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

FORM 10-Q

[X] **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2021

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	**47-4428421**
(State or other jurisdiction of incorporation or organization)	*(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)

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

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

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. [X] 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). [X] 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	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[X]

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 [X] No

As of May 14, 2021, there were 24,426,993 shares of the Company's common stock, par value $0.001 per share, issued and outstanding.

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PART I – FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Guardion Health Sciences, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets		
Cash	$ 43,329,674	$ 8,518,732
Accounts receivable	64,897	11,248
Inventories	288,527	384,972
Prepaid expenses	312,523	179,931
Total current assets	**43,995,621**	**9,094,883**
Deposits	11,751	11,751
Property and equipment, net	265,978	285,676
Right of use asset, net	379,120	418,590
Intangible assets	50,000	50,000
Total assets	**$ 44,702,470**	**$ 9,860,900**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 230,403	$ 608,313
Accrued expenses	518,826	127,637
Payable to former officer	67,708	148,958
Derivative warrant liability	-	25,978
Operating lease liability – current	165,757	162,845
Total current liabilities	982,694	1,073,731
Operating lease liability – long term	229,430	271,903
Total liabilities	1,212,124	1,345,634
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized; 24,426,993 and 15,170,628 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	24,427	15,171
Additional paid-in capital	100,192,794	62,583,423
Accumulated deficit	(56,726,875)	(54,083,328)
Total stockholders' equity	**43,490,346**	**8,515,266**
Total liabilities and stockholders' equity	**$ 44,702,470**	**$ 9,860,900**

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2021	**2020**
	(Unaudited)	**(Unaudited)**
Revenue		
Medical foods	$ 162,143	$ 139,789
Medical devices	71,154	91,190
Other	-	14,744
Total revenue	233,297	245,723
Cost of goods sold		
Medical foods	84,917	66,196
Medical devices	48,098	40,642
Other	-	2,270
Total cost of goods sold	133,015	109,108
Gross profit	100,282	136,615
Operating expenses		
Research and development	20,608	31,188
Sales and marketing	457,727	488,846
General and administrative	2,291,472	1,952,803
Total operating expenses	2,769,807	2,472,837
Loss from operations	(2,669,525)	(2,336,222)
Other expenses:		
Interest expense	-	(1,747)
Change in fair value of derivative liability	-	(8,944)
Total other expenses	-	(10,691)
Net loss	**$ (2,669,525)**	**$ (2,346,913)**
Net loss per common share – basic and diluted	$ (0.13)	$ (0.18)
Weighted average common shares outstanding – basic and diluted	21,351,380	13,105,061

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
			Three Months Ended March 31, 2021		
Balance at December 31, 2020	15,170,628	$ 15,171	$ 62,583,423	$ (54,083,328)	$ 8,515,266
Cumulative effect adjustment from the impact of adoption of Accounting Standards Update (ASU) 2020-06 related to warrants (See Notes 2 and 7)	-	-	-	25,978	25,978
Fair value of vested stock options	-	-	205,772	-	205,772
Fair value of common stock issued for services	-	-	181,843	-	181,843
Common stock issued for cash, net of offering costs	7,608,674	7,608	33,654,989	-	33,662,597
Common stock issued upon exercise of warrants	1,647,691	1,648	3,566,767	-	3,568,415
Net loss	-			(2,669,525)	(2,669,525)
Balance at March 31, 2021	24,426,993	$ 24,427	$100,192,794	$ (56,726,875)	$ 43,490,346
			Three Months Ended March 31, 2020		
Balance at December 31, 2019	12,497,094	$ 12,497	$ 57,531,014	$ (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
Fair value of common stock issued for services	4,167	25	12,300	-	12,325
Common stock issued upon exercise of warrants	1,730,400	10,382	3,540,399	-	3,550,781
Net loss	-	-	-	(2,346,913)	(2,346,913)
Balance at March 31, 2020	14,231,661	$ 22,904	$ 61,575,281	$ (47,858,584)	$ 13,739,601

See accompanying notes to condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2021	**2020**
	(Unaudited)	**(Unaudited)**
Operating Activities		
Net loss	$ (2,669,525)	$ (2,346,913)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	19,698	23,114
Amortization of operating lease right-of-use asset	39,470	37,983
Fair value of vested stock options	205,772	55,281
Fair value of common stock issued for services	181,843	12,325
Fair value of vested stock options – officer and director	-	436,287
Change in fair value of derivative liability	-	8,944
Changes in operating assets and liabilities:		
(Increase) / decrease:		
Accounts receivable	(53,649)	47,255
Inventories	96,445	(131,195)
Prepaid expenses	(132,592)	(568,199)
Increase / (decrease):		
Accounts payable	(377,910)	179,093
Customer deposit	-	437,500
Operating lease liability	(39,561)	(36,803)
Accrued expenses	391,189	109,918
Payable to former officer	(81,250)	-
Net cash used in operating activities	(2,420,070)	(1,735,410)
Investing Activities		
Purchase of property and equipment	-	(40,733)
Net cash used in investing activities	-	(40,733)
Financing Activities		
Proceeds from sale of common stock, net	33,662,597	-
Proceeds from exercise of warrants	3,568,415	3,550,781
Net cash provided by financing activities	37,231,012	3,550,781
Cash:		
Net increase	34,810,942	1,774,638
Balance at beginning of period	8,518,732	11,115,502
Balance at end of period	$ 43,329,674	$ 12,890,140
Supplemental disclosure of cash flow information:		
Cash paid for:		
Income taxes	$ 9,355	-
Non-cash financing activities:		
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, 2021 and 2020

1. Organization and Business Operations

Business

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.

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.

Liquidity

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. For the three months ended March 31, 2021, the Company incurred a net loss of $2,669,525 and used cash in operating activities of $2,420,070. At March 31, 2021, the Company had cash on hand of $43,329,674 and working capital of $43,012,927. Notwithstanding the net loss for 2021, management believes that its current cash balance is sufficient to fund operations for at least the next twelve months.

The Company expects to continue to incur net losses and negative operating cash flows in the near-term and will continue to incur significant expenses for development and commercialization of its medical foods and medical devices, and the successful development and commercialization of any new products or product lines. The Company may also utilize cash to fund acquisitions.

The Company may seek to raise additional debt and/or equity capital to fund future operations and strategic initiatives, 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. Over time, 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 of the COVID-19 pandemic that could adversely impact our business. The Company has implemented additional health and safety precautions and protocols in response to the pandemic and government guidelines, including curtailing employee travel and working from its executive offices, with many employees continuing their work remotely. During 2020 and the first quarter of 2021, sales of certain products remained flat, as many eye doctor offices were closed, or operating with limited capacity, due to COVID-19 related orders. During 2020 and through the first quarter of 2021, we did not experience a jeopardization of our supply chain due to the COVID-19 outbreak.

The extent of the impact of the COVID-19 pandemic has had and will continue to have on the Company's business is highly uncertain and difficult to predict and quantify. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, including vaccination efforts, as well as the economic impact on local, regional, national and international markets.

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 the rules and regulations of the SEC. 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 fiscal year ended December 31, 2020, as filed with the SEC. The condensed consolidated balance sheet as of December 31, 2020 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, 2021.

Reverse Stock Split

On March 1, 2021, following stockholder and board approval, the Company effectuated a 1-for-6 reverse split of its outstanding shares of common stock, without any change to its par value. The authorized number of shares of common stock were not affected by the reverse stock split. No fractional shares were issued in connection with the reverse stock split, as all fractional shares were rounded up to the next whole share.

Accordingly, all share and per share amounts presented herein with respect to common stock have been retroactively adjusted to reflect the above-described reverse stock split for all periods presented.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, VectorVision Ocular Health, Inc., NutriGuard Formulations, Inc., and Transcranial Doppler Solutions, Inc. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of our financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities. Actual results could differ from those estimates. On an ongoing basis, management reviews its estimates and if deemed appropriate, those estimates are adjusted. Significant estimates include those related to assumptions used in valuing inventories at net realizable value, assumptions used in valuing assets acquired in business acquisitions, impairment testing of goodwill and other long-term assets, assumptions used in valuing stock-based compensation, the valuation allowance for deferred tax assets, accruals for potential liabilities, and assumptions used in the determination of the Company's liquidity. Actual results could differ from those estimates.

Revenue Recognition

The Company generates its revenue from two business segments:

- Medical Foods and Nutraceuticals Segment
- Medical Devices Segment

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*. Revenue is recognized when control of promised goods or services is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products 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.

All products sold by the Company are distinct individual products and 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.

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. Historically the Company has not experienced any significant payment delays from customers.

The Company provides a 30-day right of return to its retail 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 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.

Revenues by segment:

	Three Months Ended March 31,	
	2021	**2020**
Medical foods and nutraceuticals	$ 162,143	$ 139,789
Medical devices	71,154	91,190
Other	-	14,744
Total	$ 233,297	$ 245,723

The Company's Medical Foods and Nutraceuticals revenues earned during the three months ended March 31, 2021 and 2020 are derived from individual retail customers in North America. Medical Device revenues are derived from a worldwide customer base consisting of both retail customers and distributors. Sales to distributors were approximately 25% and 2% of total revenues for the three months ended March 31, 2021 and 2020, respectively.

Revenues by geographical area:

	Three Months Ended March 31,	
	2021	**2020**
North America	$ 172,140	$ 234,354
Asia	58,262	2,800
Europe & Other	2,895	8,569
Total	$ 233,297	$ 245,723

Concentrations

During the three months ended March 31, 2021, one customer accounted for approximately 25% of the Company's sales. No other customer accounted for more than 10% of such sales in either the 2021 or 2020 three-month periods.

Cash balances are maintained at large, well-established financial institutions. At times, cash balances exceed federally insured limits. Insurance coverage limits are $250,000 per depositor at each financial institution. The Company believes that no significant concentration of credit risk exists with respect to its cash balances because of its assessment of the creditworthiness and financial viability of the financial institutions that hold such cash balances.

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 Nutraceuticals and related products. Research and development expenditures are expensed as incurred and totaled $20,608 and $31,188 for the three months ended March 31, 2021 and 2020, 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 three months ended March 31, 2021 and 2020, patent costs were $24,297 and $27,181, 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 employees and non-employees in non-capital raising transactions for services and for financing costs. Such grants vest and expire according to terms established at the issuance date. The Company accounts for such grants issued and vesting based on ASC 718, *Compensation-Stock Compensation* whereby the value of the award is measured on the date of grant and recognized for employees as compensation expense on a straight-line or graded basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

The fair value of stock options granted is estimated using the Black-Scholes option-pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life, and future dividends. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods.

Loss per Common Share

Basic loss per share is computed by dividing net loss by the weighted-average common shares outstanding during a period. Diluted earnings per share is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method. Dilutive potential common shares include shares from unexercised warrants and options. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive. 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 options are anti-dilutive.

The following potentially dilutive shares were excluded from the shares used to calculate diluted earnings per share:

	March 31,	
	2021	**2020**
Warrants	485,067	3,065,056
Options	930,867	542,084
	1,415,934	3,607,140

Fair Value of Financial Instruments

Accounting standards require certain assets and liabilities be reported at fair value in the financial statements and provide a framework for establishing that fair value. Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining fair value, the Company considers the principal or most advantageous market in which it transacts and considers assumptions that market participants would use when pricing the asset or liability. The framework for determining fair value is based on a hierarchy that prioritizes the inputs and valuation techniques used to measure fair value:

Level 1 - Quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date.

Level 2 - Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data.

Level 3 - Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The Company believes the carrying amount of its financial instruments (consisting of cash, accounts receivable, and accounts payable and accrued liabilities) approximates fair value due to the short-term nature of such instruments.

As of March 31, 2021, and December 31, 2020, the Company's balance sheets included Level 2 liabilities comprised of the fair value of warrant liabilities aggregating $0 and $25,978, respectively (See Note 7).

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06 ("ASU 2020-06") "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40).*" ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion models. As a result, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost as long as no other features require bifurcation and recognition as derivatives. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. This update simplifies the related settlement assessment by removing the requirements to (i) consider whether the contract would be settled in registered shares, (ii) consider whether collateral is required to be posted, and (iii) assess shareholder rights. ASU 2020-06 is effective January 1, 2024, for the Company and the provisions of this update can be adopted using either the modified retrospective method or a fully retrospective method. Early adoption is permitted, but no earlier than January 1, 2021.

At December 31, 2020, the Company had recorded a derivative liability of $25,978 related to 10,417 warrants issued in 2019 because the settlement provisions of the warrants contained language that the shares underlying the warrants are required to be registered. Effective January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective approach. ASU 2020-06 removed the requirement to consider if the warrants would be settled in registered shares, and accordingly, the adoption of ASU 2020-06 resulted in a decrease to accumulated deficit of $25,978 and a decrease in derivative warrant liability of $25,978 on January 1, 2021.

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, ASU 2016-13 will be effective for us beginning January 1, 2023, with early adoption permitted. The Company is currently assessing the impact of adopting this standard on the Company's financial statements and related disclosures.

Other recent accounting pronouncements issued by the FASB, its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future financial statements.

3. Inventories

Inventories consisted of the following:

	March 31, 2021	December 31, 2020
Raw materials	$ 57,264	$ 218,307
Finished goods	231,263	166,665
	$ 288,527	$ 384,972

The Company's inventories are stated at the lower of cost or net realizable value on a FIFO basis. During the quarter ended March 31, 2021 the Company recorded an inventory write down of approximately $6,000 related to raw materials inventory.

4. Property and Equipment, net

Property and equipment consisted of the following:

	March 31, 2021	December 31, 2020
Leasehold improvements	$ 103,255	$ 103,255
Testing equipment	348,124	348,124
Furniture and fixtures	197,349	197,349
Computer equipment	68,460	68,460
Office equipment	9,835	9,835
	727,023	727,023
Less accumulated depreciation and amortization	(461,045)	(441,347)
	$ 265,978	$ 285,676

For the three months ended March 31, 2021 and 2020, depreciation and amortization expense was $19,698 and $23,114, respectively.

5. Operating Leases

The Company leases its office and certain warehouse space under two operating leases. The Company accounts for its leases under ASC 842, *Leases.* During the three months ended March 31, 2021 and 2020, lease costs totaled $45,901 and $43,581, respectively.

As of December 31, 2020, the Company's net right of use asset totaled $418,590. During the three months ended March 31, 2021, the Company recorded amortization of right-of-use asset of $39,470. At March 31, 2021, the net right-of-use assets was $379,120.

As of December 31, 2020, the Company's operating lease liabilities totaled $434,748. During the three months ended March 31, 2021, the Company made payments of $39,561 towards the operating lease liability. As of March 31, 2021, the operating lease liabilities totaled $395,187.

As of March 31, 2021, the weighted average remaining lease terms for operating leases are 2.25 years, and the weighted average discount rate for operating lease is 4.6%.

Future minimum lease payments under the leases are as follows:

Year ending	Operating Leases
Remainder of 2021	$ 131,033
2022	182,249
2023	98,417
Total lease payments	411,699
Less: Imputed interest/present value discount	(16,512)
Present value of lease liabilities	395,187
Less: Current portion	(165,757)
	$ 229,430

6. Payable to Former Officer

Effective June 15, 2020, Michael Favish resigned as Chief Executive Officer of the Company and resigned from the Company's Board of Directors. Terms of the settlement agreement between the parties included the continuation of his previous salary of $325,000 during the twelve months subsequent to his resignation. The $325,000 of aggregate settlement payments was recorded in costs related to resignation of former officer expense in the consolidated statements of operations in the quarter ended June 30, 2020. As of March 31, 2021, $67,708 of the amount due remains accrued on our consolidated balance sheet and is payable through June 15, 2021.

7. Derivative Liability

On April 9, 2019, the Company issued 10,417 warrants with an exercise price of $30.00 per share. The Company accounted for the conversion feature of these warrants as a derivative liability because 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.

At December 31, 2020, the Company had recorded a derivative liability of $25,978 related to the 10,417 warrants issued in 2019. Effective January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective approach. ASU 2020-06 removed the requirement to consider if the warrants would be settled in registered shares, and accordingly, the adoption of ASU 2020-06 resulted in a decrease to accumulated deficit of $25,978 and a decrease in derivative warrant liability of $25,978 on January 1, 2021.

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 December 31, 2020
Stock price	$ 2.49
Risk free interest rate	0.17%
Expected volatility	148%
Expected life in years	3.8
Expected dividend yield	0%
Number of warrants	10,417
Fair value of warrants	$ 25,978

8. Stockholders' Equity

Common Stock

January 2021 and February 2021 At the Market Offerings

On January 8, 2021, the Company entered into a sales agreement with Maxim Group LLC and filed a prospectus supplement pursuant to which the Company could sell up to $10,000,000 worth of shares of our common stock in an "at the market" offering through the distribution agent (the "January 2021 1st ATM Offering"). The offer and sale of the shares was made pursuant to a shelf registration statement on Form S-3 and the related prospectus filed by the Company with the Securities and Exchange Commission and declared effective by the SEC on September 24, 2020. The Company agreed to pay Maxim a commission equal to 3.0% of the aggregate gross proceeds from each sale of shares. On January 15, 2021, the Company completed the January 2021 1st ATM Offering, pursuant to which the Company sold an aggregate of 2,559,834 shares of its common stock and raised net proceeds (after deduction for sales commissions) of approximately $9,700,000.

On January 28, 2021, the Company entered into a sales agreement with Maxim Group LLC and filed a prospectus supplement pursuant to which the Company could sell up to $25,000,000 worth of shares of our common stock in an "at the market" offering through the distribution agent (the "January 2021 2nd ATM Offering"). On February 10, 2021, the Company completed the January 2021 2nd ATM Offering, pursuant to which the Company sold an aggregate of 5,006,900 shares of its common stock and raised net proceeds (after deduction for sales commissions) of approximately $24,250,000.

The Company incurred costs related to these financings of approximately $327,000 which is reflected as a reduction to the proceeds from the shares issued. The net cash received from both offerings after all expenses were approximately $33,623,000.

Nasdaq Compliance

As previously noted in the Company's Form 10-K for the fiscal year ended December 31, 2020, on September 20, 2019, the Company received notice from the Listing Qualifications staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the Company's common stock for the previous 30 consecutive business days, the Company no longer satisfied the requirement to maintain a minimum bid price of $1.00 per share, as required by Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). The Company originally had until March 18, 2020, to regain compliance with the Bid Price Rule; however, Nasdaq granted an extension until November 30, 2020. The Company was unable to regain compliance with the Bid Price Rule by November 30, 2020. Accordingly, on December 1, 2020, the Company received a letter from the Staff notifying it that its Common Stock would be subject to delisting from Nasdaq unless the Company timely appealed Nasdaq's determination to a Nasdaq Listing Qualifications Panel (the "Panel"). The Company timely appealed Nasdaq's determination to the Panel. On January 26, 2021, the Company received written notification that the Panel granted the Company an extension for continued listing through March 15, 2021.

On March 1, 2021, the Company implemented the Reverse Stock Split (see Note 1) in an effort to regain compliance with the Bid Price Rule.

Following the Reverse Stock Split mentioned above, on March 15, 2021, the Company received a letter from the Staff notifying it that it had regained compliance with the Bid Price Rule. The letter stated the staff had determined that for the prior 10 consecutive business days, from March 1, 2021 to March 12, 2021, the closing bid price of the Company's common stock had been at $1.00 per share or greater and that accordingly, the Company had regained compliance with the Bid Price Rule, and that the matter was closed.

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, 2020	**2,132,758**	$ **2.48**	**3.81**
Granted	-	-	-
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	(1,647,691)	2.26	-
March 31, 2021, all exercisable	**485,067**	**$ 2.71**	**3.56**

The exercise prices of warrants outstanding and exercisable as of March 31, 2021 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
160,108	$ 2.05
146,667	2.67
112,001	3.30
37,700	3.51
28,591	17.25
485,067	

During the three months ended March 31, 2021, investors exercised a total of 1,647,691 warrants for 1,647,691 shares of common stock. The warrants were exercisable for an average price of $2.17 per share, which resulted in cash proceeds to the Company of $3,568,415.

As of March 31, 2021, the Company had an aggregate of 485,067 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of $2.71 and a weighted average remaining life of 3.56 years.

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, 2020	**778,196**	**9.48**	**6.38**
Granted	152,671	3.95	9.80
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
March 31, 2021, outstanding	**930,867**	**$ 8.48**	**6.60**
March 31, 2021, exercisable	**479,932**	**$ 10.92**	**4.70**

The exercise prices of options outstanding and exercisable as of March 31, 2021 are as follows:

Options Outstanding (Shares)	Exercise Prices
41,667	$ 1.48
5,001	1.91
41,667	2.33
1,667	2.46
16,667	3.25
152,671	3.95
375,000	6.00
104,167	12.00
69,445	13.20
10,415	13.80
112,500	15.00
930,867	

During the three months ended March 31, 2021, the Company granted options to purchase 152,671 shares of common stock to the Company's CEO with a grant date fair value of $514,171 using a Black-Scholes option pricing model based on the following assumptions: (i) volatility rate of 119%, (ii) discount rate of 0.38%, (iii) zero expected dividend yield, and (iv) expected life of 6 years. The options have an exercise price of $3.95 per share. 50,891 of the options will vest on the one-year anniversary of the grant date and the remaining options will vest on monthly basis over two years.

The Company's volatility is based on an average volatility of similar companies in the same industry. The risk-free interest rate was based on rates established by the Federal Reserve Bank. The expected dividend yield was based on the fact that the Company has not paid dividends to its common stockholders in the past and does not expect to pay dividends to its common stockholders in the future. The expected life of the stock options granted is estimated using the "simplified" method, whereby the expected term equals the average of the vesting term and the original contract.

During the three months ended March 31, 2021 and 2020, we recognized stock-compensation expense related to the fair value of vested stock options of $205,772 and $491,568, respectively, which was recorded in general and administrative expense.

As of March 31, 2021, the Company had an aggregate of 450,935 remaining unvested options outstanding, with a remaining fair value of $911,444, to be amortized over a weighted average remaining life of 9.34 years. The aggregate intrinsic value of options outstanding as of March 31, 2021 was $43,293.

Restricted Common Stock

In January 2021, the Company granted 152,671 shares of the Company's common stock with vesting terms to the Company's CEO. The shares vest on the first anniversary of the award. If the CEO's employment with the Company is terminated for any reason, any shares not then vested will be forfeited. Also effective in January 2021, the Company granted 41,667 shares of the Company's common stock with vesting terms to a consultant for services. 4,167 of the shares vested immediately and the balance of 37,500 shares vesting through August 15, 2021. In the event the consultant's service with the Company terminates, any shares not then vested will be forfeited.

The total fair value of the 194,338 shares was determined to be $662,412 based on the price per shares of the Company's common stock on the dates granted. The Company accounts for the share awards using the straight-line attribution or graded vesting method over the requisite service period provided that the amount of compensation cost recognized at any date is no less than the portion of the grant-date fair value of the award that is vested at that date. During the three months ended March 31, 2021, total share-based expense recognized related to vested restricted shares totaled $181,843. At March 31, 2021, there was $480,569 of unvested compensation related to these awards that will be amortized over a remaining vesting period of 3.7 years.

The following table summarizes restricted common stock activity for the three months ended March 31, 2021:

	Number of shares	Fair value of shares
Non-vested shares, December 31, 2020	-	$ -
Granted	194,338	662,412
Vested	(22,917)	(181,843)
Forfeited	-	-
Non-vested shares, March 31, 2021	171,421	$ 480,569

9. Related Party Transactions

Dr. David Evans, interim chief executive officer of the Company from June 12, 2020 to January 6, 2021, together with his spouse, wholly owns Ceatus Media Group LLC ("Ceatus") and DWT Evans LLC ("DWT"). For the three months ended March 31, 2021 and 2020, the Company paid Ceatus $22,500 and $38,000, respectively, for services related to digital marketing for the Company. The Company's wholly owned subsidiary, VectorVision Ocular Health, leases office and warehouse space from DWT. For the three months ended March 31, 2021 and 2020, the Company paid DWT rent in the amounts of $5,571 and $5,307, respectively.

In 2017, the Company acquired VectorVision, Inc. from David Evans, and also acquired AcQviz from Dr. 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 embedded in the product 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. During the three months ended March 31, 2021 and 2020, the Company did not incur any royalties due to net revenue from AcQviz.

10. Segment Reporting

The Company determined its reporting units in accordance with ASC 280, "Segment Reporting". The Company currently operates in two reportable segments: Medical Foods and Nutraceuticals and Medical Devices.

The Medical Foods and Nutraceuticals segment provides a portfolio of science-based, clinically supported nutrition, medical foods, and supplements. The Medical Devices segment includes a portfolio of medical diagnostic devices currently focused on the ocular space and contrast testing. The Company's medical devices and accessories are used to measure visual function and certain anatomical features of the eye that detect early disease and monitor changes over time.

The segments are based on the discrete financial information reviewed by the Chief Executive Officer, who is the Company's Chief Operating Decision Maker ("CODM"), to make resource allocation decisions and to evaluate performance. The reportable segments are each managed separately because they manufacture and distribute distinct products or provide services with different processes. All reported segment revenues are derived from external customers.

The accounting policies of the Company's reportable segments are the same as those described in the summary of significant accounting policies (see Note 2). Certain corporate general and administrative expenses, including general overhead functions such as information systems, accounting, human resources, Board of Director fees, corporate legal fees, other compliance costs and certain administrative expenses, as well as interest and tax expense, are not allocated to the segments. The following tables set forth our results of operations by segment:

	For the Three Months Ended March 31, 2021			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ -	$ 162,143	$ 71,154	$ 233,297
Cost of goods sold	-	84,917	48,098	133,015
Gross profit	-	77,226	23,056	100,282
Stock compensation expense	387,615	-	-	387,615
Operating expenses	1,150,600	1,176,127	55,465	2,382,192
Loss from operations	**$ (1,538,215)**	**$ (1,098,901)**	**$ (32,409)**	$ **(2,669,525)**

	For the Three Months Ended March 31, 2020			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ 14,744	$ 139,789	$ 91,190	$ 245,723
Cost of goods sold	-	78,439	30,669	109,108
Gross profit	14,744	61,350	60,521	136,615
Stock compensation expense	503,893	-	-	503,893
Operating expenses	915,552	937,123	116,269	1,968,944
Loss from operations	**$ (1,404,701)**	**$ (875,773)**	**$ (55,748)**	**$ (2,336,222)**

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

	As of March 31, 2021			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Current assets				
Cash	$ 43,329,674	$ -	$ -	$ 43,329,674
Inventories	-	194,081	94,446	288,527
Other	-	224,660	152,759	377,419
Total current assets	**43,329,674**	**418,741**	**247,205**	**43,995,620**
Right of use asset, net	-	339,873	39,247	379,120
Property and equipment, net	-	125,158	140,821	265,979
Intangible assets, net	-	50,000	-	50,000
Other	-	11,751	-	11,751
Total assets	**$ 43,329,674**	**$ 945,523**	**$ 427,273**	**$ 44,702,470**

	As of December 31, 2020			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Current assets				
Cash	$ 8,518,732	$ -	$ -	$ 8,518,732
Inventories	-	254,879	130,093	384,972
Other	-	89,333	101,846	191,179
Total current assets	**8,518,732**	**344,212**	**231,939**	**9,094,883**
Right of use asset	-	374,447	44,143	418,590
Property and equipment, net	-	135,641	150,035	285,676
Intangible assets, net	-	50,000	-	50,000
Other	-	11,751	-	11,751
Total assets	**$ 8,518,732**	$ **916,051**	$ **426,117**	$ **9,860,900**

11. Commitments and 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, 2021 with respect to such matters.

Effective January 6, 2021, the Board of Directors appointed Bret Scholtes as President, Chief Executive Officer, and as a director of the Company. The Company and Mr. Scholtes entered into an employment agreement pursuant to which Mr. Scholtes' annual base salary is $400,000. The employment agreement provides that Mr. Scholtes shall have an annual target cash bonus of no less than $400,000 based on performance objectives determined by the Board of Directors. Additionally, Mr. Scholtes shall be granted (i) stock options equal to 2% of the Company's issued and outstanding shares of common stock on the date of grant if the Company achieves specified performance objectives established by the Board for the Company's fiscal years ending December 31, 2021, and December 31, 2022, and (ii) additional stock options equal to either 2% or 3% of the Company's issued and outstanding shares of common stock on the date of grant if the Company meets certain financial objectives during the first five years following January 6, 2021. If Mr. Scholtes' employment is terminated by the Company without cause, as defined, if the term expires after a notice of non-renewal is delivered by the Company, or if Mr. Scholtes' employment is terminated following a change of control, as defined, Mr. Scholtes will be entitled to (a) twelve months' base salary, (b) the prorated portion of the any bonus, based on actual performance, and (c) base salary and benefits accrued through the date of termination.

12. Subsequent Events

The Company performed an evaluation of subsequent events through the date of filing of these consolidated financial statements with the SEC. There were no material subsequent events which affected, or could affect, the amounts or disclosures in the consolidated financial statements.

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

FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for the three-month period ended March 31, 2021 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, 2020 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.

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., and its affiliates 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, 2020, and the notes thereto, which are set forth in the Company's 2020 Annual Report on 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.

We see opportunities to grow our business and create value by developing and distributing condition-specific, clinically proven nutrition, medical foods, and diagnostic devices. Our portfolio of science-based, clinically supported products support healthcare professionals, their patients, and consumers in achieving health goals.

Recent Trends – Market Conditions

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 the effectiveness of COVID-19 mitigation and vaccination 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

Appointment of New CEO

Effective as of January 6, 2021, the Board of Directors appointed Bret Scholtes as President and Chief Executive Officer and as a director of the Company.

The Company and Mr. Scholtes entered into an employment agreement pursuant to which Mr. Scholtes' annual base salary is $400,000. The Employment Agreement provides that Mr. Scholtes shall have an annual target cash bonus opportunity of no less than $400,000 (the "Bonus") based on the achievement of Company and individual performance objectives to be determined by the Board of Directors.

Mr. Scholtes was granted an award of stock options equal to one percent (1%) of the issued and outstanding number of shares of the Company's common stock (the "Stock Options") pursuant to the Company's 2018 Equity Incentive Plan (the "Incentive Plan"), at an exercise price equal to the closing price of the Company's common stock on the Effective Date (152,671 shares, exercise price of $3.95 per share). One third (1/3) of the Stock Options shall vest and become exercisable the first anniversary of the Effective Date, and the balance of the Stock Options shall vest ratably in equal installments for the twenty-four (24) months thereafter, subject to continued service, and shall vest in full upon a Change in Control (as defined in the Incentive Plan). Additionally, the Company shall grant unvested shares of common stock in an amount equal to one percent (1%) of the number of shares of Company common stock issued and outstanding on the Effective Date (the "Stock Grant") to Mr. Scholtes under the Incentive Plan (152,671 shares). The shares underlying the Stock Grant shall become vested in full on the first anniversary of the Effective Date. Additionally, Mr. Scholtes shall be granted (i) additional stock options equal to two percent (2%) of the Company's issued and outstanding shares of common stock on the date of grant if the Company achieves specified written performance objectives established by the Board for the Company's fiscal years ending December 31, 2021 and December 31, 2022 and (ii) additional stock options equal to either two percent (2%) or three percent (3%) of the Company's issued and outstanding shares of common stock on the date of grant if the Company meets certain financial objectives during the first five years following the Effective Date.

If Mr. Scholtes' employment is terminated by the Company without cause (as defined in the Employment Agreement), if the Term expires after a notice of non-renewal is delivered by the Company or if Mr. Scholtes' employment is terminated following a change of control (as defined in the Incentive Plan), Mr. Scholtes will be entitled to (a) twelve months' base salary, (b) the prorated portion of the Bonus for the year in which the termination occurs, based on actual performance and (c) base salary and benefits accrued through the date of termination.

January and February 2021 At the Market Offerings

On January 8, 2021, the Company entered into a sales agreement with Maxim Group LLC and filed a prospectus supplement pursuant to which the Company could sell up to $10,000,000 worth of shares of its common stock in an "at the market" offering through the distribution agent (the "January 2021 1st ATM Offering"). On January 15, 2021, the Company completed the January 2021 1st ATM Offering, pursuant to which the Company sold an aggregate of 2,559,834 shares of its common stock and raised gross proceeds (after deduction for sales commissions) of approximately $9,700,000.

On January 28, 2021, the Company entered into a sales agreement with Maxim Group LLC and filed a prospectus supplement pursuant to which the Company could sell up to $25,000,000 worth of shares of its common stock in an "at the market" offering through the distribution agent (the "January 2021 2nd ATM Offering"). On February 10, 2021, the Company completed the January 2021 2nd ATM Offering, pursuant to which the Company sold an aggregate of 5,006,900 shares of its common stock and raised gross proceeds (after deduction for sales commissions) of approximately $24,250,000.

The Company incurred costs related to these financings of approximately $327,000 which are reflected in APIC as a reduction that offsets to the proceeds for shares issued. The net cash received from both offering after all expense is approximately $33,623,000.

Warrant Exercises

From January 1, 2021 through March 31, 2021, the Company received total gross proceeds of $3,568,415 from the exercise of 1,647,691 warrants issued.

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 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 three months ended March 31, 2021, the Medical Devices segment had three customers who accounted for approximately 82% of the Company's sales. No other customer accounted for more than 10% of sales.

Critical Accounting Policies and Estimates

The Company's financial statements have been prepared in conformity with 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.

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*. Revenue is recognized when control of promised goods or services is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products 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.

All products sold by the Company are distinct individual products and 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.

Inventories

Inventories are stated at the lower of cost or net realizable value, with cost determined on a first-in, first-out ("FIFO") basis. The Company records adjustments to its inventory for estimated obsolescence or diminution in net realizable value equal to the difference between the cost of the inventory and the estimated net realizable value. The difference is recognized as a loss in the period in which it occurs. Once inventory has been written down, it creates a new cost basis for inventory that is not subsequently written up.

Stock-Based Compensation

The Company periodically issues stock-based compensation to employees and non-employees in non-capital raising transactions for services and for financing costs. Such grants vest and expire according to terms established at the issuance date. The Company accounts for such grants issued and vesting based on *ASC 718, Compensation-Stock Compensation,* whereby the value of the award is measured on the date of grant and recognized for employees as compensation expense on a straight-line or graded basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services.

The fair value of stock options granted is estimated using the Black-Scholes option-pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life, and future dividends. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods. 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.

Plan of Operations

General Overview

The Company is focused on building a leading clinical nutrition company with the objective that it become a top performing growth company. Our team has taken the first part of 2021 to assess the business, the core fundamentals, and the market opportunity for the Company's products and services.

Our team still has work to do before we can fully implement and accelerate our growth initiatives, but we are focused on building a strong foundation by developing a business model and infrastructure that are designed for long-term commercial success. We have started this process by concentrating on certain key areas, including our business strategy, go-to-market capabilities, scientific affairs and human capital. We are also beginning the process of establishing our nascent brands and identifying core customer bases where we can accelerate our marketing efforts once our clinical support and scientific evidence is in place.

This process will take time, but we are taking important steps required to build a stronger company. We raised equity in two at-the-market equity financings and the Company implemented a reverse stock split that enabled us to come into full compliance with Nasdaq's continued listing rules regarding minimum bid stock price. Based on the availability of sufficient funding, the Company intends to increase its commercialization and business development activities to capitalize on growth opportunities. We will also seek opportunities to utilize mergers and acquisitions and similar transactions to advance our business strategy.

Over the long-term, the key to our success will be to create value in well-differentiated and robust brands through strong clinically proven claims that address consumer needs in growing markets, both domestically and internationally. We are committed to bringing compelling products to market under meaningful and differentiated brands supported by strong science.

In addition to the commercialization and business development activities described above, we will also seek opportunities to utilize mergers and acquisitions and similar transactions to advance our business strategy.

Results of Operations

Through March 31, 2021, 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 nutrition, medical foods, supplements and medical devices. These products support healthcare professionals, their patients and consumers in achieving health goals. The Company had limited revenue during the three months ended March 31, 2021 and 2020.

Comparison of Three Months Ended March 31, 2021 and 2020

	Three Months Ended March 31,			
	2021	2020	Change	
Revenue	$ 233,297	$ 245,723	$ (12,426)	(5)%
Cost of goods sold	133,015	109,108	(23,907)	22%
Gross Profit	100,282	136,615	(36,333)	(27)%
Operating Expenses:				
Research and development	20,608	31,188	(10,580)	(34)%
Sales and marketing	457,727	488,846	(31,119)	(6)%
General and administrative	2,291,472	1,952,803	338,669	(17)%
Total Operating Expenses	2,769,807	2,472,837	296,970	(12)%
Loss from Operations	(2,669,525)	(2,336,222)	(333,303)	(14)%
Other Expense:				
Interest expense	-	(1,747)	1,747	%
Change in fair value of derivative warrants	-	(8,944)	8,944	%
Net Loss	$ (2,669,525)	$ (2,346,913)	$ (322,612)	(14)%

Revenue

For the three months ended March 31, 2021, revenue from product sales was $233,297 compared to $245,723 for the three months ended March 31, 2020, resulting in a decrease of $12,426 or 5%. The relatively flat overall performance reflects a combination of improved sales of Medical Foods and Nutraceuticals offset by a decrease in Medical Device sales primarily due to the impact of COVID-19 office closures for many in our customer base. In addition, the Company sold one MapcatSF devices in first quarter of 2020 for approximately $25,000. There have been no further sales of MapcatSF devices.

Cost of Goods Sold

For the three months ended March 31, 2021, cost of goods sold was $133,015 compared to $109,108 for the three months ended March 31, 2020, an increase of $23,907 or 22%. This increase is primarily driven by a change in product mix in the Medical Device business. In the quarter ended March 31, 2021, 91% of the Medical Device sales were attributable to products which require assembly and have a cost of goods sold of 48% versus the quarter ended March 31, 2020 where 60% of the items sold were individual parts and assemblies, which have a cost of goods sold of approximately 33%. During the quarter ended March 31, 2021, the Company recorded an inventory write down of approximately $6,000 related to Vector Vision raw materials inventory.

Gross Profit

For the three months ended March 31, 2021, gross profit was $100,282 compared to $136,615 for the three months ended March 31, 2020, a decrease of $36,333 or 27%, primarily as a result in the decrease in Medical Device sales and the increase in cost of goods sold. Gross profit represented 43% of revenues for the three months ended March 31, 2021, versus 56% of revenue for the three months ended March 31, 2020.

Research and Development

For the three months ended March 31, 2021, research and development costs were $20,608 compared to $31,188 for the three months ended March 31, 2020, a decrease of $10,580 or 34%, primarily as a result of the timing of certain studies conducted on a periodic basis. Research and development costs primarily consist of engineering efforts related to our medical devices and clinical studies related to our medical foods.

Sales and Marketing

For the three months ended March 31, 2021, sales and marketing expenses were $457,727 as compared to $488,846 for the three months ended March 31, 2020, representing a slight decrease in sales and marketing expenses of $31,119 or 6% compared to the prior three-month period.

General and Administrative

For the three months ended March 31, 2021, general and administrative expenses were $2,291,472 as compared to $1,952,803 for the three months ended March 31, 2020. The increase of $338,669 or 17% compared to the prior period was primarily due to an increase of approximately $239,000 in consulting fees, an increase in insurance costs of approximately $51,000 and an increase in professional and legal fees of approximately $154,000 partially offset by a reduction of $79,000 in stock-based compensation cost and a reduction of approximately $58,000 in licenses and fees and a decrease of approximately $2,000 in supplies expense.

Interest Expense

For the three months ended March 31, 2021, interest expense was $0 compared to $1,747 for the three months ended March 31, 2020. In 2020 we financed various insurance policies and incurred interest expense. We did not finance the 2021 policies therefore we incurred no interest in the quarter ended March 31, 2021.

Net Loss

For the three months ended March 31, 2021, the Company incurred a net loss of $2,669,525, compared to a net loss of $2,346,913 for the three months ended March 31, 2020. The increase in net loss of $322,612 or 14% compared to the prior year period is primarily attributable to the increase in costs of goods sold and general and administrative costs described above.

Segment Information

The following tables set forth our results of operations by segment:

The Medical Foods and Nutraceuticals segment provides a portfolio of science-based, clinically supported nutrition, medical foods, and supplements. Our products include, among others, Lumega-Z, GlaucoCetin and ImmuneSF.

The Medical Device segment includes a portfolio of medical diagnostic devices currently focused on the ocular space and is the industry leader in contrast testing. Our products include VectorVision CSV-1000, CSV-1000HGT, CSV-2000 and associated accessories as well as the MapcatSF.

See Note 10 to the condensed consolidated financial statements for further details on our reportable segments.

	For the Three Months Ended March 31, 2021			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ -	$ 162,143	$ 71,154	$ 233,297
Cost of goods sold	-	84,917	48,098	133,015
Gross profit	-	77,226	23,056	100,282
Stock compensation expense	387,615	-	-	387,615
Operating expenses	1,150,600	1,176,127	55,465	2,382,192
Loss from operations	**$ (1,538,215)**	**$ (1,098,901)**	**$ (32,409)**	**$ (2,669,525)**

	For the Three Months Ended March 31, 2020			
	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	$ 14,744	$ 139,789	$ 91,190	$ 245,723
Cost of goods sold	-	78,439	30,669	109,108
Gross profit	14,744	61,350	60,521	136,615
Stock compensation expense	503,893	-	-	-
Operating expenses	915,552	937,123	116,269	2,472,837
Loss from operations	**$ (1,404,701)**	$ **(875,773)**	$ **(55,748)**	$ **(2,336,222)**

Revenue

For the three months ended March 31, 2021, revenue from our Medical Foods and Nutraceuticals segment was $162,143 compared to $139,789 for the three months ended March 31, 2020, an increase of $22,354 or 16%. For the three months ended March 31, 2021, revenue from our Medical Devices segment was $71,154 compared to $91,190 for the three months ended March 31, 2020, a decrease of $20,036 or 22% primarily due to the sale of MapcatSF devices in first quarter of 2020.

Cost of Goods Sold

For the three months ended March 31, 2021, cost of goods sold from our Medical Foods and Nutraceuticals segment was $84,917 as compared to $74,439 for the three months ended March 31, 2020, an increase of $10,478 or 14%. The increase was primarily due to an increase in merchant fees of approximately $6,000. For the three months ended March 31, 2021, cost of goods sold from our Medical Device segment was $48,098 as compared to $30,669 for the three months ended March 31, 2020, an increase of $17,429 or 57%. This increase is primarily driven by a change in product mix in the medical devices business. In the quarter ended March 31, 2021, 91% of the sales were attributable to products which require assembly and have a cost of goods sold of 48% versus the quarter ended March 31, 2020 where 60% of the items sold were individual parts which have a cost of goods sold of approximately 33%.

Gross Profit

For the three months ended March 31, 2021, gross profit from the Medical Foods and Nutraceuticals segment was $77,227 compared to $95,994 for the three months ended March 31, 2020, a decrease of $18,767 or 19%. For the three months ended March 31, 2021, gross profit from the Medical Device segment was $23,056 as compared to $40,621 for the three months ended March 31, 2020, resulting in a decrease of $17,565 or 43%. Gross profit overall represented 43% of revenues for the three months ended March 31, 2021, versus 56% of revenue for the three months ended March 31, 2020. This decrease of 13% is primarily driven by the mix of products sold in the Medical Device business as described above in addition to the additional shipping and bank fees being reflected as cost of sales in the current year.

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. For the three months ended March 31, 2021, the Company incurred a net loss of $2,669,525 and used cash in operating activities of $2,420,070. At March 31, 2021, the Company had cash on hand of $43,329,674 and working capital of $43,012,927. Notwithstanding the net loss for the first quarter of 2021, management believes that its current cash balance is sufficient to fund operations for at least the next twelve months.

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. The Company will continue to incur significant expenses for continued commercialization activities related to its medical foods, medical devices and its nutraceuticals product line, and building its infrastructure. 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.

The Company may continue to seek to raise additional debt and/or equity capital to fund future operations and acquisitions 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. Over time, 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.

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,	
	2021	**2020**
Net cash used in operating activities	$ (2,420,070)	$ (1,735,410)
Net cash used in investing activities	-	(40,733)
Net cash provided by financing activities	37,231,012	3,550,781
Net increase (decrease) in cash	$ 34,810,942	$ (1,774,638)

Operating Activities

Net cash used in operating activities was $2,420,070 during the three months ended March 31, 2021, versus $1,735,410 used during the comparable prior year period. The increase over 2020 was due primarily to higher legal, insurance, professional services, and labor costs paid in the current three-month period.

Investing Activities

Net cash used in investing activities was $0 for the three months ended March 31, 2021 and $40,733 for the three months ended March 31, 2020. Cash was used in the prior year period for the purchase of testing equipment, furniture and fixtures. There were no purchases of furniture, fixtures and equipment in the quarter ended March 31, 2021.

Financing Activities

Net cash provided by financing activities was $37,231,012 for the three months ended March 31, 2021 and consisted of the sale of common stock with net proceeds of $33,662,597 and warrant exercises during the period with proceeds of $3,568,415. Net cash provided by financing activities was $3,550,781 for the three months ended March 31, 2020 and is all attributable to the exercise of warrants.

Off-Balance Sheet Arrangements

At March 31, 2021 and December 31, 2020, 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

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Securities and Exchange Act of 1934 Rules 13a-15(f). Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that the Company's disclosure controls and procedures were not effective as of March 31, 2021. As of March 31, 2021, management's assessment identified the following material weakness in the Company's internal control over financial reporting:

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 in 2021 in conjunction with the process of developing our various business initiatives. 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 or subsequent to the period ended March 31, 2021 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.

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.

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

Exhibit No.	Description
1.1	Equity Distribution Agreement, dated January 8, 2021, by and between Guardion Health Sciences, Inc. and Maxim Group LLC (incorporated by reference to exhibit 1.1 of the Company's Form 8-K filed on January 8, 2021)
3.1	Certificate of Amendment to the Certificate of Incorporation of Guardion Health Sciences, Inc. (incorporated by reference to exhibit 3.1 of the Company's Form 8-K filed on March 1, 2021)
10.1+	Employment Agreement by and between the Company and Bret Scholtes (incorporated by reference to exhibit 10.1 of the Company's Form 8-K filed on December 29, 2020)
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 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
32.1*	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
101	The following materials from the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2021, 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.

\+ Indicates a management contract or any compensatory plan, contract or arrangement.

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 17th day of May 2021.

Signature	Title	Date
/s/ Bret Scholtes Bret Scholtes	Chief Executive Officer (Principal Executive Officer)	May 17, 2021
/s/ Andrew Schmidt Andrew Schmidt	Chief Financial Officer (Principal Financial and Accounting Officer)	May 17, 2021