited consolidated financial statements as of that date, but does not include all disclosures, including notes, required by GAAP.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements contain all adjustments necessary to fairly present the Company's financial position and results of operations for the interim periods reflected. Except as noted, all adjustments contained herein are of a normal recurring nature. The results of operations for the interim periods presented are not necessarily indicative of the results of operations to be expected for the full fiscal year ending December 31, 2020.

### ***Use of Estimates***

The preparation of the financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect 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 expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates include those related to assumptions used in valuing assets acquired in business acquisitions, impairment testing of goodwill and other long-term assets, accruals for potential liabilities, valuing equity instruments issued during the period, and realization of deferred tax assets.

### ***Revenue Recognition***

The Company's revenue is comprised of sales of medical foods, nutraceuticals and supplements to consumers through a direct sales/credit card process. In addition, the Company sells medical device equipment and supplies to customers both in the U.S. and internationally.

The Company recognizes revenue in accordance with ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09" or "Topic 606") and all related amendments. The standard provides authoritative guidance clarifying the principles for recognizing revenue and developing a common revenue standard for U.S. generally accepted accounting principles. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods and services to customers in an amount that reflects the consideration to which the entity expects to be entitled in the exchange for those goods or services.

Under the guidance, revenue is recognized when control of promised goods or services is transferred to the Company's customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. The Company reviews its sales transactions to identify contractual rights, performance obligations, and transaction prices, including the allocation of prices to separate performance obligations, if applicable. Revenue and costs of sales are recognized once products are delivered to the customer's control and performance obligations are satisfied.

All products sold by the Company are distinct individual products and consist of medical foods, nutraceuticals, supplemental formulas, medical devices and related supplies. The products are offered for sale as finished goods only, and there are no performance obligations required post-shipment for customers to derive the expected value from them. Contracts with customers contain no incentives or discounts that could cause revenue to be allocated or adjusted over time.

Control of products sold transfers to customers upon shipment from the Company's or suppliers' facilities, and the Company's performance obligations are satisfied at that time. Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer. Payments for sales of medical foods and nutraceuticals are generally made by approved credit cards. Payments for medical device sales are generally made by check, credit card, or wire transfer. Historically the Company has not experienced any significant payment delays from customers.

The Company provides a 30-day right of return to its retail Medical Foods customers. A right of return does not represent a separate performance obligation, but because customers are allowed to return products, the consideration to which the Company expects to be entitled is variable. Upon evaluation of historical Medical Foods and Medical Device product returns, the Company determined that less than one percent of products is returned, and therefore believes it is probable that such returns will not cause a significant reversal of revenue in the future. Due to the insignificant amount of historical returns as well as the standalone nature of the Company's products and assessment of performance obligations and transaction pricing for the Company's sales contracts, the Company does not currently maintain a contract asset or liability balance at this time. The Company assesses its contracts and the reasonableness of its conclusions on a quarterly basis.

The following table presents the Company's revenues disaggregated by segment:

|                                  | Three Months Ended<br>June 30, |                   | Six Months Ended<br>June 30, |                   |
|----------------------------------|--------------------------------|-------------------|------------------------------|-------------------|
|                                  | 2020                           | 2019              | 2020                         | 2019              |
| Medical foods and nutraceuticals | \$ 1,152,894                   | \$ 104,448        | \$ 1,304,028                 | \$ 204,382        |
| Medical devices                  | 35,315                         | 150,222           | 126,505                      | 292,826           |
| Other                            | 2,700                          | 6,300             | 6,100                        | 6,300             |
|                                  | <u>\$ 1,190,909</u>            | <u>\$ 260,970</u> | <u>\$ 1,436,633</u>          | <u>\$ 503,508</u> |

The following table presents the Company's revenues disaggregated by geography:

|                  | Three Months Ended<br>June 30, |                   | Six Months Ended<br>June 30, |                   |
|------------------|--------------------------------|-------------------|------------------------------|-------------------|
|                  | 2020                           | 2019              | 2020                         | 2019              |
| North America    | \$ 270,664                     | \$ 116,611        | \$ 505,023                   | \$ 227,322        |
| Malaysia         | 890,000                        | -                 | 890,000                      | -                 |
| Asia             | 22,990                         | 63,650            | 25,790                       | 128,950           |
| Europe and other | 7,255                          | 80,709            | 15,820                       | 147,236           |
|                  | <u>\$ 1,190,909</u>            | <u>\$ 260,970</u> | <u>\$ 1,436,633</u>          | <u>\$ 503,508</u> |

The Company's medical foods and nutraceuticals revenues are derived from individual retail customers in North America and international distributors. 68% of Medical Foods and Nutraceuticals revenues for the six months ended June 30, 2020 were due to the sale in June of a nutraceutical product to a Malaysian distributor. Medical Devices revenues are derived from a worldwide customer base consisting of both retail customers and distributors. International customers contributed approximately 94% and 39% of Medical Devices revenues for the six months ended June 30, 2020 and 2019, respectively. Distributors contributed approximately 58% and 32% of Medical Devices revenues for the six months ended June 30, 2020 and 2019, respectively.

During February 2020, the Company contracted with a Malaysian company to develop an immune-supportive formula for its consumer base. An initial order was placed for \$875,000, and in connection with this order, on March 31, 2020, the Malaysian company paid \$437,500 as a deposit for this order. The Company completed shipment of the product, received payment in full, and has recognized revenue for this order of \$890,000 during the three months ended June 30, 2020. The sample product order is a proprietary immune-supportive formula that consists of a two-bottle package, each bottle containing different blends of certain ingredients the formulation of which is proprietary to the Malaysian company. The product is designed by the Malaysian company to boost immune system capability, which the Malaysian company intends to sell to its consumer base.

### **Concentrations**

During the three months ended June 30, 2020, the Medical Foods and Nutraceuticals segment had one customer who accounted for approximately 75% of the Company's sales. During the three months ended June 30, 2019, the Medical Devices segment had one customer who accounted for approximately 24% of the Company's sales. No other customer accounted for more than 10% of sales in either period.

During the six months ended June 30, 2020, the Medical Foods and Nutraceuticals segment had one customer who accounted for approximately 62% of the Company's sales. During the six months ended June 30, 2019, the Medical Devices segment had one customer who accounted for approximately 26% of the Company's sales. No other customer accounted for more than 10% of sales in either period.

During the three months ended June 30, 2020, three of the Company's largest vendors accounted for 12%, 36%, and 44% of all purchases. During the three months ended June 30, 2019, two vendors accounted for 34%, and 47% of all purchases. During the six months ended June 30, 2020, three of the Company's largest vendors accounted for 17%, 24%, and 40% of all purchases. During the six months ended June 30, 2019, three vendors accounted for 20%, 24%, and 32% of all purchases. No other vendors exceeded 10% of all purchases during any periods presented.

### ***Research and Development Costs***

Research and development costs consist primarily of fees paid to consultants and outside service providers, and other expenses relating to the acquisition, design, development and testing of the Company's medical foods and related products. Research and development expenditures are expensed as incurred and totaled \$75,769 and \$106,716 for the six months ended June 30, 2020 and 2019, respectively.

### ***Patent Costs***

The Company is the owner of four issued domestic patents, two pending domestic patent applications, one issued foreign patent in Europe and the United Kingdom, two issued foreign patents in Ireland, and one issued foreign patent in Hong Kong. Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, patent costs, including patent-related legal fees, filing fees and internally generated costs, are expensed as incurred. During the six months ended June 30, 2020 and 2019, patent costs were \$60,501 and \$64,482, respectively, and are included in general and administrative costs in the statements of operations.

### ***Stock-Based Compensation***

The Company periodically issues stock-based compensation to officers, directors, contractors and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors, employees, and for acquiring goods and services from nonemployees, which include grants of employee stock options, are recognized in the financial statements based on their fair values in accordance with Topic 718. Stock option grants, which are generally time vested, will be measured at the grant date fair value and charged to operations on a straight-line basis over the vesting period. The fair value of stock options is determined utilizing the Black-Scholes option-pricing model, which is affected by several variables, including the risk-free interest rate, the expected dividend yield, the expected life of the equity award, the exercise price of the stock option as compared to the fair market value of the common stock on the grant date and the estimated volatility of the common stock over the term of the equity award.

### ***Net Loss per Share***

The Company's computation of basic and diluted net loss per common share is measured as net loss divided by the weighted average common shares outstanding during the respective periods, excluding unvested restricted common stock. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Potential common shares such as from unexercised warrants and options that have an anti-dilutive effect are excluded from the calculation of diluted net loss per share. The Company's basic and diluted net loss per share is the same for all periods presented because all shares issuable upon exercise of warrants and conversion of convertible debt outstanding are anti-dilutive as they decrease loss per share.

The following table sets forth the number of shares excluded from the computation of diluted loss per share, as their inclusion would have been anti-dilutive:

|          | <b>June 30,</b>   |                  |
|----------|-------------------|------------------|
|          | <b>2020</b>       | <b>2019</b>      |
| Warrants | 15,470,338        | 261,538          |
| Options  | 2,919,167         | 2,612,500        |
|          | <u>18,389,505</u> | <u>2,874,038</u> |

### ***Fair Value Measurements***

Assets and liabilities recorded at fair value on the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure the fair value. Level inputs are as follows:

Level 1 – quoted prices in active markets for identical assets or liabilities.

Level 2 – other significant observable inputs for the assets or liabilities through corroboration with market data at the measurement date.

Level 3 – significant unobservable inputs that reflect management’s best estimate of what market participants would use to price the assets or liabilities at the measurement date.

We consider carrying amounts of accounts receivable, accounts payable and accrued expenses to approximate fair value due to the short-term nature of these financial instruments. Our non-financial assets are measured at fair value when there is an indicator of impairment and recorded at fair value only when an impairment charge is recognized.

As of June 30, 2020, and December 31, 2019, the Company’s balance sheets included Level 2 liabilities comprised of the fair value of warrant liabilities aggregating \$19,411 and \$13,323, respectively.

### ***Recent Accounting Pronouncements***

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (“ASU 2019-12”), which is intended to simplify the accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2021. The Company is assessing the impact ASU 2019-12 will have on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Credit Losses - Measurement of Credit Losses on Financial Instruments (“ASC 326”). The standard significantly changes how entities will measure credit losses for most financial assets, including accounts and notes receivables. The standard will replace today’s “incurred loss” approach with an “expected loss” model, under which companies will recognize allowances based on expected rather than incurred losses. Entities will apply the standard’s provisions as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. As a smaller reporting company, the standard will be effective for us for interim and annual reporting periods beginning after December 15, 2022. The Company is currently assessing the impact of adopting this standard on the Company’s financial statements and related disclosures.

The Company’s management does not believe that there are any recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company’s financial statement presentation or disclosures.

### **3. Acquisition of NutriGuard**

Effective September 20, 2019 (the “Effective Date”), the Company’s newly-formed wholly-owned subsidiary, NutriGuard Formulations, Inc., a Delaware corporation, completed an asset purchase agreement (the “Asset Purchase Agreement”) with NutriGuard Research, Inc., a California corporation (“NutriGuard”), and NutriGuard’s sole shareholder, Mark McCarty.

Pursuant to the Asset Purchase Agreement, the Company purchased specified assets of the NutriGuard brand and business, consisting primarily of inventory, trademarks, copyrights and other intellectual property. In exchange, the Company agreed to pay a 3% royalty, payable quarterly, to NutriGuard based on the operating results of the NutriGuard branded products in future periods, after \$500,000 in specified gross revenues have been achieved by the Company. As of June 30, 2020 and December 31, 2019 no amounts were owed or accrued to NutriGuard.

The following preliminary unaudited pro forma financial information gives effect to the Company's acquisition of NutriGuard as if the acquisition had occurred on January 1, 2019 and had been included in the Company's consolidated statements of operations during the three and six months ended June 30, 2019:

|  | <b>Three Months<br/>Ended June 30,<br/>2019</b> |
|--|---|
| Pro forma net revenues                                 | \$ 279,044                                      |
| Pro forma net loss attributable to common shareholders | \$ (3,069,472)                                  |
| Pro forma net loss per share                           | \$ (0.14)                                       |

  

|  | <b>Six Months<br/>Ended June 30,<br/>2019</b> |
|--|---|
| Pro forma net revenues                                 | \$ 546,724                                    |
| Pro forma net loss attributable to common shareholders | \$ (4,477,053)                                |
| Pro forma net loss per share                           | \$ (0.21)                                     |

#### 4. Inventories

Inventories consisted of the following:

|                | <b>June 30,<br/>2020</b> | <b>December 31,<br/>2019</b> |
|----------------|--------------------------|------------------------------|
| Raw materials  | \$ 870,384               | \$ 246,875                   |
| Finished goods | 364,668                  | 64,066                       |
|                | <u>\$ 1,235,052</u>      | <u>\$ 310,941</u>            |

#### 5. Property and Equipment, net

Property and equipment consisted of the following:

|  | <b>June 30,<br/>2020</b> | <b>December 31,<br/>2019</b> |
|--|--------------------------|------------------------------|
| Leasehold improvements                         | \$ 98,357                | \$ 98,357                    |
| Testing equipment                              | 336,959                  | 394,427                      |
| Furniture and fixtures                         | 199,132                  | 185,799                      |
| Computer equipment                             | 68,460                   | 68,460                       |
| Office equipment                               | 8,193                    | 8,193                        |
|  | <u>711,101</u>           | <u>755,236</u>               |
| Less accumulated depreciation and amortization | <u>(406,567)</u>         | <u>(380,598)</u>             |
|  | <u>\$ 304,534</u>        | <u>\$ 374,638</u>            |

For the six months ended June 30, 2020 and 2019, depreciation expense was \$46,619 and \$29,810, respectively, of which \$26,169 and \$11,244 was included in research and development expense, \$7,821 and \$7,821 was included in sales and marketing expense, and \$12,629 and \$10,745 was included in general and administrative expense, respectively.

## 6. Lease Liabilities

In October 2012, the Company entered into a lease agreement for 9,605 square feet of office and warehouse space commencing March 1, 2013. Upon entering into the agreement, the Company paid a deposit of \$47,449, of which \$36,979 represented prepaid rent. As of June 30, 2020, \$11,751 remained on deposit under the lease agreement. The lease (“Lease 1”) was renewed for an additional five years in 2018. As of June 30, 2020, remaining lease payments under the amended lease agreement averaged \$13,103 per month through July 2023.

In connection with the VectorVision acquisition on September 29, 2017, the Company assumed a lease agreement for 5,000 square feet of office and warehouse space which commenced on October 1, 2017. The lease (“Lease 2”) was renewed for an additional 65 months. As of June 30, 2020, remaining lease payments averaged \$1,864 per month through February 2023.

The leases have been accounted for in accordance with ASC 842, which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. The Company classified the leases as operating leases and determined that the present value of Lease 1 at the inception of the lease was \$639,520 using a discount rate of 3.9% and the present value of Lease 2 at the inception of the lease was \$81,634 using a discount rate of 3.9%.

The aggregate balance of the lease liabilities at December 31, 2019 was \$586,315. During the six months ended June 30, 2020, the Company made combined payments on both leases of \$74,069 towards the lease liabilities. As of June 30, 2020, the lease liability for Lease 1 was \$455,711, and the lease liability for Lease 2 was \$56,535. The aggregate balance of the lease liabilities at June 30, 2020 was \$512,246, of which \$157,119 was current.

Combined rent expense for both leases for the six months ended June 30, 2020 and 2019 was \$87,161 and \$87,161, respectively. The balance of the right of use asset as of December 31, 2019 was \$572,714. During the six months ended June 30, 2020, the Company reflected amortization of right of use asset of \$76,327 related to the leases, resulting in a net asset balance of \$496,387 as of June 30, 2020.

## 7. Stockholders’ Equity

### *Common Stock*

During the six months ended June 30, 2020, the Company issued 25,000 fully vested shares of common stock for services rendered and recognized \$12,325 in stock compensation expense related to these shares.

### *Warrants*

A summary of the Company’s warrant activity is as follows:

|                                       | <u>Shares</u>     | <u>Weighted<br/>Average<br/>Exercise Price</u> | <u>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Term (Years)</u> |
|---------------------------------------|-------------------|--|--|
| <b>December 31, 2019</b>              | <b>28,802,738</b> | <b>0.38</b>                                    | <b>4.91</b>  |
| Granted                               | -                 | -  | -  |
| Forfeitures                           | -                 | -  | -  |
| Expirations                           | (30,000)          | (1.50)   | -  |
| Exercised                             | (13,302,400)      | (0.34)   | -  |
| <b>June 30, 2020, all exercisable</b> | <b>15,470,338</b> | <b>\$ 0.41</b>                                 | <b>4.39</b>  |

The exercise prices of warrants outstanding and exercisable as of June 30, 2020 are as follows:

| <b>Warrants Outstanding and<br/>Exercisable (Shares)</b> | <b>Exercise Prices</b> |
|--|------------------------|
| 12,037,600   | \$ 0.34                |
| 1,960,000  | 0.44                   |
| 1,040,000  | 0.50                   |
| 226,200  | 0.59                   |
| 35,000   | 1.50                   |
| 109,038  | 2.88                   |
| 62,500   | 5.00                   |
| <b>15,470,338</b>  |                        |

During the six months ended June 30, 2020, investors exercised a total of 13,302,400 warrants for 13,302,400 shares of common stock. The warrants were exercisable for \$0.34 per share, which resulted in cash proceeds to the Company of \$4,549,421.

As of June 30, 2020, the Company had an aggregate of 15,470,338 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of \$0.41 and a weighted average remaining life of 4.39 years. The aggregate intrinsic value of warrants outstanding as of June 30, 2020 was \$1,073,026.

#### ***Warrant Liability***

On April 9, 2019, the Company issued 62,500 warrants with an exercise price of \$5.00 per share to the underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants is remeasured at each reporting period, and the change in the fair value is recognized in earnings in the accompanying Statements of Operations. The fair value of the warrants at December 31, 2019 was \$13,323. As of June 30, 2020, the fair value of the warrants was determined to be \$19,411 and the change in fair value of \$6,088 was recognized in the accompanying statements of operations.

The fair value of the warrant liability was determined at the following reporting dates using the Black-Scholes-Merton option pricing model and the following assumptions:

|                         | <b>Warrant Liability<br/>As of<br/>June 30, 2020</b> | <b>Warrant Liability<br/>As of<br/>December 31, 2019</b> |
|-------------------------|--|--|
| Stock price             | \$ 0.44  | \$ 0.22  |
| Risk free interest rate | 0.18%  | 1.62%  |
| Expected volatility     | 142%   | 145%   |
| Expected life in years  | 3.76   | 4.26   |
| Expected dividend yield | 0%   | 0%   |
| Number of warrants      | 62,500   | 62,500   |
| Fair value of warrants  | <u>\$ 19,411</u>                                     | <u>\$ 13,323</u>   |

## Stock Options

A summary of the Company's stock option activity is as follows:

|                                   | Shares           | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) |
|-----------------------------------|------------------|---------------------------------|---|
| <b>December 31, 2019</b>          | <b>2,962,500</b> | <b>2.94</b>                     | <b>3.64</b>   |
| Granted                           | 790,000          | 0.77                            | 9.83  |
| Forfeitures                       | (833,333)        | -                               | -   |
| Expirations                       | -                | -                               | -   |
| Exercised                         | -                | -                               | -   |
| <b>June 30, 2020, outstanding</b> | <b>2,919,167</b> | <b>\$ 1.93</b>                  | <b>4.77</b>   |
| <b>June 30, 2020, exercisable</b> | <b>2,084,167</b> | <b>\$ 2.40</b>                  | <b>3.10</b>   |

The exercise prices of options outstanding and exercisable as of June 30, 2020 are as follows:

| Options Outstanding (Shares) | Options Exercisable (Shares) | Exercise Prices |
|------------------------------|------------------------------|-----------------|
| 250,000                      | 187,500                      | \$ 0.25         |
| 30,000                       | 30,000                       | 0.32            |
| 250,000                      | 62,500                       | 0.39            |
| 10,000                       | -                            | 0.41            |
| 100,000                      | 25,000                       | 0.54            |
| 500,000                      | -                            | 1.00            |
| 625,000                      | 625,000                      | 2.00            |
| 62,500                       | 62,500                       | 2.30            |
| 675,000                      | 675,000                      | 2.50            |
| 416,667                      | 416,667                      | 4.40            |
| <b>2,919,167</b>             | <b>2,084,167</b>             |                 |

The Company accounts for share-based payments in accordance with ASC 718 wherein grants are measured at the grant date fair value and charged to operations over the vesting periods.

During the three months ended March 31, 2020, the Company granted options to purchase 290,000 shares of common stock to five employees with a grant date fair value of \$110,887. The options have an exercise price of \$0.32 to \$0.41 per share. 250,000 of the options vest on a quarterly basis over two years and 40,000 options vest in full six months after the grant date.

On June 30, 2020, the Company granted options to purchase 500,000 shares of common stock to the members of the Company's Board of Directors with a grant date fair value of \$216,093. The options have an exercise price of \$1.00 per share. The options vest on a quarterly basis over two years beginning three months after the grant date.

During the six months ended June 30, 2020 and 2019, we recognized aggregate stock-compensation expense, including the modification and forfeiture accounting described above; of \$(831,548) and \$1,309,155, based upon stock prices ranging from \$0.25 to \$3.30 per share. During the six months ended June 30, 2020, \$66,194 was recorded to sales and marketing expense and \$(921,975) was recorded in general and administrative expense. All of the stock compensation expense recognized during the six months ended June 30, 2019 was recorded in general and administrative expense. See Note 9 for discussion of forfeited options related to a settlement with a former officer.

As of June 30, 2020, the Company had an aggregate of 835,000 remaining unvested options outstanding, with a fair value of \$349,007, weighted average exercise price of \$0.76, and weighted average remaining life of 8.94 years. The aggregate intrinsic value of options outstanding as of June 30, 2020 was \$23,006. The aggregate intrinsic value of unvested options outstanding as of June 30, 2020 was \$19,616.

### 8. Settlement with Former Officer

Effective June 15, 2020, Michael Favish resigned as Chief Executive Officer and as an employee of the Company and resigned from the Company's Board of Directors. Terms of the settlement agreement included the continuation of his previous salary of \$325,000 during the following twelve months. The \$325,000 of settlement payments were recorded in costs related to resignation of former officer expense in the accompanying condensed consolidated statements of operations for the three and six months ended June 30, 2020. As of June 30, 2020, \$311,458 of the amount remains accrued on our condensed consolidated balance sheet.

In connection with his separation, the expiration date of his vested stock options was extended for twelve months from June 15, 2020. In accordance with ASC 718, the extension of the exercise period for the vested options constitutes a modification of the original option agreement. In accounting for the modification, the Company calculated the fair value of the vested options immediately before modification using current valuation inputs including the Company's closing stock price of \$0.49 on June 15, 2020, a volatility metric of 142%, and a risk-free interest rate of 0.22%. The Company also calculated the fair value of the vested options immediately following the modification using the extended 12-month exercise period. An incremental stock compensation charge of \$24,359 was recorded in costs related to resignation of former officer.

Mr. Favish's unvested options at the time of his separation were forfeited. All compensation from prior periods related to these unvested options was reversed, resulting in an adjustment to stock compensation expense during the three and six months ended June 30, 2020 of \$(1,401,582) and \$(965,295), respectively, that was recorded in costs related to resignation of former officer.

## 9. Related Party Transactions

During the six months ended June 30, 2020 and 2019, the Company incurred and paid salaries of \$50,313 and \$47,104, respectively, to Karen Favish, spouse of Michael Favish, our former CEO. During the six months ended June 30, 2020 and 2019, the Company incurred and paid salaries of \$30,000 and \$22,863, respectively, to Kristine Townsend, spouse of Controller and Chief Accounting Officer John Townsend. During the six months ended June 30, 2020 and 2019, the Company paid consulting expenses of \$27,500 and \$60,000, respectively, to Ceatus Media Group, LLC, a web design company owned by Interim CEO David Evans and his spouse Tamara Evans. During the six months ended June 30, 2020 and 2019, the Company paid building rent of \$10,708 and \$10,398, respectively, to DWT Evans LLC, a company owned by David Evans and his spouse Tamara Evans.

When the Company acquired VectorVision, it also acquired AcQviz from the Company's current Chief Science Officer and Interim CEO, Dr. David Evans, which is a patented methodology for auto-calibrating and standardizing the testing light level for computer generated vision testing systems. Dr. Evans is entitled to receive a royalty on net revenue from AcQviz. As part of the development of the CSV-2000, AcQviz was created in a miniaturized circuit board by Radiant Technologies, Inc. in exchange for a 3% royalty on the sales of AcQviz. Radiant Technologies is owned by Joseph T. Evans, the brother of Dr. David Evans.

## 10. Segment Reporting

The Company determined its reporting units are as follows in accordance with ASC 280, "Segment Reporting" ("ASC 280").

|                             | <b>For the Three Months Ended June 30, 2020</b> |   |                            |                     |
|-----------------------------|---|---|----------------------------|---------------------|
|                             | <b>Corporate</b>                                | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>        |
| <b>Revenue</b>              | \$ 2,700  | \$ 1,152,894                                    | \$ 35,315                  | \$ 1,190,909        |
| <b>Cost of goods sold</b>   | 1,096   | 628,205   | 15,278                     | 644,579             |
| <b>Gross profit</b>         | 1,604   | 524,689   | 20,037                     | 546,330             |
| <b>Operating expenses</b>   | 88,428  | 1,072,508                                       | 93,620                     | 1,254,556           |
| <b>Loss from operations</b> | <b>\$ (86,824)</b>                              | <b>\$ (547,819)</b>                             | <b>\$ (73,583)</b>         | <b>\$ (708,226)</b> |

|                             | <b>For the Three Months Ended June 30, 2019</b> |   |                            |                       |
|-----------------------------|---|---|----------------------------|-----------------------|
|                             | <b>Corporate</b>                                | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>          |
| <b>Revenue</b>              | \$ 6,300  | \$ 104,448                                      | \$ 150,222                 | \$ 260,970            |
| <b>Cost of goods sold</b>   | 2,559   | 40,681  | 53,816                     | 97,056                |
| <b>Gross profit</b>         | 3,741   | 63,767  | 96,406                     | 163,914               |
| <b>Operating expenses</b>   | 72,021  | 2,643,725                                       | 260,362                    | 2,976,108             |
| <b>Loss from operations</b> | <b>\$ (68,280)</b>                              | <b>\$ (2,579,958)</b>                           | <b>\$ (163,956)</b>        | <b>\$ (2,812,194)</b> |

|                             | <b>For the Six Months Ended June 30, 2020</b> |   |                            |                       |
|-----------------------------|---|---|----------------------------|-----------------------|
|                             | <b>Corporate</b>                              | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>          |
| <b>Revenue</b>              | \$ 6,100                                      | \$ 1,304,028                                    | \$ 126,505                 | \$ 1,436,633          |
| <b>Cost of goods sold</b>   | 2,477   | 695,291   | 55,920                     | 753,688               |
| <b>Gross profit</b>         | 3,623   | 608,737   | 70,585                     | 682,945               |
| <b>Operating expenses</b>   | 172,911                                       | 3,344,411                                       | 210,070                    | 3,727,392             |
| <b>Loss from operations</b> | <b>\$ (169,288)</b>                           | <b>\$ (2,735,674)</b>                           | <b>\$ (139,485)</b>        | <b>\$ (3,044,447)</b> |

|                             | <b>For the Six Months Ended June 30, 2019</b> |   |                            |                       |
|-----------------------------|---|---|----------------------------|-----------------------|
|                             | <b>Corporate</b>                              | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>          |
| <b>Revenue</b>              | \$ 6,300                                      | \$ 204,382                                      | \$ 292,826                 | \$ 503,508            |
| <b>Cost of goods sold</b>   | 2,559   | 78,953  | 109,036                    | 190,548               |
| <b>Gross profit</b>         | 3,741   | 125,429   | 183,790                    | 312,960               |
| <b>Operating expenses</b>   | 120,783                                       | 3,719,338                                       | 470,256                    | 4,310,377             |
| <b>Loss from operations</b> | <b>\$ (117,042)</b>                           | <b>\$ (3,593,909)</b>                           | <b>\$ (286,466)</b>        | <b>\$ (3,997,417)</b> |

The following tables set forth our total assets by segment. Intersegment balances and transactions have been removed:

|                             | <b>As of June 30, 2020</b> |   |                            |                      |
|-----------------------------|----------------------------|---|----------------------------|----------------------|
|                             | <b>Corporate</b>           | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>         |
| <b>Current assets</b>       |                            |   |                            |                      |
| Cash                        | \$ 11,603,459              | \$ -  | \$ -                       | \$ 11,603,459        |
| Inventories                 | -                          | 868,409   | 366,643                    | 1,235,052            |
| Other                       | 25,980                     | 259,479   | 47,361                     | 332,820              |
| <b>Total current assets</b> | <b>11,629,439</b>          | <b>1,127,888</b>                                | <b>414,004</b>             | <b>13,171,331</b>    |
| Right of use asset, net     | -                          | 442,596   | 53,791                     | 496,387              |
| Property and equipment, net | -                          | 169,267   | 135,267                    | 304,534              |
| Intangible assets, net      | -                          | 50,000  | -                          | 50,000               |
| Other                       | -                          | 11,751  | -                          | 11,751               |
| <b>Total assets</b>         | <b>\$ 11,629,439</b>       | <b>\$ 1,801,502</b>                             | <b>\$ 603,062</b>          | <b>\$ 14,034,003</b> |

|                             | <b>As of December 31, 2019</b> |   |                            |                      |
|-----------------------------|--------------------------------|---|----------------------------|----------------------|
|                             | <b>Corporate</b>               | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>         |
| <b>Current assets</b>       |                                |   |                            |                      |
| Cash                        | \$ 11,115,502                  | \$ -  | \$ -                       | \$ 11,115,502        |
| Inventories                 | 5,003                          | 126,708   | 179,230                    | 310,941              |
| Other                       | 7,399                          | 219,223   | 214,653                    | 441,275              |
| <b>Total current assets</b> | <b>11,127,904</b>              | <b>345,931</b>                                  | <b>393,883</b>             | <b>11,867,718</b>    |
| Right of use asset          | -                              | 509,464   | 63,250                     | 572,714              |
| Property and equipment, net | 70,542                         | 148,514   | 155,582                    | 374,638              |
| Intangible assets, net      | -                              | 50,000  | -                          | 50,000               |
| Other                       | -                              | 11,751  | -                          | 11,751               |
| <b>Total assets</b>         | <b>\$ 11,198,446</b>           | <b>\$ 1,065,660</b>                             | <b>\$ 612,715</b>          | <b>\$ 12,876,821</b> |

## 11. Contingencies

The Company is periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. As of June 30, 2020, management is not aware of any pending or threatened matters that it believes warrant a contingency reserve, and therefore there is no provision in the Company's financial statements with respect to such matters.

## 12. Subsequent Events

Effective July 20, 2020, the Company appointed Andrew C. Schmidt as Vice President and Chief Financial Officer of the Company. The Company and Mr. Schmidt entered into an employment agreement (the "Employment Agreement"), dated July 20, 2020 (the "Effective Date"), pursuant to which Mr. Schmidt's annual base salary is \$250,000. The Employment Agreement provides that Mr. Schmidt shall have an annual target cash bonus opportunity of no less than \$175,000 (the "Bonus") based on the achievement of Company and individual performance objectives to be determined in good faith by the Board in advance and in consultation with Mr. Schmidt (the "Performance Objectives"), provided, however, that the parties acknowledged and agreed that up to an aggregate of \$100,000 of the Bonus shall be payable upon the closing(s) of one or more mergers and acquisition transactions as determined at the discretion of the Board, and \$75,000 shall be based upon the satisfactory completion of the Performance Objectives. The initial term of the Employment Agreement is through July 20, 2021, with automatic one-year renewals, unless either party provides written notice of a non-renewal in accordance with the terms of the Employment Agreement (the "Term").

Mr. Schmidt will also be entitled to certain other benefits consistent with those provided to other senior executives of the Company. In addition, on the Effective Date, Mr. Schmidt was granted an award of one million (1,000,000) stock options (the "Stock Options") under the Company's 2018 Equity Incentive Plan (the "Incentive Plan"), at an exercise price of one dollar (\$1.00) per share. The Stock Options shall vest and become exercisable in twelve (12) equal installments on the last day of each of the subsequent twelve (12) calendar quarter-end dates following the Effective Date (the first of such dates to be September 30, 2020), subject to continued service, and shall vest in full upon a Change in Control (as defined in the Incentive Plan).

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Presentation of Information

As used in this Quarterly Report on Form 10-Q, the terms "we," "us" "our" and the "Company" mean Guardion Health Sciences, Inc. unless the context requires otherwise. The following discussion and analysis should be read in conjunction with our audited financial statements and the related notes that appear elsewhere in this report and our audited financing statements for the year ended December 31, 2019, and the notes thereto, which are set forth in the 2019 Form 10-K. All dollar amounts refer to U.S. dollars unless otherwise indicated.

### **Overview**

Guardion Health Sciences, Inc. (the "Company" or "we") was formed in December 2009 in California as a limited liability company under the name P4L Health Sciences, LLC, and it subsequently changed its name to Guardion Health Sciences, LLC. On June 30, 2015, the Company converted from a California limited liability company to a Delaware corporation, changing its name to Guardion Health Sciences, Inc.

The Company is a specialty health sciences company (1) that has developed medical foods and medical devices in the ocular health space and (2) that has developed and is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers. Management is reviewing all of its business segments and operations with the assistance of an outside consulting firm in order to determine its future business strategies and focus. Furthermore, management is reviewing its expense profile, with its consulting firm, in order to increase efficiencies and reduce its cash utilization over the near and long term, while hoping to increase stockholder value.

### **Recent Trends – COVID-19**

The COVID-19 pandemic has and will continue affecting economies and businesses around the world. The impacts of the pandemic could be material, but due to the evolving nature of this situation, we are not able at this time to estimate the impact on our financial or operational results. Among the factors that could impact our results are: effectiveness of COVID-19 mitigation measures, global economic conditions, consumer spending, work from home trends, supply chain sustainability and other factors. These factors could result in increased or decreased demand for our products and services and impact our ability to serve customers.

### **Recent Developments**

#### *Warrant Exercises*

From January 1, 2020 through June 30, 2020, the Company received total gross proceeds of \$4,549,421 from the exercise of 13,302,400 warrants issued in the Company's October 2019 follow-on offering.

#### *Nutraceutical Sales*

During February 2020, the Company contracted with a Malaysian company to develop an immune-supportive formula for its consumer base. An initial order was placed for \$875,000, and in connection with this order, on March 31, 2020, the Malaysian company paid \$437,500 as a deposit for this order. The Company completed shipment of the product, received payment in full, and has recognized revenue for this order of \$890,000 during the three months ended June 30, 2020.

### **Going Concern**

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of \$3,054,073 and utilized cash in operating activities of \$4,020,731 during the six months ended June 30, 2020. The Company expects to continue to incur net losses and negative operating cash flows in the near-term. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern within one year of the date that the financial statements are issued.

The Company's independent registered public accounting firm has also included explanatory language in their opinion accompanying the Company's audited financial statements for the year ended December 31, 2019, stating there is substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from the possible inability of the Company to continue as a going concern.

The Company will continue to incur significant expenses for commercialization activities related to its medical foods, nutraceuticals, the MapcatSF medical device, VectorVision diagnostic equipment, and with respect to efforts to continue to build the Company's infrastructure. Development and commercialization of medical foods, nutraceuticals and medical devices involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines. Management is reviewing all of its business segments and operations with the assistance of an outside consulting firm in order to determine its future business strategies and focus. Furthermore, management is reviewing its expense profile, with its consulting firm, in order to increase efficiencies and reduce its cash utilization over the near and long term, while hoping to increase stockholder value.

The Company intends to seek to raise additional debt and/or equity capital to fund future operations, but there can be no assurances that the Company will be able to secure such additional financing in the amounts necessary to fully fund its operating requirements on acceptable terms or at all. If the Company is unable to access sufficient capital resources on a timely basis, the Company may be forced to reduce or discontinue its technology and product development programs and curtail or cease operations.

### **Recent Accounting Pronouncements**

See Note 2 to the condensed consolidated financial statements for management's discussion of recent accounting pronouncements.

### **Concentration of Risk**

Cash balances are maintained at large, well-established financial institutions. At times, cash balances may exceed federally insured limits. Insurance coverage limits are \$250,000 per depositor at each financial institution. The Company has never experienced any losses related to these balances.

During the six months ended June 30, 2020, the Medical Foods and Nutraceuticals segment had one customer who accounted for approximately 62% of the Company's sales. During the six months ended June 30, 2019, the Medical Devices segment had one customer who accounted for approximately 26% of the Company's sales. No other customer accounted for more than 10% of sales in either period.

### **Critical Accounting Policies and Estimates**

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of its financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect 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 expenses during the reporting period. Actual results could differ from those estimates. The Company's financial statements included herein include all adjustments, consisting of only normal recurring adjustments, necessary to present fairly the Company's financial position, results of operations and cash flows.

The following critical accounting policies affect the more significant judgments and estimates used in the preparation of the Company's financial statements.

### ***Stock-Based Compensation***

The Company accounts for share-based awards to employees and nonemployees directors and consultants in accordance with the provisions of ASC 718, Compensation—Stock Compensation, and under the recently issued guidance following FASB's pronouncement, ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting. Under ASC 718, and applicable updates adopted, share-based awards are valued at fair value on the date of grant and that fair value is recognized over the requisite service, or vesting, period. The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur.

Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using a blend of its own historical stock price volatility as well as that of market comparable entities since the Company's common stock has limited trading history and limited observable volatility of its own. The expected term of the options is estimated by using the Securities and Exchange Commission Staff Bulletin No. 107's Simplified Method for Estimate Expected Term. The risk-free interest rate is estimated using comparable published federal funds rates.

## Results of Operations

Through June 30, 2020, the Company has primarily been engaged in product development, commercialization, and raising capital. The Company has incurred and will continue to incur significant expenditures for the development of its products and intellectual property, which includes medical foods, nutraceuticals and medical devices for the treatment of various eye diseases. The Company had limited revenue during the six months ended June 30, 2020 and 2019.

### Comparison of Three Months Ended June 30, 2020 and 2019

|  | Three Months Ended<br>June 30, |                | Change       |        |
|--|--------------------------------|----------------|--------------|--------|
|  | 2020                           | 2019           |              |        |
| Revenue  | \$ 1,190,909                   | \$ 260,970     | \$ 929,939   | 356%   |
| Cost of goods sold                             | 644,579                        | 97,056         | 547,523      | 564%   |
| Gross Profit                                   | 546,330                        | 163,914        | 382,416      | 233%   |
| Operating Expenses:                            |                                |                |              |        |
| Research and development                       | 44,581                         | 77,688         | (33,107)     | (43)%  |
| Sales and marketing                            | 519,067                        | 409,409        | 109,658      | 27%    |
| General and administrative                     | 1,712,183                      | 2,489,011      | (776,828)    | (31)%  |
| Costs related to resignation of former officer | (1,052,223)                    | -              | (1,052,223)  | (100)% |
| Impairment loss on equipment held for sale     | 30,948                         | -              | 30,948       | 100%   |
| Total Operating Expenses                       | 1,254,556                      | 2,976,108      | (1,721,552)  | (58)%  |
| Loss from Operations                           | (708,226)                      | (2,812,194)    | 2,103,968    | (75)%  |
| Other Expense:                                 |                                |                |              |        |
| Interest expense                               | 1,790                          | 234,065        | (232,275)    | (99)%  |
| Finance cost upon issuance of warrants         | -                              | 229,921        | (229,921)    | (100)% |
| Change in fair value of derivative warrants    | (2,856)                        | (227,832)      | 224,976      | (99)%  |
| Net Loss                                       | \$ (707,160)                   | \$ (3,048,348) | \$ 2,341,188 | (77)%  |

### Revenue

For the three months ended June 30, 2020, revenue from product sales was \$1,190,909 compared to \$260,970 for the three months ended June 30, 2019, resulting in an increase of \$929,939 or 356%. The increase is due primarily to the fulfillment of a Malaysian order for an immune-supportive formula that was delivered in June. The Company completed shipment of the product, received payment in full, and has recognized revenue for this order of \$890,000 during the three months ended June 30, 2020.

### Cost of Goods Sold

For the three months ended June 30, 2020, cost of goods sold was \$644,579 compared to \$97,056 for the three months ended June 30, 2019, resulting in an increase of \$547,523 or 564%. This reflects the costs of goods sold associated with the Malaysian order noted above.

### ***Gross Profit***

For the three months ended June 30, 2020, gross profit was \$546,330 compared to \$163,914 for the three months ended June 30, 2019, resulting in an increase of \$382,416 or 233%. Gross profit represented 46% of revenues the three months ended June 30, 2020, versus 63% of revenue for the three months ended June 30, 2019. The lower gross profit percentage in 2020 is reflective of lower distributor pricing given to the Malaysian customer.

### ***Research and Development***

For the three months ended June 30, 2020, research and development costs were \$44,581 compared to \$77,688 for the three months ended June 30, 2019, resulting in a decrease of \$33,107 or 43%. Research and development costs consist of engineering efforts related to our medical devices. The decrease in the current period reflects higher development costs associated with the CSV-2000 that were incurred in 2019.

### ***Sales and Marketing***

For the three months ended June 30, 2020, sales and marketing expenses were \$519,067 compared to \$409,409 for the three months ended June 30, 2019. The increase in sales and marketing expenses of \$109,658 or 27% compared to the prior period was primarily due to a \$98,000 increase in labor costs stemming from our new sales force initiatives.

### ***General and Administrative***

For the three months ended June 30, 2020, general and administrative expenses were \$1,712,183 compared to \$2,489,011 for the three months ended June 30, 2019. The decrease of \$776,828 or 31% compared to the prior period was primarily due to a \$1,240,000 decrease in stock compensation expense. This reduction was partially offset by increases of \$263,000 in consulting costs, \$179,000 in legal costs, and \$92,000 in labor costs.

### ***Costs related to resignation of former officer***

Effective June 15, 2020, Michael Favish resigned as Chief Executive Officer and as an employee of the Company and resigned from the Company's Board of Directors. Terms of the settlement agreement included the continuation of his previous salary of \$325,000 during the following twelve months. The \$325,000 settlement was recorded in costs related to resignation of former officer expense in the accompanying condensed consolidated statement of operations for the three months ended June 30, 2020.

In connection with his separation, the expiration date of his vested stock options was extended for twelve months from June 15, 2020. In accordance with ASC 718, the extension of the exercise period for the vested options constitutes a modification of the original option agreement. In accounting for the modification, the Company calculated the fair value of the vested options immediately before modification using current valuation inputs including the Company's closing stock price of \$0.49 on June 15, 2020, a volatility metric of 142%, and a risk-free interest rate of 0.22%. The Company also calculated the fair value of the vested options immediately following the modification using the extended 12-month exercise period. An incremental stock compensation charge of \$24,359 was recorded in costs related to resignation of former officer.

Mr. Favish's unvested options at the time of his separation were forfeited. All compensation from prior periods related to these unvested options was reversed, resulting in an adjustment to stock compensation expense during the three months ended June 30, 2020 of \$(1,401,582) that was recorded in costs related to resignation of former officer.

### ***Impairment Loss on Equipment Held for Sale***

During June 2020, in an effort to reduce costs and focus on other segments of the business, the Company began to wind down the Transcranial Doppler Solutions, Inc. ("TDSI") subsidiary and ceased its operations. The wind down is currently expected to be completed in the third quarter of 2020. TDSI holds a group of ultrasound machines as fixed assets. We intend to sell these machines, and therefore have reflected their value as the lower of carrying value or fair value less estimated selling costs. An impairment charge of \$30,948 has been recorded in the condensed consolidated statements of operations for the three months ended June 30, 2020.

### *Interest Expense*

For the three months ended June 30, 2020, interest expense was \$1,790 compared to \$234,065 for the three months ended June 30, 2019. The decrease of \$232,275 or 99%, was due primarily to the amortization of the valuation discount of the March 2019 convertible notes of \$233,455 that was reflected as an expense when the notes were converted in April of 2019.

### *Finance Cost Upon Issuance of Warrants*

Finance costs for the three months ended June 30, 2019 were \$229,921. There were no such costs for the comparable period in 2020. On April 4, 2019, the Company issued 62,500 warrants with an exercise price of \$5.00 per share to the underwriter (the "Underwriter") in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants at the date of issuance was determined to be \$229,291 and was recorded as a finance cost.

### *Change in Fair Value of Derivative Warrants*

On April 4, 2019, the Company issued 62,500 warrants with an exercise price of \$5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants will be remeasured at each reporting period, with the change in the fair value recognized in earnings in the accompanying Statements of Operations. The fair value of the warrants at the date of issuance was determined to be \$229,921 and was recorded as a finance cost in April of 2019. As of June 30, 2020, the fair value of the warrant liability was determined to be \$19,411 and the Company recorded a change in fair value of derivative warrants for the three months ended June 30, 2020 of \$2,856.

### *Net Loss*

For the three months ended June 30, 2020, the Company incurred a net loss of \$701,160, compared to a net loss of \$3,048,348 for the three months ended June 30, 2019. The decrease in net loss of \$2,341,188 or 77% compared to the prior year period was primarily due to the revenue from the Malaysian order and the reduced stock compensation costs during the current period.

### *Segment Information*

The following tables set forth our results of operations by segment (results allocated to Corporate consist of the TDSI operations):

|                             | <b>For the Three Months Ended June 30, 2020</b> |   |                            |                     |
|-----------------------------|---|---|----------------------------|---------------------|
|                             | <b>Corporate</b>                                | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>        |
| <b>Revenue</b>              | \$ 2,700  | \$ 1,152,894                                    | \$ 35,315                  | \$ 1,190,909        |
| <b>Cost of goods sold</b>   | 1,096   | 628,205   | 15,278                     | 644,579             |
| <b>Gross profit</b>         | 1,604   | 524,689   | 20,037                     | 546,330             |
| <b>Operating expenses</b>   | 88,428  | 1,072,508                                       | 93,620                     | 1,254,556           |
| <b>Loss from operations</b> | <b>\$ (86,824)</b>                              | <b>\$ (547,819)</b>                             | <b>\$ (73,583)</b>         | <b>\$ (708,226)</b> |

|                             | <b>For the Three Months Ended June 30, 2019</b> |   |                            |                       |
|-----------------------------|---|---|----------------------------|-----------------------|
|                             | <b>Corporate</b>                                | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>          |
| <b>Revenue</b>              | \$ 6,300  | \$ 104,448                                      | \$ 150,222                 | \$ 260,970            |
| <b>Cost of goods sold</b>   | 2,559   | 40,681  | 53,816                     | 97,056                |
| <b>Gross profit</b>         | 3,741   | 63,767  | 96,406                     | 163,914               |
| <b>Operating expenses</b>   | 72,021  | 2,643,725                                       | 260,362                    | 2,976,108             |
| <b>Loss from operations</b> | <u>\$ (68,280)</u>                              | <u>\$ (2,579,958)</u>                           | <u>\$ (163,956)</u>        | <u>\$ (2,812,194)</u> |

### **Revenue**

For the three months ended June 30, 2020, revenue from our Medical Foods and Nutraceuticals segment was \$1,152,894 compared to \$104,448 for the three months ended June 30, 2019, resulting in an increase of \$1,048,446 or 1004%. The increase is due primarily to the completion of a Malaysian order for an immune-supportive formula that was delivered in June. The Company completed shipment of the product, received payment in full, and has recognized revenue for this order of \$890,000 during the three months ended June 30, 2020. Medical Foods revenues of \$131,114 grew approximately 26% during the three months ended June 30, 2020, as compared to the prior year period of \$104,448. For the three months ended June 30, 2020, revenue from our Medical Devices segment was \$35,315 compared to \$150,222 for the three months ended June 30, 2019, resulting in a decrease of \$114,907 or 76%, primarily as a result of medical facility closures due to COVID-19 “Stay at Home” orders. The severity of the impact of the COVID-19 pandemic on the Company’s business will continue to depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company’s customers, service providers and suppliers, all of which are uncertain and cannot be predicted.

### **Cost of Goods Sold**

For the three months ended June 30, 2020, cost of goods sold from our Medical Foods and Nutraceuticals segment was \$628,205 compared to \$40,681 for the three months ended June 30, 2019, resulting in an increase of \$587,524 or 1,444%. The increase was due to the Malaysian order noted above. For the three months ended June 30, 2020, cost of goods sold from our Medical Devices segment was \$15,278 compared to \$53,816 for the three months ended June 30, 2019, resulting in a decrease of \$38,538 or 72%. The decrease was due to the decrease in sales noted above.

### **Gross Profit**

For the three months ended June 30, 2020, gross profit from the Medical Foods and Nutraceuticals segment was \$524,689 compared to \$63,767 for the three months ended June 30, 2019, resulting in an increase of \$460,922 or 723%. For the three months ended June 30, 2020, gross profit from the Medical Devices segment was \$20,037 compared to \$96,406 for the three months ended June 30, 2019, resulting in a decrease of \$76,369 or 79%. Gross profit overall represented 46% of revenues for the three months ended June 30, 2020, versus 63% of revenue for the three months ended June 30, 2019. The lower gross profit percentage in the current period is reflective of lower distributor pricing given to the Malaysian customer.

## Comparison of Six Months Ended June 30, 2020 and 2019

|  | Six Months Ended<br>June 30, |                       | Change              |              |
|--|------------------------------|-----------------------|---------------------|--------------|
|  | 2020                         | 2019                  |                     |              |
| Revenue  | \$ 1,436,633                 | \$ 503,508            | \$ 933,125          | 185%         |
| Cost of goods sold                             | 753,688                      | 190,548               | 563,140             | 296%         |
| Gross Profit                                   | 682,945                      | 312,960               | 369,985             | 118%         |
| Operating Expenses:                            |                              |                       |                     |              |
| Research and development                       | 75,769                       | 106,716               | (30,947)            | (29)%        |
| Sales and marketing                            | 1,007,913                    | 764,028               | 243,885             | 32%          |
| General and administrative                     | 3,228,698                    | 3,439,633             | (210,935)           | (24)%        |
| Costs related to resignation of former officer | (615,936)                    | -                     | (615,936)           | (100)%       |
| Impairment loss on equipment held for sale     | 30,948                       | -                     | 30,948              | 100%         |
| Total Operating Expenses                       | 3,727,392                    | 4,310,377             | (582,985)           | (14)%        |
| Loss from Operations                           | (3,044,447)                  | (3,997,417)           | 952,970             | (24)%        |
| Other Expense:                                 |                              |                       |                     |              |
| Interest expense                               | 3,538                        | 251,637               | (248,099)           | (99)%        |
| Finance cost upon issuance of warrants         | -                            | 415,955               | (415,955)           | (100)%       |
| Change in fair value of derivative warrants    | 6,088                        | (227,832)             | 233,920             | (103)%       |
| Net Loss                                       | <u>\$ (3,054,073)</u>        | <u>\$ (4,437,177)</u> | <u>\$ 1,383,104</u> | <u>(31)%</u> |

### **Revenue**

For the six months ended June 30, 2020, revenue from product sales was \$1,436,633 compared to \$503,508 for the six months ended June 30, 2019, resulting in an increase of \$933,125 or 185%. The increase is due primarily to the completion of a Malaysian order for an immune-supportive formula that was delivered in June. The Company completed shipment of the product, received payment in full, and has recognized revenue for this order of \$890,000.

### **Cost of Goods Sold**

For the six months ended June 30, 2020, cost of goods sold was \$753,688 compared to \$190,548 for the six months ended June 30, 2019, resulting in an increase of \$563,140 or 296%. This reflects the costs of goods sold associated with the Malaysian order noted above.

### **Gross Profit**

For the six months ended June 30, 2020, gross profit was \$682,945 compared to \$312,960 for the six months ended June 30, 2019, resulting in an increase of \$369,985 or 118%. Gross profit represented 48% of revenues the six months ended June 30, 2020, versus 62% of revenue for the six months ended June 30, 2019. The lower gross profit percentage in 2020 is reflective of lower distributor pricing given to the Malaysian customer.

### **Research and Development**

For the six months ended June 30, 2020, research and development costs were \$75,769 compared to \$106,716 for the six months ended June 30, 2019, resulting in a decrease of \$30,947 or 29%. Research and development costs consist of engineering efforts related to our medical devices. The decrease in the current period reflects higher development costs associated with the CSV-2000 that were incurred in 2019.

### **Sales and Marketing**

For the six months ended June 30, 2020, sales and marketing expenses were \$1,007,913 compared to \$764,028 for the six months ended June 30, 2019. The increase in sales and marketing expenses of \$243,885 or 32% compared to the prior period was primarily due to a \$203,000 increase in labor costs stemming from our new sales force initiatives.

### ***General and Administrative***

For the six months ended June 30, 2020, general and administrative expenses were \$3,228,698 compared to \$3,439,633 for the six months ended June 30, 2019. The decrease of \$210,935 or 24% compared to the prior period was primarily due to a \$1,266,000 decrease in stock compensation expense. This decrease was partially offset by increases of \$252,000 in consulting costs, \$152,000 in professional fees, \$324,000 in legal costs, \$206,000 in labor costs, and \$116,000 in corporate insurance costs. Management is reviewing its expense profile, with its consulting firm, in order to increase efficiencies and reduce its cash utilization over the near and long term, while hoping to increase stockholder value.

### ***Costs related to resignation of former officer***

Effective June 15, 2020, Michael Favish resigned as Chief Executive Officer and as an employee of the Company and resigned from the Company's Board of Directors. Terms of the settlement agreement included the continuation of his previous salary of \$325,000 during the following twelve months. The \$325,000 settlement was recorded in costs related to resignation of former officer expense in the accompanying condensed consolidated statement of operations for the six months ended June 30, 2020.

In connection with his separation, the expiration date of his vested stock options was extended for twelve months from June 15, 2020. In accordance with ASC 718, the extension of the exercise period for the vested options constitutes a modification of the original option agreement. In accounting for the modification, the Company calculated the fair value of the vested options immediately before modification using current valuation inputs including the Company's closing stock price of \$0.49 on June 15, 2020, a volatility metric of 142%, and a risk-free interest rate of 0.22%. The Company also calculated the fair value of the vested options immediately following the modification using the extended 12-month exercise period. An incremental stock compensation charge of \$24,359 was recorded in costs related to resignation of former officer.

Mr. Favish's unvested options at the time of his separation were forfeited. All compensation from prior periods related to these unvested options was reversed, resulting in an adjustment to stock compensation expense during the six months ended June 30, 2020 of \$(965,295) that was recorded in costs related to resignation of former officer.

### ***Impairment Loss on Equipment Held for Sale***

During June 2020, in an effort to reduce costs, the Company began to wind down the TDSI subsidiary. The wind down is currently expected to be completed in the third quarter of 2020. TDSI holds a group of ultrasound machines as fixed assets. We intend to sell these machines, and therefore have reflected their value as the lower of carrying value or fair value less estimated selling costs. An impairment charge of \$30,948 has been recorded in the condensed consolidated statements of operations for the six months ended June 30, 2020.

### ***Interest Expense***

For the six months ended June 30, 2020, interest expense was \$3,538 compared to \$251,637 for the six months ended June 30, 2019. The decrease of \$248,099 or 99%, was due primarily to the amortization of the valuation discount of the March 2019 convertible notes of \$233,455 that was reflected as an expense when the notes were converted in April of 2019.

### ***Finance Cost Upon Issuance of Warrants***

Finance costs for the six months ended June 30, 2019 of \$415,955 include the following; (I) In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at March 31, 2019. The fair value of the warrants at the closing of the IPO was determined to be \$436,034, of which \$250,000 was recorded as a valuation discount, and \$186,034 was recorded as a finance cost. (II) On April 4, 2019, the Company issued 62,500 warrants with an exercise price of \$5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. There were no such costs for the comparable period in 2020.

### *Change in Fair Value of Derivative Warrants*

On April 4, 2019, the Company issued 62,500 warrants with an exercise price of \$5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants will be remeasured at each reporting period, with the change in the fair value recognized in earnings in the accompanying Statements of Operations. The fair value of the warrants at the date of issuance was determined to be \$229,921 and was recorded as a finance cost in April of 2019. As of June 30, 2020, the fair value of the warrant liability was determined to be \$19,411 and the Company recorded a change in fair value of derivative warrants for the six months ended June 30, 2020 of \$6,088.

### *Net Loss*

For the six months ended June 30, 2020, the Company incurred a net loss of \$3,054,073, compared to a net loss of \$4,437,177 for the six months ended June 30, 2019. The decrease in net loss of \$1,383,104 or 31% compared to the prior year period was primarily due to the reduced stock compensation costs during the current period.

### *Segment Information*

The following tables set forth our results of operations by segment (results allocated to Corporate consist of the TDSI operations):

|                             | <b>For the Six Months Ended June 30, 2020</b> |   |                            |                       |
|-----------------------------|---|---|----------------------------|-----------------------|
|                             | <b>Corporate</b>                              | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>          |
| <b>Revenue</b>              | \$ 6,100                                      | \$ 1,304,028                                    | \$ 126,505                 | \$ 1,436,633          |
| <b>Cost of goods sold</b>   | <u>2,477</u>                                  | <u>695,291</u>                                  | <u>55,920</u>              | <u>753,688</u>        |
| <b>Gross profit</b>         | 3,623   | 608,737   | 70,585                     | 682,945               |
| <b>Operating expenses</b>   | <u>172,911</u>                                | <u>3,344,411</u>                                | <u>210,070</u>             | <u>3,727,392</u>      |
| <b>Loss from operations</b> | <u>\$ (169,288)</u>                           | <u>\$ (2,735,674)</u>                           | <u>\$ (139,485)</u>        | <u>\$ (3,044,447)</u> |

|                             | <b>For the Six Months Ended June 30, 2019</b> |   |                            |                       |
|-----------------------------|---|---|----------------------------|-----------------------|
|                             | <b>Corporate</b>                              | <b>Medical<br/>Foods and<br/>Nutraceuticals</b> | <b>Medical<br/>Devices</b> | <b>Total</b>          |
| <b>Revenue</b>              | \$ 6,300                                      | \$ 204,382                                      | \$ 292,826                 | \$ 503,508            |
| <b>Cost of goods sold</b>   | <u>2,559</u>                                  | <u>78,953</u>                                   | <u>109,036</u>             | <u>190,548</u>        |
| <b>Gross profit</b>         | 3,741   | 125,429   | 183,790                    | 312,960               |
| <b>Operating expenses</b>   | <u>120,783</u>                                | <u>3,719,338</u>                                | <u>470,256</u>             | <u>4,310,377</u>      |
| <b>Loss from operations</b> | <u>\$ (117,042)</u>                           | <u>\$ (3,593,909)</u>                           | <u>\$ (286,466)</u>        | <u>\$ (3,997,417)</u> |

### ***Revenue***

For the six months ended June 30, 2020, revenue from our Medical Foods and Nutraceuticals segment was \$1,304,028 compared to \$204,382 for the six months ended June 30, 2019, resulting in an increase of \$1,099,646 or 538%. The increase is due primarily to the completion of a Malaysian order for an immune-supportive formula that was delivered in June. The Company completed shipment of the product, received payment in full, and has recognized revenue for this order of \$890,000 during June 2020. Medical Foods revenues of \$270,903 grew approximately 33% during the six months ended June 30, 2020, as compared to the prior year period of \$204,382. For the six months ended June 30, 2020, revenue from our Medical Devices segment was \$126,505 compared to \$292,826 for the six months ended June 30, 2019, resulting in a decrease of \$166,321 or 57%, primarily as a result of medical facility closures due to COVID-19 “Stay at Home” orders. The decrease was offset in part from the sale of a MapCat device in January 2020. The severity of the impact of the COVID-19 pandemic on the Company’s business will continue to depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on the Company’s customers, service providers and suppliers, all of which are uncertain and cannot be predicted.

### ***Cost of Goods Sold***

For the six months ended June 30, 2020, cost of goods sold from our Medical Foods and Nutraceuticals segment was \$695,291 compared to \$78,953 for the six months ended June 30, 2019, resulting in an increase of \$616,338 or 781%. The increase was primarily due to the Malaysian order noted above. For the six months ended June 30, 2020, cost of goods sold from our Medical Devices segment was \$55,920 compared to \$109,036 for the six months ended June 30, 2019, resulting in a decrease of \$53,116 or 49%. The decrease was due to the decrease in sales noted above. In addition, a \$13,000 inventory adjustment affecting cost of sales due primarily to the write off of scrap materials was recorded in March 2020.

### ***Gross Profit***

For the six months ended June 30, 2020, gross profit from the Medical Foods and Nutraceuticals segment was \$608,737 compared to \$125,429 for the six months ended June 30, 2019, resulting in an increase of \$483,308 or 385%. For the six months ended June 30, 2020, gross profit from the Medical Devices segment was \$70,585 compared to \$183,790 for the six months ended June 30, 2019, resulting in a decrease of \$113,205 or 62%. Gross profit overall represented 48% of revenues for the six months ended June 30, 2020, versus 62% of revenue for the six months ended June 30, 2019. The lower gross profit percentage in the current period is reflective of lower distributor pricing given to the Malaysian customer.

### ***Liquidity and Capital Resources***

Since its formation in 2009, the Company has devoted substantial effort and capital resources to the development and commercialization activities related to its product candidates. As a result of these and other activities, the Company utilized cash in operating activities of \$4,020,731 during the six months ended June 30, 2020. The Company had working capital of \$12,188,095 at June 30, 2020. As of June 30, 2020, the Company had cash in the amount of \$11,603,459 and no available borrowings. The Company’s financing has historically come primarily from the issuance of convertible notes, promissory notes and from the sale of common and preferred stock and other equity securities.

The COVID-19 pandemic has and will continue affecting economies and businesses around the world. The impacts of the pandemic could be material, but due to the evolving nature of this situation, we are not able at this time to estimate the impact on our financial or operational results. Among the factors that could impact our results are: effectiveness of COVID-19 mitigation measures, global economic conditions, consumer spending, work from home trends, supply chain sustainability and other factors. These factors could result in increased or decreased demand for our products and services and impact our ability to serve customers.

The Company will continue to incur significant expenses for continued commercialization activities related to its medical foods, medical devices and its nutraceuticals product line. Development and commercialization of medical foods, medical devices and nutraceuticals involves a lengthy and complex process. Additionally, the Company’s long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines. On April 9, 2019, the Company completed its initial public offering (the “IPO”), resulting in net cash proceeds of \$3,888,000 to the Company. On August 15, 2019, the Company consummated an underwritten public offering resulting in net proceeds to the Company of \$4,944,340. On October 30, 2019, the Company consummated an underwritten public offering resulting in net proceeds to the Company of \$7,392,467.

The Company received total gross proceeds of \$4,549,421 during the six months ended June 30, 2020 from the exercise of 13,302,400 warrants issued in the Company's October 2019 follow-on offering.

The Company will continue to seek to raise additional debt and/or equity capital to fund future operations as necessary, but there can be no assurances that the Company will be able to secure such additional financing in the amounts necessary to fully fund its operating requirements on acceptable terms or at all. If the Company is unable to access sufficient capital resources on a timely basis, the Company may be forced to reduce or discontinue its technology and product development programs and curtail or cease operations. Management is reviewing all of its business segments and operations with the assistance of an outside consulting firm in order to determine its future business strategies and focus. Furthermore, management is reviewing its expense profile, with its consulting firm, in order to increase efficiencies and reduce its cash utilization over the near and long term, while hoping to increase stockholder value.

Management believes that the Company has adequate funding to pursue its planned business initiatives and operations through at least December 31, 2020.

### ***Sources and Uses of Cash***

The following table sets forth the Company's major sources and uses of cash for each of the following periods:

|   | <b>Six Months Ended<br/>June 30,</b> |                     |
|---|--------------------------------------|---------------------|
|   | <b>2020</b>                          | <b>2019</b>         |
| Net cash used in operating activities     | \$ (4,020,731)                       | \$ (2,493,696)      |
| Net cash used in investing activities     | (40,733)                             | (58,934)            |
| Net cash provided by financing activities | 4,549,421                            | 4,250,327           |
| Net increase in cash                      | <u>\$ 487,957</u>                    | <u>\$ 1,697,697</u> |

### ***Operating Activities***

Net cash used in operating activities was \$4,020,731 during the six months ended June 30, 2020, versus \$2,493,696 used during the comparable prior year period. The increase in 2020 was due primarily to inventory purchases and higher legal, insurance, professional services, consulting, and labor costs paid in the current period.

### ***Investing Activities***

Net cash used in investing activities was \$40,733 for six months ended June 30, 2020 and \$58,934 for the six months ended June 30, 2019. Cash was used in both periods for the purchase of testing equipment, furniture and fixtures.

### ***Financing Activities***

Net cash provided by financing activities was \$4,549,421 for the six months ended June 30, 2020 and was due to warrant exercise during the period. Net cash provided by financing activities was \$4,250,327 for the six months ended June 30, 2019 was due primarily to the completion of our IPO, which resulted in net proceeds of \$3,888,000. In addition, in March 2019, the Company issued \$350,000 in promissory and convertible promissory notes and received cash of \$131,875 from the exercise of warrants. These proceeds were partially offset by payment of \$100,000 to settle a promissory note.

### **Off-Balance Sheet Arrangements**

At June 30, 2020 and December 31, 2019, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

### ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this Quarterly Report on Form 10-Q, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon this evaluation, the interim Chief Executive Officer and Chief Financial Officer each concluded that the Company's disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms, and that such information has been accumulated and communicated to the Company's management, including the Company's interim Chief Executive Officer and Chief Financial Officer, in a manner that allows timely decisions regarding required disclosure.

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework 2013. Based on this evaluation, our interim Chief Executive Officer and our Chief Financial Officer determined, based upon the existence of the material weakness described below, that we did not maintain effective internal control over financial reporting as of June 30, 2020.

*Segregation of Duties* – The Company did not maintain effective policies to ensure adequate segregation of duties within its accounting processes. Specifically, due to the size of the Company and the smaller nature of department teams, opportunities are limited to segregate duties, resulting in one individual having almost complete responsibility for the processing of certain financial information.

While we have designed and implemented, or expect to implement, measures that we believe address or will address this control weakness, we continue to develop our internal controls, processes and reporting systems by, among other things, hiring qualified personnel with expertise to perform specific functions, and designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight. We plan to remediate the identified material weakness through the redistribution of job responsibilities, by hiring additional senior accounting staff, and through the design and implementation of additional internal controls and policies in order to promote adequate segregation of duties. We expect to complete the remediation and improvements by the end of 2020. We expect to incur additional costs to address this weakness, primarily personnel costs.

#### ***Changes in Internal Control Over Financial Reporting***

There have been no changes in the Company's internal control over financial reporting identified in connection with the evaluation that occurred during the second quarter ended in 2020 that have materially affected, or are reasonably likely to materially affect, the internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

The Company is not currently a party to any material legal proceedings and is not aware of any pending or threatened legal proceeding against the Company that the Company believes could have a material adverse effect on its business, operating results, cash flows or financial condition. The Company is periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on the Company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained. As of June 30, 2020, management is not aware of any pending or threatened matters that it believes warrant a contingency reserve, and therefore there is no provision in the Company's financial statements with respect to such matters.

### ITEM 1A. RISK FACTORS

Our business, financial condition, results of operations, and cash flows may be impacted by a number of factors, many of which are beyond our control, including those set forth in our Form 10-K and our Form 10-Q for the quarter ended March 30, 2020, the occurrence of any one of which could have a material adverse effect on our actual results.

There have been no material changes to the Risk Factors previously disclosed in our Form 10-K and our Form 10-Q for the quarter ended March 30, 2020, except as noted below.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

Not applicable.

### ITEM 6. EXHIBITS

| <u>Exhibit No.</u> | <u>Description</u>   |
|--------------------|--|
| 31.1               | <a href="#"><u>Certification of Chief Executive Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>   |
| 31.2               | <a href="#"><u>Certification of Chief Financial Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>   |
| 32.1*              | <a href="#"><u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002</u></a>   |
| 101                | The following materials from the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2020, formatted in XBRL (eXtensible Business Reporting Language), (i) Balance Sheets, (ii) Statements of Income, (iii) Statements of Comprehensive Income, (iv) Statements of Cash Flows, (v) Statement of Stockholders' Equity and (vi) Notes to Financial Statements |

\* A certification furnished pursuant to Item 601(b)(2) of the Regulation S-K will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 14th day of May, 2020.

| <b>Signature</b>                            | <b>Title</b>   | <b>Date</b>     |
|---|--|-----------------|
| <u>/s/ David W. Evans</u><br>David W. Evans | Interim CEO and President<br>(Principal Executive Officer) | August 12, 2020 |
| <u>/s/ Andrew Schmidt</u><br>Andrew Schmidt | Chief Financial Officer<br>(Principal Financial Officer)   | August 12, 2020 |

## CERTIFICATION

I, David Evans, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Guardion Health Sciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2020

*/s/ David W. Evans*

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David W. Evans  
Interim Chief Executive Officer  
(Principal Executive Officer)

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## CERTIFICATION

I, Andrew Schmidt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Guardion Health Sciences, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2020

*/s/ Andrew Schmidt*  
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Andrew Schmidt  
Chief Financial Officer  
(Principal Financial Officer)

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**CERTIFICATIONS PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ENACTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Guardion Health Sciences, Inc. (the “Company”) on Form 10-Q for the period ended June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of David Evans, Chief Executive Officer of the Company, and Andrew Schmidt, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as enacted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 12, 2020

*/s/ David W. Evans*

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David W. Evans  
Interim Chief Executive Officer  
(Principal Executive Officer)

August 12, 2020

*/s/ Andrew Schmidt*

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Andrew Schmidt  
Chief Financial Officer  
(Principal Financial Officer)

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