
**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 March 31, 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
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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 May 13, 2020, there were 85,619,962 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 March 31, 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).

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

	March 31, 2020 <u>(Unaudited)</u>	December 31, 2019
Assets		
Current assets		
Cash	\$ 12,890,140	\$ 11,115,502
Accounts receivable	31,083	78,337
Inventories	759,085	310,941
Prepaid expenses	<u>622,959</u>	<u>362,938</u>
Total current assets	14,303,267	11,867,718
Deposits	11,751	11,751
Property and equipment, net	383,486	374,638
Right of use asset, net	534,730	572,714
Intangible assets	<u>50,000</u>	<u>50,000</u>
Total assets	\$ 15,283,234	\$ 12,876,821
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 249,383	\$ 70,291
Accrued expenses	284,970	175,052
Customer deposit	437,500	-
Derivative warrant liability	22,267	13,323
Lease liability – current	<u>154,327</u>	<u>151,568</u>
Total current liabilities	1,148,447	410,234
Lease liability – long term	<u>395,186</u>	<u>434,747</u>
Total liabilities	1,543,633	844,981
Commitments and contingencies		
Stockholders' Equity		
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; 85,389,962 and 74,982,562 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	85,390	74,983
Additional paid-in capital	61,512,795	57,468,528
Accumulated deficit	<u>(47,858,584)</u>	<u>(45,511,671)</u>
Total stockholders' equity	13,739,601	12,031,840
Total liabilities and stockholders' equity	\$ 15,283,234	\$ 12,876,821

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	(Unaudited)
Revenue		
Medical foods	\$ 139,789	\$ 99,934
Medical Devices	91,190	142,604
Other	14,744	-
Total Revenue	245,723	242,538
Cost of goods sold		
Medical foods	66,196	38,272
Medical Devices	40,642	55,220
Other	2,270	-
Total Cost of goods sold	109,108	93,492
Gross profit	136,615	149,046
Operating expenses		
Research and development	31,188	29,028
Sales and marketing	488,846	353,537
General and administrative	1,952,803	947,974
Total operating expenses	2,472,837	1,330,539
Loss from operations	(2,336,222)	(1,181,493)
Other expenses:		
Interest expense	1,747	17,572
Change in fair value of derivative warrants	8,944	186,034
Total other expenses	10,691	203,606
Net loss	\$ (2,346,913)	\$ (1,385,099)
Net loss per common share – basic and diluted	\$ (0.03)	\$ (0.07)
Weighted average common shares outstanding – basic and diluted	78,630,366	20,709,469

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 Paid-In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>			
Three Months Ended March 31, 2020					
Balance at December 31, 2019	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)
Balance at March 31, 2020	<u>85,389,962</u>	<u>\$ 85,390</u>	<u>\$ 61,512,795</u>	<u>\$ (47,858,584)</u>	<u>\$ 13,739,601</u>
Three Months Ended March 31, 2019					
Balance at December 31, 2018	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)
Balance at March 31, 2019	<u>20,856,611</u>	<u>\$ 20,857</u>	<u>\$ 37,885,751</u>	<u>\$ (36,018,462)</u>	<u>\$ 1,888,146</u>

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	(Unaudited)
Operating Activities		
Net loss	\$ (2,346,913)	\$ (1,385,099)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	23,114	68,102
Amortization of debt discount	-	16,545
Amortization of lease right	37,983	30,502
Accrued interest expense included in notes payable	-	1,027
Stock-based compensation	67,606	56,231
Stock-based compensation – officer and director	436,287	-
Change in fair value of warrants – derivative liability	8,944	186,034
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	47,255	13,116
Inventories	(131,195)	54,178
Prepaid expenses	(568,199)	(3,388)
Increase (decrease) in -		
Accounts payable	179,093	463,900
Customer deposit	437,500	-
Lease liability	(36,803)	(28,088)
Accrued expenses	109,918	(59,145)
Net cash used in operating activities	(1,735,410)	(586,085)
Investing Activities		
Purchase of property and equipment	(40,733)	(4,815)
Net cash used in investing activities	(40,733)	(4,815)
Financing Activities		
Proceeds from issuance of convertible notes	-	250,000
Proceeds from issuance of promissory notes	-	100,000
Proceeds from exercise of warrants	3,550,781	31,250
Deferred financing costs of IPO	-	(287,000)
Net cash provided by financing activities	3,550,781	94,250
Cash:		
Net increase (decrease)	1,774,638	(496,650)
Balance at beginning of period	11,115,502	670,948
Balance at end of period	\$ 12,890,140	\$ 174,298
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	\$ -	\$ -
Income taxes	\$ -	\$ -
Non-cash financing activities:		
Fair value of warrants issued in connection with convertible notes	\$ -	\$ 436,034
Recording of lease asset and liability upon adoption of ASU 2016-02	\$ -	\$ 721,154
Reclass of prepaid costs to inventory	\$ 308,178	\$ -
Reclass of equipment sold from property and equipment to equipment held for sale	\$ 8,771	\$ -

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)
Three Months Ended March 31, 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 is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers.

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 \$2,346,913 and utilized cash in operating activities of \$1,735,410 during the three months ended March 31, 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 consolidated 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, the TDSI business 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.

The Company is seeking 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 it could cause a local 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. The magnitude and overall effectiveness of these actions remain uncertain.

To date, we have not experienced any significant changes in our business that would have a significant negative impact on our consolidated statements of operations or cash flows.

The severity of the impact of the COVID-19 pandemic on the Company's business will 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 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 has 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. 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 has 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 dietary 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, 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 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 dietary supplements 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 Lumega-Z 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 Lumega-Z and VectorVision 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 March 31,	
	2020	2019
Medical Foods	\$ 139,789	\$ 99,934
Medical Devices	91,190	142,604
Other	14,744	-
Total	<u>\$ 245,723</u>	<u>\$ 242,538</u>

All of the Company's Medical Foods revenues are derived from individual retail customers in North America. Medical Devices revenues are derived from a worldwide customer base consisting of both retail customers and distributors. International customers contributed approximately 91% and 20% of Medical Devices revenues for the three months ended March 31, 2020 and 2019, respectively. Distributors contributed approximately 63% and 15% of Medical Devices revenues for the three months ended March 31, 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 deposit is recorded as a current liability on our condensed consolidated balance sheet at March 31, 2020. The Company currently anticipates shipping the order during the second quarter of 2020.

Research and Development Costs

Research and development costs consist primarily of fees paid to consultants and outside service providers, patent fees and costs, 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 \$31,188 and \$29,028 for the three months ended March 31, 2020 and 2019, respectively.

Patent Costs

The Company is the owner of three issued domestic patents, three pending domestic patent applications, one issued foreign patent in Europe, one issued foreign patent in Hong Kong, and three foreign patent applications in Canada, Europe and 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 three months ended March 31, 2020 and 2019, patent costs were \$27,181 and \$29,025, 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:

	March 31,	
	2020	2019
Warrants	18,390,338	896,712
Options	3,252,500	1,362,500
	<u>21,642,838</u>	<u>2,259,212</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.

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 gross revenues have been achieved by the Company. As of March 31, 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, 2018 and had been included in the Company's consolidated statements of operations during the three months ended March 31, 2019:

	Three Months Ended March 31, 2019
Pro forma net revenues	\$ 267,680
Pro forma net loss attributable to common shareholders	\$ (1,403,851)
Pro forma net loss per share	\$ (0.07)

4. Inventories

Inventories consisted of the following:

	March 31, 2020	December 31, 2019
Raw materials	\$ 542,849	\$ 246,875
Finished goods	216,236	64,066
	<u>\$ 759,085</u>	<u>\$ 310,941</u>

5. Property and Equipment, net

Property and equipment consisted of the following:

	March 31, 2020	December 31, 2019
Leasehold improvements	\$ 98,357	\$ 98,357
Testing equipment	412,429	394,427
Furniture and fixtures	199,132	185,799
Computer equipment	68,460	68,460
Office equipment	8,193	8,193
	<u>786,571</u>	<u>755,236</u>
Less accumulated depreciation and amortization	<u>(403,085)</u>	<u>(380,598)</u>
	<u>\$ 383,486</u>	<u>\$ 374,638</u>

For the Three Months Ended March 31, 2020 and 2019, depreciation and amortization expense was \$23,114 and \$14,443, respectively, of which \$12,856 and \$5,198 was included in research and development expense, \$3,910 and \$3,910 was included in sales and marketing expense, and \$6,348 and \$5,335 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 March 31, 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 March 31, 2020, remaining lease payments under the amended lease agreement averaged \$13,048 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 March 31, 2020, remaining lease payments averaged \$1,859 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 fair value of Lease 1 at the inception of the lease was \$639,520 using a discount rate of 3.9% and the fair 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 three months ended March 31, 2020, the Company made combined payments on both leases of \$42,400 towards the lease liabilities. As of March 31, 2020, the lease liability for Lease 1 was \$488,155, and the lease liability for Lease 2 was \$61,358. The aggregate balance of the lease liabilities at March 31, 2020 was \$549,513, of which \$154,327 was current.

Combined rent expense for both leases for the three months ended March 31, 2020 and 2019 was \$43,581 and \$43,581, respectively. The balance of the right of use asset as of December 31, 2019 was \$572,714. During the three months ended March 31, 2020, the Company reflected amortization of right of use asset of \$37,984 related to the leases, resulting in a net asset balance of \$534,730 as of March 31, 2020.

7. Stockholders' Equity

Common Stock

During the three months ended March 31, 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:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
December 31, 2019	28,802,738	0.38	4.91
Granted	-	-	-
Forfeitures	-	-	-
Expirations	(30,000)	(1.50)	-
Exercised	(10,382,400)	(0.34)	-
March 31, 2020, all exercisable	18,390,338	\$ 0.40	4.65

The exercise prices of warrants outstanding and exercisable as of March 31, 2020 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
14,957,600	\$ 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
18,390,338	

During the three months ended March 31, 2020, investors exercised a total of 10,382,400 warrants for 10,382,400 shares of common stock. The warrants were exercisable for \$0.34 per share, which resulted in cash proceeds to the Company of \$3,550,781.

As of March 31, 2020, the Company had an aggregate of 18,390,338 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of \$0.40 and a weighted average remaining life of 4.65 years. The aggregate intrinsic value of warrants outstanding as of March 31, 2020 was \$1,712,273.

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 March 31, 2020, the fair value of the warrants was determined to be \$22,267 and the change in fair value of \$8,944 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:

	Warrant Liability As of March 31, 2020	Warrant Liability As of December 31, 2019
Stock price	\$ 0.46	\$ 0.22
Risk free interest rate	0.29%	1.62%
Expected volatility	143%	145%
Expected life in years	4.01	4.26
Expected dividend yield	0%	0%
Number of warrants	62,500	62,500
Fair value of warrants	\$ 22,267	\$ 13,323

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)
December 31, 2019	2,962,500	2.94	3.64
Granted	290,000	-	-
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
March 31, 2020, outstanding	3,252,500	\$ 2.71	3.96
March 31, 2020, exercisable	1,991,667	\$ 2.50	3.13

The exercise prices of options outstanding and exercisable as of March 31, 2020 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
250,000	156,250	\$ 0.25
30,000	-	0.32
250,000	31,250	0.39
10,000	-	0.41
100,000	25,000	0.54
625,000	625,000	2.00
62,500	62,500	2.30
675,000	675,000	2.50
1,250,000	416,667	4.40
3,252,500	1,991,667	

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.

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 and 2019, we recognized aggregate stock-compensation expense of \$503,893 and \$56,231, based upon stock prices ranging from \$0.25 to \$3.30 per share respectively, and of which \$436,287 related to options granted to our chairman and CEO. Of the stock compensation expense recognized during the three months ended March 31, 2020, \$36,902 was recorded to sales and marketing expense and \$466,991 was recorded in general and administrative expense. All of the stock compensation expense recognized during the three months ended March 31, 2019 was recorded in general and administrative expense.

As of March 31, 2020, the Company had an aggregate of 1,260,833 remaining unvested options outstanding, with a fair value of \$2,910,828, weighted average exercise price of \$3.04, and weighted average remaining life of 5.27 years. The aggregate intrinsic value of options outstanding as of March 31, 2020 was \$73,185. The aggregate intrinsic value of unvested options outstanding as of March 31, 2020 was \$38,544.

8. Related Party Transactions

During the three months ended March 31, 2020 and 2019, the Company incurred and paid \$81,250 and \$75,000, respectively, of salary expense to our Board Chairman and CEO, Mr. Michael Favish. In addition, compensation cost of \$436,287 was recognized on amortization of stock option awards during the three months ended March 31, 2020. During the three months ended March 31, 2020 and 2019, the Company incurred and paid salaries of \$28,750 and \$28,750, respectively, to Karen Favish, spouse of Michael Favish. During the three months ended March 31, 2020 and 2019, the Company incurred and paid salaries of \$15,000 and \$13,750, respectively, to Kristine Townsend, spouse of Controller and Chief Accounting Officer John Townsend.

9. Segment Reporting

The Company determined its reporting units in accordance with ASC 280, "Segment Reporting" ("ASC 280"). The Company historically has reported its operating results as a single reportable segment described as the business of developing and commercializing a variety of products that support the detection, intervention and monitoring of a range of eye diseases. The Company's chief executive officer, who is the Chief Operating Decision Maker ("CODM"), has historically reviewed financial information on an aggregated basis for purposes of allocating resources and evaluating financial performance.

In September 2017, the Company, through its wholly-owned subsidiary VectorVision Ocular Health, Inc., acquired substantially all of the assets and certain liabilities of VectorVision, Inc., a company that specialized in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study visual acuity testing. In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). The Company has established TDSI operations with selected clinics and is focusing on expanding its client base. In September 2019, the Company's newly-formed wholly-owned subsidiary, NutriGuard Formulations, Inc. ("NGFI"), completed an asset purchase agreement with NutriGuard Research, Inc., and NutriGuard's sole shareholder, Mark McCarty. The Company intends to utilize the NGFI subsidiary to build a nutraceutical brand and product portfolio based on updated and reformulated compounds.

The addition of potential new products or services as the Company grows requires management to periodically reevaluate its reporting structure. As sales of our medical foods as well as sales of VectorVision products grow, there is an increased need for the CODM to evaluate revenue and gross profit on a product line or group basis for purposes of resource allocation. As of March 31, 2020, the TDSI and NGFI subsidiaries do not meet the required quantitative criteria to be considered a reportable operating segment. Additionally, these subsidiaries do not share similar economic characteristics or a majority of the aggregation criteria set forth in ASC 280, and therefore are included in the category "Corporate" below. The TDSI and NGFI businesses earned \$3,400 and \$11,344 of service revenue, respectively, and incurred approximately \$84,483 and \$22,995 of operating costs, respectively, during the three months ended March 31, 2020. As of March 31, 2020, based on anticipated growth and the expanding diversity of product and service offerings by the Company, management has concluded that results should be reported in two segments: Medical Foods and Medical Devices. The following tables set forth our results of operations by segment (results allocated to Corporate consist of the TDSI and NGFI operations):

	For the Three Months Ended March 31, 2020			
	Corporate	Medical Foods	Medical Devices	Total
Revenue	\$ 14,744	\$ 139,789	\$ 91,190	\$ 245,723
Cost of goods sold	2,270	66,196	40,642	109,108
Gross profit	12,474	73,593	50,548	136,615
Operating expenses	107,478	2,248,909	116,450	2,472,837
Loss from operations	\$ (95,004)	\$ (2,175,316)	\$ (65,902)	\$ (2,336,222)

For the Three Months Ended March 31, 2019

	Corporate	Medical Foods	Medical Devices	Total
Revenue	\$ -	\$ 99,934	\$ 142,604	\$ 242,538
Cost of goods sold	-	38,272	55,220	93,492
Gross profit	-	61,662	87,384	149,046
Operating expenses	48,763	1,076,744	205,032	1,330,539
Loss from operations	<u>\$ (48,763)</u>	<u>\$ (1,015,082)</u>	<u>\$ (117,648)</u>	<u>\$ (1,181,493)</u>

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

As of March 31, 2020

	Corporate	Medical Foods	Medical Devices	Total
Current assets				
Cash	\$ 12,890,140	\$ -	\$ -	\$ 12,890,140
Inventories	157,557	243,992	357,536	759,085
Other	266,663	340,849	46,530	654,042
Total current assets	<u>13,314,360</u>	<u>584,841</u>	<u>404,066</u>	<u>14,303,267</u>
Right of use asset, net	-	476,187	58,543	534,730
Property and equipment, net	-	247,205	136,281	383,486
Intangible assets, net	-	50,000	-	50,000
Other	-	11,751	-	11,751
Total assets	<u>\$ 13,314,360</u>	<u>\$ 1,369,984</u>	<u>\$ 598,890</u>	<u>\$ 15,283,234</u>

As of December 31, 2019

	Corporate	Medical Foods	Medical Devices	Total
Current assets				
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
Total current assets	<u>11,127,904</u>	<u>345,931</u>	<u>393,883</u>	<u>11,867,718</u>
Right of use asset	-	509,464	63,250	572,714
Property and equipment, net	-	219,056	155,582	374,638
Intangible assets, net	-	50,000	-	50,000
Other	-	11,751	-	11,751
Total assets	<u>\$ 11,127,904</u>	<u>\$ 1,136,202</u>	<u>\$ 612,715</u>	<u>\$ 12,876,821</u>

10. 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. In the opinion of management of the Company, adequate provision has been made in the Company's financial statements at March 31, 2020 with respect to such matters.

11. Subsequent Events

On April 14, 2020, investors exercised warrants for 150,000 shares of common stock. The warrants were exercisable for \$0.34 per share, and the Company received net proceeds of \$51,300 in cash.

On April 15, 2020, investors exercised warrants for 80,000 shares of common stock. The warrants were exercisable for \$0.34 per share, and the Company received net proceeds of \$27,360 in cash.

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 is developing nutraceuticals that the Company believes will provide supportive health benefits to consumers.

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. Additionally, see Item 1A. *Risk Factors* for further discussion of the possible impact of the COVID-19 pandemic on our business.

Recent Developments

Warrant Exercises

From January 1, 2020 through March 31, 2020, the Company received total gross proceeds of \$3,550,781 from the exercise of 10,382,400 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 deposit is recorded as a current liability on our condensed consolidated balance sheet at March 31, 2020. The Company currently anticipates shipping the order during the second quarter of 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 \$2,346,913 and utilized cash in operating activities of \$1,735,410 during the three months ended March 31, 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 Company's 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, the TDSI business and with respect to efforts to continue to build the Company's infrastructure. Development and commercialization of medical foods 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.

The Company is seeking 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.

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 March 31, 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 Three Months Ended March 31, 2020 and 2019.

Comparison of Three Months Ended March 31, 2020 and 2019

	Three Months Ended March 31,		Change	
	2020	2019		
Revenue	\$ 245,723	\$ 242,538	\$ 3,185	1%
Cost of goods sold	109,108	93,492	15,616	17%
Gross Profit	136,615	149,046	(12,431)	(8)%
Operating Expenses:				
Research and development	31,188	29,028	2,160	7%
Sales and marketing	488,846	353,537	135,309	38%
General and administrative	1,952,803	947,974	1,004,829	106%
Total Operating Expenses	2,472,837	1,330,539	1,142,298	86%
Loss from Operations	(2,336,222)	(1,181,493)	(1,154,729)	98%
Other Expense:				
Interest expense	1,747	17,572	(15,825)	(90)%
Change in fair value of derivative warrants	8,944	186,034	(177,090)	(95)%
Net Loss	\$ (2,346,913)	\$ (1,385,099)	\$ (961,814)	69%

Revenue

For the three months ended March 31, 2020, revenue from product sales was \$245,723 compared to \$242,538 for the three months ended March 31, 2019, resulting in an increase of \$3,185 or 1%. The relatively flat overall performance reflects a combination of improved sales of medical foods offset by a decrease in device sales due to the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device. Although the CSV-1000 will continue to be sold, the Company plans to put a greater focus on sales and marketing efforts of the new CSV-2000. The Company commenced sales of the next generation CSV-2000 device in February 2020.

Cost of Goods Sold

For the three months ended March 31, 2020, cost of goods sold was \$109,108 compared to \$93,492 for the three months ended March 31, 2019, resulting in an increase of \$15,616 or 17%. This reflects the increase in medical food sales and the decrease in device 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 three months ended March 31, 2020, gross profit was \$136,615 compared to \$149,046 for the three months ended March 31, 2019, resulting in a decrease of \$12,431 or 8%. Gross profit represented 56% of revenues the three months ended March 31, 2020, versus 61% of revenue for the three months ended March 31, 2019.

Research and Development

For the three months ended March 31, 2020, research and development costs were \$31,188 compared to \$29,028 for the three months ended March 31, 2019, resulting in an increase of \$2,160 or 7%. Research and development costs consist of engineering efforts related to our medical devices.

Sales and Marketing

For the three months ended March 31, 2020, sales and marketing expenses were \$488,846 compared to \$353,537 for the three months ended March 31, 2019. The increase in sales and marketing expenses of \$135,309 or 38% compared to the prior period was primarily due to a \$105,000 increase in labor costs stemming from our new sales force initiatives. Additionally, non-cash stock compensation expense increased by \$37,000.

General and Administrative

For the three months ended March 31, 2020, general and administrative expenses were \$1,952,803 compared to \$947,974 for the three months ended March 31, 2019. The increase of \$1,004,829 or 106% compared to the prior period was primarily due to a \$411,000 increase in non-cash stock compensation expense. Additionally, there was a \$145,000 increase in legal costs, a \$122,000 increase in professional services, a \$80,000 increase in corporate insurance, and a \$115,000 increase in labor costs.

Interest Expense

For the three months ended March 31, 2020, interest expense was \$1,747 compared to \$17,572 for the three months ended March 31, 2019. The decrease of \$15,825 or 90%, was due primarily to a non-cash amortization expense related to the debt discount associated warrants issued in March 2019.

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 March 31, 2020, the fair value of the warrant liability was determined to be \$22,267 and the Company recorded a change in fair value of derivative warrants for the three months ended March 31, 2020 of \$8,944.

On March 15, 2019, warrants were issued 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 with a fair value of \$436,034. Upon completion of the IPO on April 9, 2019, the exercise price and the number of warrants were fixed and the warrants were no longer accounted for as liabilities. The Company recognized a debt discount of \$250,000 equal to the face amount of the convertible notes and recorded a financing cost equal to the difference between the fair value of the warrants and the debt discount. The financing cost of \$186,034 is shown as fair value of warrants on the accompanying statement of operations for the three months ended March 31, 2019.

Net Loss

For the three months ended March 31, 2020, the Company incurred a net loss of \$2,346,913, compared to a net loss of \$1,385,099 for the three months ended March 31, 2019. The increase in net loss of \$961,814 or 69% compared to the prior year period was primarily due to increases in stock compensation, legal, and professional services 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 and NGFI operations):

	For the Three Months Ended March 31, 2020			
	Corporate	Medical Foods	Medical Devices	Total
Revenue	\$ 14,744	\$ 139,789	\$ 91,190	\$ 245,723
Cost of goods sold	2,270	66,196	40,642	109,108
Gross profit	12,474	73,593	50,548	136,615
Operating expenses	107,478	2,248,909	116,450	2,472,837
Loss from operations	<u>\$ (95,004)</u>	<u>\$ (2,175,316)</u>	<u>\$ (65,902)</u>	<u>\$ (2,336,222)</u>

	For the Three Months Ended March 31, 2019			
	Corporate	Medical Foods	Medical Devices	Total
Revenue	\$ -	\$ 99,934	\$ 142,604	\$ 242,538
Cost of goods sold	-	38,272	55,220	93,492
Gross profit	-	61,662	87,384	149,046
Operating expenses	48,763	1,076,744	205,032	1,330,539
Loss from operations	<u>\$ (48,763)</u>	<u>\$ (1,015,082)</u>	<u>\$ (117,648)</u>	<u>\$ (1,181,493)</u>

Revenue

For the three months ended March 31, 2020, revenue from our Medical Foods segment was \$139,789 compared to \$99,934 for the three months ended March 31, 2019, resulting in an increase of \$39,855 or 40%. The increase reflects an increased customer base for Lumega-Z as the Company expands into new clinics. For the three months ended March 31, 2020, revenue from our Medical Devices segment was \$91,190 compared to \$142,604 for the three months ended March 31, 2019, resulting in a decrease of \$51,414 or 36%. The decrease was due to the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device. The decrease was offset in part from the sale of a MapCat device in January 2020. The Company also earned \$14,744 from a combination of diagnostic imaging services revenue from its TDSI business and nutraceutical product sales from its NGFI business during the three months ended March 31, 2020, as shown in the Corporate category above.

Cost of Goods Sold

For the three months ended March 31, 2020, cost of goods sold from our Medical Foods segment was \$66,196 compared to \$38,272 for the three months ended March 31, 2019, resulting in an increase of \$27,924 or 73%. The increase was due to the additional sales recorded in 2020 as well as an inventory adjustment related primarily to the write off of scrap materials recorded in March 2020. For the three months ended March 31, 2020, cost of goods sold from our Medical Devices segment was \$40,642 compared to \$55,220 for the three months ended March 31, 2019, resulting in a decrease of \$14,578 or 26%. The decrease was due to the decrease in sales noted above.

Gross Profit

For the three months ended March 31, 2020, gross profit from the Medical Foods segment was \$73,593 compared to \$61,662 for the three months ended March 31, 2019, resulting in an increase of \$11,931 or 19%. For the three months ended March 31, 2020, gross profit from the Medical Devices segment was \$50,548 compared to \$87,384 for the three months ended March 31, 2019, resulting in a decrease of \$36,836 or 42%. Gross profit overall represented 56% of revenues for the three months ended March 31, 2020, versus 61% of revenue for the three months ended March 31, 2019.

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 \$1,735,410 during the three months ended March 31, 2020. The Company had working capital of \$13,154,820 at March 31, 2020. As of March 31, 2020, the Company had cash in the amount of \$12,890,140 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 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 \$3,550,781 during the three months ended March 31, 2020 from the exercise of 10,382,400 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 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:

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	\$ (1,735,410)	\$ (586,085)
Net cash used in investing activities	(40,733)	(4,815)
Net cash provided by financing activities	3,550,781	94,250
Net increase (decrease) in cash	<u>\$ 1,774,638</u>	<u>\$ (496,650)</u>

Operating Activities

Net cash used in operating activities was \$1,735,410 during the three months ended March 31, 2020, versus \$586,085 used during the comparable prior year period. The decrease in 2020 was due primarily to higher legal, insurance, professional services, and labor costs paid in the current period.

Investing Activities

Net cash used in investing activities was \$40,733 for the three months ended March 31, 2020 and \$4,185 for the three months ended March 31, 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 \$3,550,781 for the three months ended March 31, 2020 and was due to warrant exercise during the period. Net cash provided by financing activities was \$94,250 for the three months ended March 31, 2019 and was due to the issuance in March 2019 of \$350,000 in promissory and convertible promissory notes as well as from the exercise of warrants for proceeds of \$31,250. These proceeds were partially offset by payment of costs directly related to the Company's IPO.

Off-Balance Sheet Arrangements

At March 31, 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 Accounting 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 Chief Executive Officer and Chief Accounting 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 Chief Executive Officer and Chief Accounting 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 Chief Executive Officer and our Chief Accounting 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 March 31, 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 in order to promote adequate segregation of duties. We expect to complete the remediation by the end of 2020. We expect to incur additional costs to remediate 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 first 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. In the opinion of management of the Company, adequate provision has been made in the Company's condensed consolidated financial statements at March 31, 2020 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, 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, except as noted below.

The COVID-19 global pandemic could adversely impact our business, including the commercialization of our medicines, our supply chain, our clinical trials, our liquidity and access to capital markets and our business development activities.

On March 11, 2020, the World Health Organization made the assessment that a novel strain of coronavirus, which causes the COVID-19 disease, can be characterized as a pandemic. The President of the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the United States have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions). The effects of government actions and our policies and those of third parties to reduce the spread of COVID-19 may negatively impact productivity and our ability to market and sell our products, cause disruptions to our supply chain and impair our ability to execute our business development strategy. These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

The commercialization of our products may be adversely impacted by COVID-19 and actions taken to slow its spread. For example, patients may postpone visits to healthcare provider facilities, certain healthcare providers have temporarily closed their offices or are restricting patient visits, healthcare provider employees may become generally unavailable and there could be disruptions in the operations of payors, distributors, logistics providers and other third parties that are necessary for our products to be recommended and administered to patients.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our products.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, it may make any additional debt or equity financing more difficult, more costly or more dilutive. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position or our business development activities.

COVID-19 continues to rapidly evolve. The extent to which COVID-19 may impact the commercialization of our products, our supply chain, our access to capital and our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the pandemic, the duration of the pandemic and the efforts by governments and business to contain it, business closures or business disruptions and the impact on the economy and capital markets.

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	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
31.2	Certification of Chief Accounting Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Accounting Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002
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.

Signature	Title	Date
<u>/s/ Michael Favish</u> Michael Favish	CEO, President and Chairman of the Board (Principal Executive Officer)	May 14, 2020
<u>/s/ John Townsend</u> John Townsend	Controller and Chief Accounting Officer (Principal Accounting Officer)	May 14, 2020

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CERTIFICATION

I, Michael Favish, 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: May 14, 2020

/s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, John Townsend, 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: May 14, 2020

/s/ John Townsend

John Townsend
Controller and Chief Accounting Officer
(Principal Accounting Officer)

**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 March 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of Michael Favish, Chief Executive Officer of the Company, and John Townsend, Controller and Chief Accounting 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.

May 14, 2020

/s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

May 14, 2020

/s/ John Townsend

John Townsend
Controller and Chief Accounting Officer
(Principal Accounting Officer)
