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 September 30, 2019

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	**15150 Avenue of Science, Suite 200 San Diego, California 92128 Telephone: 858-605-9055**	**47-4428421**
(State or other jurisdiction of incorporation or organization)	*(Address and telephone number of principal executive offices)*	*(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 November 13, 2019, there were 74,982,562 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 (this "Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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.

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.

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, 2018 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). The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, in each case, except to the extent required by applicable law.

PART I – FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Guardion Health Sciences, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets		
Cash	$ 5,554,960	$ 670,948
Accounts receivable	21,927	28,203
Inventories	320,355	357,997
Prepaid expenses	234,384	47,773
Total current assets	**6,131,626**	**1,104,921**
Deposits	11,751	11,751
Property and equipment, net	389,074	274,804
Right of use asset, net	563,948	-
Deferred offering costs	-	270,000
Intangible assets, net	295,127	456,104
Goodwill	1,563,520	1,563,520
Total assets	**$ 8,955,046**	**$ 3,681,100**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 218,815	$ 413,925
Accrued expenses and deferred rent	63,964	81,412
Derivative warrant liability	47,118	-
Lease liability – current	129,025	-
Total current liabilities	458,922	495,337
Lease liability – long term	447,292	-
Total liabilities	906,214	495,337
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized	-	-
Common stock, $0.001 par value; 90,000,000 shares authorized; 50,482,562 and 20,564,328 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	50,483	20,564
Additional paid-in capital	49,454,265	37,798,562
Accumulated deficit	(41,455,916)	(34,633,363)
Total stockholders' equity	**8,048,832**	**3,185,763**
Total liabilities and stockholders' equity	**$ 8,955,046**	**$ 3,681,100**

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**
Revenue				
Medical foods	$ 112,957	$ 86,082	$ 317,338	$ 238,213
Vision testing diagnostics	44,705	208,148	337,531	469,834
Other	3,500	-	9,800	-
Total revenue	161,162	294,230	664,669	708,047
Cost of goods sold				
Medical foods	41,655	37,076	120,608	110,462
Vision testing diagnostics	27,922	88,330	136,958	181,999
Other	1,422	-	3,981	-
Total cost of goods sold	70,999	125,406	261,547	292,461
Gross profit	90,163	168,824	403,122	415,586
Operating expenses				
Research and development	31,897	4,793	138,613	199,500
Sales and marketing	448,387	240,028	1,246,846	1,224,491
General and administrative	2,022,367	1,064,645	5,427,573	3,779,325
Total operating expenses	2,502,651	1,309,466	6,813,032	5,203,316
Loss from operations	(2,412,488)	(1,140,642)	(6,409,910)	(4,787,730)
Other (income) expense:				
Interest expense	4,205	545	255,842	2,090
Finance cost upon issuance of warrants	-	-	415,955	-
Change in fair value of derivative warrants	(31,322)	-	(259,154)	-
Costs associated with extension of warrant expiration dates	-	1,007,006	-	1,501,397
Total other (income) expense	(27,117)	1,007,551	412,643	1,503,487
Net loss	**$ (2,385,371)**	**$ (2,148,193)**	**$ (6,822,553)**	**$ (6,291,217)**
Net loss per common share – basic and diluted	$ (0.07)	$ (0.11)	$ (0.26)	$ (0.31)
Weighted average common shares outstanding – basic and diluted	36,035,309	20,164,761	26,483,713	20,162,354

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, Six and Nine Months Ended September 30, 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	20,856,611	20,857	37,885,751	(36,018,462)	1,888,146
Fair value of vested stock options – officer and director	-	-	1,066,159	-	1,066,159
Fair value of vested stock options	-	-	62,763	-	62,763
Reclass of warrant liability to equity	-	-	359,683	-	359,683
Sale of common stock	1,250,000	1,250	3,886,750	-	3,888,000
Issuance of common stock for services	54,387	55	123,947	-	124,002
Issuance of common stock – warrant exercises	463,726	463	100,162	-	100,625
Fair value of common stock – conversion of notes payable and related interest	109,038	109	250,679	-	250,788
Net loss				(3,052,078)	(3,052,078)
Balance at June 30, 2019	22,733,762	22,734	43,735,894	(39,070,540)	4,688,088
Fair value of vested stock options – officer and director	-	-	722,592	-	722,592
Fair value of vested stock options	-	-	56,688	-	56,688
Sale of common stock	12,000,000	12,000	4,932,340	-	4,944,340
Issuance of common stock – warrant exercises	15,748,800	15,749	6,751	-	22,500
Net loss	-	-	-	(2,385,376)	(2,385,376)
Balance at September 30, 2019	50,482,562	$ 50,483	$49,454,265	$ (41,455,916)	$ 8,048,832
	Three, Six and Nine Months Ended September 30, 2018				
Balance at December 31, 2017	20,091,761	$ 20,092	$33,716,140	$(26,865,956)	$ 6,870,276
Fair value of vested stock options	-	-	777,513	-	777,513
Issuance of common stock – warrant exercises	73,000	73	1,387	-	1,460
Net loss	-	-	-	(2,333,461)	(2,333,461)
Balance at March 31, 2018	20,164,761	20,165	34,495,040	(29,199,417)	5,315,788
Fair value of vested stock options	-	-	277,372	-	277,372
Costs associated with extension of warrant expiration dates	-	-	494,391	-	494,391
Net loss	-	-	-	(1,809,564)	(1,809,564)
Balance at June 30, 2018	20,164,761	20,165	35,266,803	(31,008,981)	4,277,987
Fair value of vested stock options	-	-	350,337	-	350,337
Costs associated with extension of warrant expiration dates	-	-	1,007,006	-	1,007,006
Net loss	-	-	-	(2,148,192)	(2,148,192)
Balance at September 30, 2018	20,164,761	$ 20,165	$36,624,146	$(33,157,173)	$ 3,487,138

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
	(Unaudited)	**(Unaudited)**
Operating Activities		
Net loss	$ (6,822,553)	$ (6,291,217)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	209,813	223,014
Amortization of debt discount	250,000	-
Accrued interest expense included in notes payable	788	-
Amortization of right of use asset	93,222	-
Stock-based compensation	299,684	1,405,222
Stock-based compensation – officer and director	1,788,751	-
Non-cash financing costs – derivative liability	415,955	-
Change in fair value of warrants – derivative liability	(259,154)	-
Costs associated with extension of warrant expiration dates	-	1,501,397
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	6,275	55,761
Inventories	37,642	(226,537)
Deposits and prepaid expenses	(186,611)	77,147
Lease liability	(86,902)	-
Increase (decrease) in -		
Accounts payable and accrued expenses	75,439	(43,117)
Accrued expenses and deferred rent	(11,399)	10,390
Net cash used in operating activities	(4,189,050)	(3,287,940)
Investing Activities		
Purchase of property and equipment	(163,105)	(228,311)
Purchase of intellectual property	-	(50,000)
Net cash used in investing activities	(163,105)	(278,311)
Financing Activities		
Proceeds from initial public offering	3,888,000	-
Proceeds from follow-on public offering	4,944,340	-
Proceeds from issuance of convertible notes	250,000	-
Proceeds from issuance of promissory note	100,000	-
Payments on promissory note	(100,548)	-
Payments on line of credit	-	(30,535)
Proceeds from exercise of warrants	154,375	1,460
Decrease in due to related parties	-	(38,114)
Net cash provided by (used in) financing activities	9,236,167	(67,189)
Cash:		
Net increase (decrease)	4,884,012	(3,633,440)
Balance at beginning of period	670,948	4,735,230
Balance at end of period	$ 5,554,960	$ 1,101,790
Supplemental disclosure of cash flow information:		
Cash paid for-		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash financing activities:		
Fair value of warrant liability issued in connection with issuance of convertible notes	$ 436,034	$ -
Recording of lease asset and liability upon adoption of ASU 2016-02	$ 663,218	$ -
Reclass of warrant liability to equity	$ 359,683	$ -
Fair value of common stock issued upon conversion of common stock and accrued interest	$ 250,788	$ -
Reclass of deferred offering cost to equity	$ 270,000	$ -

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)
Nine Months Ended September 30, 2019 and 2018

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 formed to develop, formulate and distribute condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that is designed to replenish and restore the macular protective pigment. A depleted macular protective pigment is a modifiable risk factor for retina-based diseases such as age-related macular degeneration ("AMD"), computer vision syndrome ("CVS") and diabetic retinopathy. The Company believes this risk may be modified by taking Lumega-Z to maintain a healthy macular protective pigment. Additional research has also shown a depleted macular protective pigment to be a biomarker for neurodegenerative diseases such as Alzheimer's disease and dementia.

The Company invented a proprietary technology, embodied in the Company's medical device, the MapcatSF® that accurately measures the macular pigment optical density ("MPOD"). On November 8, 2016, the United States Patent and Trademark Office ("USPTO") issued patent number 9,486,136 for the MapcatSF invention. Using the MapcatSF to measure the MPOD allows one to monitor the increase in the density of the macular protective pigment after taking Lumega-Z. The MapcatSF is a non-mydriatic, non-invasive device that accurately measures the MPOD, the lens optical density and lens equivalent age, thereby creating an evidence-based protocol that is shared with the patient. A non-mydriatic device is one that does not require dilation of the pupil for it to function. The MapcatSF is the first medical device using a patented "single fixation" process and "automatic lens density correction" that produces accurate serialized data.

In September 2017, the Company, through its wholly-owned subsidiary VectorVision Ocular Health, Inc. ("VectorVision"), 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 ("ETDRS") visual acuity testing. VectorVision's standardization system is designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing for use by eye doctors in clinical trials, for real-world vision evaluation, and industrial vision testing. The acquisition expanded the Company's technical portfolio. CSV-1000 and CSV-3000 instruments offer auto-calibrated tests to ensure correct testing luminance and contrast levels for consistent, highly accurate and repeatable results. Recently issued patents the Company received for continuously calibrating the light source, an automated standardization technology the Company refers to as AcQviz™, are expected to be incorporated into the new CSV-2000, in which the proprietary standardized contrast sensitivity test patterns can be presented to the patient using a computer monitor as opposed to the current calibrated backlit system. The Company believes the acquisition of VectorVision further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). TDSI is dedicated to the pursuit of early predictors resulting in, the Company believes, valuable therapeutic intervention for practitioners and their patients, and additional revenue streams generated from the testing and sale of Company products to appropriate customers. The Company has established operations with selected clinics and is focusing on expanding its client base.

In November 2018, the Company launched a new medical food product, GlaucoCetin™, which the Company believes is the first vision-specific medical food designed to support and protect the mitochondrial function of optic nerve cells and improve blood flow in the ophthalmic artery in patients with glaucoma.

In September 2019, the Company, through its wholly owned subsidiary NutriGuard Formulations, Inc., acquired the nutraceuticals business from NutriGuard Research, Inc. Pursuant to the Asset Purchase Agreement, the Company purchased specified assets of the NutriGuard brand and business, primarily consisting of inventory, trademarks, copyrights and other intellectual property. Once developed, the NutriGuard Formulations nutraceutical product line should provide the Company a new direct-to-consumer ("DTC") capability. The Company intends to build a portfolio of nutraceutical products under the NutriGuard brand by developing new formulations and marketing its products to patients directly through DTC channels and through recommendations by their physicians. See Note 3 for additional information.

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 $6,822,553 and utilized cash in operating activities of $4,189,050 during the nine months ended September 30, 2019. 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, 2018. 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, the MapcatSF medical device, VectorVision diagnostic equipment, the TDSI business, the new NutriGuard line of nutraceuticals 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.

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 has been provided an initial period of 180 calendar days, or until March 18, 2020 (the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180-day period, the closing bid price of the Company's common stock is at least $1.00 for a minimum of 10 consecutive business days, the Staff will provide the Company written confirmation of compliance with the Minimum Bid Price Requirement and the matter will be closed. If the Company does not regain compliance by the Compliance Date, the Company may be eligible for an additional 180 calendar day compliance period. To qualify for such additional compliance period, the Company would have to meet the continued listing requirements of the NASDAQ Capital Market, except for the Minimum Bid Price Requirement, and the Company would need to provide written notice of its intention to cure the deficiency during the additional compliance period. If the Company is not eligible for the additional compliance period or it appears to the Staff that the Company will not be able to cure the deficiency or if the Staff exercises its discretion to not provide such additional compliance period, the Staff will provide written notice to the Company that its common stock will be subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Hearing Panel.

Reverse Stock Split

On January 30, 2019, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Amended Certificate of Incorporation, as amended (the "Amendment"), with the Secretary of State of the State of Delaware to effectuate a one-for-two (1:2) reverse stock split (the "Reverse Stock Split") of its common stock, par value $0.001 per share, without any change to its par value. The Amendment became effective on the filing date. The number of shares authorized for common and preferred 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. Proportional adjustments for the Reverse Stock Split were made to all share and per share amounts as if the split occurred at the beginning of the earliest period presented.

Board Actions

In October 2019, our board of directors approved an amendment to increase the number of authorized common stock from 90,000,000 to 250,000,000 shares. In addition, the board approved an amendment to our certificate of incorporation, as amended, to combine the outstanding shares of our common stock into a lesser number of outstanding shares (a "Reverse Stock Split").

The board of directors determined that an increase in authorized common shares is in the best interests of the Company and believes that the availability of additional authorized shares of common stock is required for several reasons, including enabling investors to exercise the Series B warrants issued pursuant to our October 30 public offering as well as the flexibility to issue common stock for a variety of general corporate purposes as the board of directors may determine to be desirable, including future financings, investment opportunities, acquisitions, or other distributions.

The short-term intent of a Reverse Stock Split is to increase the price of the common stock and thereby regain compliance with the NASDAQ minimum bid price requirement. In addition, the Company believes a Reverse Stock Split will make its common stock more attractive to a broader range of investors, as it believes that the current market price of the common stock may prevent certain institutional investors, professional investors and other members of the investing public from purchasing stock. Many brokerage houses and institutional investors have internal policies and practices that either prohibit them from investing in low-priced stocks or tend to discourage individual brokers from recommending low-priced stocks to their customers. Furthermore, some of those policies and practices may function to make the processing of trades in low-priced stocks economically unattractive to brokers. Moreover, because brokers' commissions on low-priced stocks generally represent a higher percentage of the stock price than commissions on higher-priced stocks, the current average price per share of common stock can result in individual stockholders paying transaction costs representing a higher percentage of their total share value than would be the case if the share price were higher. The Company believes that the Reverse Stock Split will make our common stock a more attractive and cost-effective investment for many investors, which in turn would enhance liquidity for holders of our common stock.

Shareholder approval for these actions is expected to be solicited at our 2019 Annual Meeting of Stockholders that is currently scheduled for December 5, 2019.

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, 2018 filed with the SEC. The condensed consolidated balance sheet as of December 31, 2018 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, 2019.

Certain prior period amounts have been reclassified to conform to current period presentation. Such amounts consist of operating segment disclosures, whereby revenue and cost of goods sold have been broken out on the Consolidated Statements of Operations to conform with the Company's reportable business segments as of September 30, 2019.

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.

These estimates and assumptions include estimates for reserves of uncollectible accounts, inventory obsolescence, depreciable lives of property and equipment, analysis of impairments of recorded long-term tangible and intangible assets, realization of deferred tax assets, accruals for potential liabilities and assumptions made in valuing stock instruments issued for services.

Intangible Assets

In connection with the VectorVision transaction, the Company identified and allocated estimated fair values to intangible assets including goodwill and customer relationships.

In accordance with Accounting Standard Codification ("ASC") 350 – Intangibles – Goodwill and Other, the Company determined whether these assets are expected to have indefinite (such as goodwill) or limited useful lives, and for those with limited lives, the Company established an amortization period and method of amortization. Its goodwill and other intangible assets are subject to periodic impairment testing.

The Company utilized the services of an independent third-party valuation firm to assist in identifying intangible assets and in estimating their fair values. The useful lives for the Company's intangible assets other than goodwill were estimated based on Management's consideration of various factors, including assumptions that market participants might use about sales expectations as well as potential effects of obsolescence, competition, technological progress and the regulatory environment. Because the future pattern in which the economic benefits of these intangible assets may not be reliably determined, amortization expense is generally calculated on a straight-line basis.

Amortization expense for the identifiable intangible assets associated with the VectorVision acquisition is approximately $54,000 per quarter and is included with general and administrative expenses in the Company's Statements of Operations.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, identifiable intangible assets, and goodwill for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell and are no longer depreciated. The Company has not historically recorded any impairment to its long-lived assets. In the future, if events or market conditions affect the estimated fair value to the extent that a long-lived asset is impaired, the Company will adjust the carrying value of these long-lived assets in the period in which the impairment occurs. As of September 30, 2019 and December 31, 2018, the Company had not deemed any long-lived assets as impaired and was not aware of the existence of any indicators of impairment at such dates.

Deferred Offering Costs

Deferred offering costs consist principally of legal, accounting, and underwriters' fees incurred related to equity financings. These deferred offering costs are charged against the gross proceeds received during the appropriate period. During the period ended June 30, 2019, $270,000 of offering costs deferred at December 31, 2018 were offset to paid in capital upon completion of our April 2019 offering. As of September 30, 2019, there were no comparable deferred offering costs.

Revenue Recognition

The Company's revenue is comprised of sales of medical foods 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. Payment for sales of Lumega-Z is 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Medical foods	$ 112,957	$ 86,082	$ 317,338	$ 238,213
Vision testing diagnostics	44,705	208,148	337,531	469,834
Other	3,500	-	9,800	-
	$ 161,162	$ 294,230	$ 664,669	$ 708,047

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 $138,613 and $199,500 for the nine months ended September 30, 2019 and 2018, 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 nine months ended September 30, 2019 and 2018, patent costs were $80,879 and $43,347, respectively, and are included in general and administrative costs in the statements of operations.

Leases

Prior to January 1, 2019, the Company accounted for leases under Accounting Standards Codification (ASC) 840, Accounting for Leases. Effective from January 1, 2019, the Company adopted the guidance of ASU 2016-02 (ASC 842), Leases, which requires an entity to recognize a right-of-use asset and a lease liability for virtually all leases. The Company adopted ASC 842 using a modified retrospective approach. As a result, the comparative financial information has not been updated and the required disclosures prior to the date of adoption have not been updated and continue to be reported under the accounting standards in effect for those periods. The adoption of ASC 842 on January 1, 2019 resulted in the recognition of operating lease right-of-use assets of $657,169, lease liabilities for operating leases of $663,218, and a zero cumulative-effect adjustment to accumulated deficit. See Note 8 for further information regarding the impact of the adoption of ASC 842 on the Company's financial statements.

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, and employees, 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.

In prior periods, the Company accounted for stock option and warrant grants issued and vesting to non-employees in accordance with the authoritative guidance of the FASB whereby the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. On January 1, 2019, the Company adopted Accounting Standards Update (ASU) 2018-07 which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company recognizes the fair value of stock-based compensation within its statements of operations with classification depending on the nature of the services rendered. The adoption of the new standard had no cumulative effect on previously reported amounts.

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, options, and shares associated with convertible debt outstanding 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:

	September 30,	
	2019	**2018**
Warrants	1,502,738	1,260,674
Options	2,712,500	1,362,500
	4,215,238	2,623,174

Recent Accounting Pronouncements

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. The Company is unable at this time to reasonably estimate the timing or amount of future revenue streams that would generate royalty payments, as the Company will need to develop new product formulations and implement a new marketing and distribution infrastructure, which will require the investment of a significant amount of capital over an extended period of time. Accordingly, any royalty payments in the future will be charged directly to operations when incurred.

In addition, on the Effective date, the Company and Mr. McCarty entered into a consulting agreement (as described below), and Mr. McCarty and NutriGuard agreed, among other terms, to no longer use the "NutriGuard" name. Mr. McCarty also entered into a non-competition covenant for a period of 5 years.

As the Company did not pay any cash or non-cash consideration, nor did it assume any liabilities, in conjunction with this acquisition, the Company did not recognize any tangible or intangible assets at closing. All costs related to this transaction, consisting primarily of legal fees, were charged to operations as incurred. Although NutriGuard has conducted limited operations with nominal revenues during the past few years, the Company has determined that the NutriGuard acquisition qualifies as the acquisition of a business under Accounting Standards Codification ("ASC") 805: Business Combinations ("ASC 805"). However, the recent historical operations of NutriGuard did not meet any of the three-element significance level tests (investment, assets and pre-tax income) with regard to the accounting standards requiring acquisition company financial statements and related pro forma financial information, and the Company has therefore concluded that the acquisition of NutriGuard was not significant. The value of the NutriGuard business consists primarily of intangible assets for which no accounting value will be attributed in the Company's financial statements. The Company intends to utilize these intangible assets to build a nutraceutical brand and product portfolio based on updated and reformulated compounds, which will require the investment of a significant amount of capital over an extended period of time.

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 and nine-month periods ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Pro forma net revenues	$ 178,176	$ 314,465	$ 724,899	$ 780,778
Pro forma net loss attributable to common shareholders	$ (2,338,296)	$ (2,181,230)	$ (6,815,355)	$ (6,396,375)
Pro forma net loss per share	$ (0.06)	$ (0.11)	$ (0.26)	$ (0.32)

Mr. McCarty's consulting agreement with the Company provides that Mr. McCarty will serve as, the Director of Research of the Company for a period of 3 years at a rate of $7,500 per month for 12 months and $5,000 per month thereafter. It is intended that Mr. McCarty will assist the Company, among other tasks, in developing new formulations for distribution under the NutriGuard brand, as well as identifying production sources for such compounds and developing distribution networks for such products.

Pursuant to the consulting agreement, the Company granted Mr. McCarty stock options to purchase 100,000 shares of th% Company's common stock, exercisable at a price of $0.5411 per share, which was the closing market price of the Company's common stock on the Effective Date. The stock options were granted under the terms of the Company's 2018 Equity Incentive Plan, which options shall vest as follows: 25% on the Effective Date, 25% on the first anniversary following the Effective Date, 25% on the second anniversary following the Effective Date, and 25% on the third anniversary following the Effective Date.

4. 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 ("ETDRS") 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.

Although all of the Company's products and services target the early detection, intervention and monitoring of a range of eye diseases, 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 September 30, 2019, the TDSI subsidiary does not meet the required quantitative criteria to be considered a reportable operating segment. Additionally, TDSI does not share similar economic characteristics or a majority of the aggregation criteria set forth in ASC 280, and therefore is included in the category "Other" below. The TDSI business earned $9,800 of service revenue and incurred approximately $205,000 of operating costs during the nine months ended September 30, 2019. As of September 30, 2019, 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 operating segments: Medical Foods and Vision Testing Diagnostics. The following tables set forth our results of operations by segment (results allocated to Other consist of non-cash stock compensation expense, depreciation and amortization, corporate legal fees, and the TDSI operations):

	For the Three Months Ended September 30, 2019			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ 3,500	$ 112,957	$ 44,705	$ 161,162
Cost of goods sold	1,422	41,655	27,922	70,999
Gross profit	2,078	71,302	16,783	90,163
Operating expenses	1,235,389	1,124,462	142,800	2,502,651
Loss from operations	**$ (1,233,311)**	**$ (1,053,160)**	**$ (126,017)**	**$ (2,412,488)**

	For the Three Months Ended September 30, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 86,082	$ 208,148	$ 294,230
Cost of goods sold	-	37,076	88,330	125,406
Gross profit	-	49,006	119,818	168,824
Operating expenses	623,791	574,974	110,701	1,309,466
Loss from operations	**$ (623,791)**	**$ (525,968)**	**$ 9,117**	**$ (1,140,642)**

	For the Nine Months Ended September 30, 2019			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ 9,800	$ 317,338	$ 337,531	$ 664,669
Cost of goods sold	3,981	120,608	136,958	261,547
Gross profit	5,819	196,730	200,573	403,122
Operating expenses	3,195,227	3,127,782	490,023	6,813,032
Loss from operations	**$ (3,189,408)**	**$ (2,931,052)**	**$ (289,450)**	**$ (6,409,910)**

	For the Nine Months Ended September 30, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 238,213	$ 469,834	$ 708,047
Cost of goods sold	-	110,462	181,999	292,461
Gross profit	-	127,751	287,835	415,586
Operating expenses	2,126,939	2,801,924	274,453	5,203,316
Loss from operations	**$ (2,126,939)**	**$ (2,674,173)**	**$ 13,382**	**$ (4,787,730)**

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

	As of September 30, 2019			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Current assets				
Cash	$ 5,759	$ 5,506,189	$ 43,012	$ 5,554,960
Inventories	-	166,410	153,945	320,355
Other	3,500	191,899	60,912	256,311
Total current assets	**9,259**	**5,864,498**	**257,869**	**6,131,626**
Right to use asset	563,948	-	-	563,948
Property and equipment, net	-	375,537	13,537	389,074
Intangible assets, net	295,127	-	-	295,127
Goodwill	1,563,520	-	-	1,563,520
Other	-	11,751	-	11,751
Total assets	**$ 2,431,854**	**$ 6,251,786**	**$ 271,406**	**$ 8,955,046**

	As of December 31, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Current assets				
Cash	$ -	$ 552,613	$ 118,335	$ 670,948
Inventories	-	235,957	122,040	357,997
Other	-	44,110	31,866	75,976
Total current assets	**-**	**832,680**	**272,241**	**1,104,921**
Property and equipment, net	-	264,178	10,626	274,804
Deferred offering	270,000	-	-	270,000
Intangible assets, net	456,104	-	-	456,104
Goodwill	1,563,520	-	-	1,563,520
Other	-	11,751	-	11,751
Total assets	**$ 2,289,624**	**$ 1,108,609**	**$ 282,867**	**$ 3,681,100**

5. Inventories

Inventories consisted of the following:

	September 30, 2019	December 31, 2018
Raw materials	$ 253,851	$ 282,574
Finished goods	66,504	75,423
	$ 320,355	$ 357,997

6. Property and Equipment, net

Property and equipment consisted of the following:

	September 30, 2019	December 31, 2018
Leasehold improvements	$ 98,357	$ 98,357
Testing equipment	394,427	249,447
Furniture and fixtures	177,828	163,186
Computer equipment	68,460	64,976
Office equipment	8,193	8,193
	747,265	584,159
Less accumulated depreciation and amortization	(358,191)	(309,355)
	$ 389,074	$ 274,804

For the nine months ended September 30, 2019 and 2018, depreciation and amortization expense was $48,836 and $62,036, respectively, of which $0 and $23,854 was included in research and development expense, $32,289 and $7,242 was included in sales and marketing expense, and $16,547 and $30,940 was included in general and administrative expense, respectively.

7. Intangible Assets

The Company’s intangible assets, including finite-lived intangible assets and $50,000 of non-amortizable purchased intellectual property, consisted of the following:

	June 30, 2019	December 31, 2018
Customer relationships	$ 430,700	$ 430,700
Technology	161,100	161,100
Trade Names	115,600	115,600
Noncompetition	17,000	17,000
	724,400	724,400
Less accumulated amortization	(429,273)	(268,296)
	$ 295,127	$ 456,104

The Company's amortization expense on its finite-lived intangible assets was $160,978 and $160,978 for the nine months ended September 30, 2019 and 2018, respectively.

The Company estimates future amortization expense on its finite-lived intangible assets as of September 30, 2019 to be as follows:

For Years Ended December 31,		
2019	$	53,659
2020		165,320
2021		16,307
2022		9,840
	$	245,126

8. Promissory Notes

Promissory Note

On March 12, 2019, the Company issued a promissory note with principal in the amount of $100,000, simple interest of 10% annually, and with a maturity date of June 10, 2019. On April 11, 2019, the Company repaid the promissory note for a total of $100,548 including accrued interest.

Convertible Notes and Related Warrants

On March 15, 2019, the Company issued a convertible note with principal in the amount of $100,000, simple interest of 5% annually, and with a maturity date of September 30, 2019. In addition, on March 20, 2019, the Company issued a convertible note with principal in the amount of $150,000, simple interest of 5% annually, and with a maturity date of September 30, 2019. The convertible notes (principal and accrued interest) were mandatorily convertible upon the consummation of the IPO. Concurrent with the issuance of the notes, the Company issued warrants to both note holders equal to the number of shares of common stock that the holders receive in connection with the converted notes. The per share exercise price of the warrants was set at 125% of the conversion price of the notes, defined in the note agreements, as the lower of (a) 75% of the price per share of common stock of the IPO or (b) $2.30. The Company determined that it would have to issue 109,038 warrants based upon the completion of the IPO in April 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 a derivative liability upon issuance. The aggregate fair value of the warrants was calculated as $436,034 based on a probability effected Black-Scholes option pricing model with a stock price of $4.00, volatility of 138%, and risk-free rates ranging from 2.34% - 2.39%. The Company recognized a debt discount of $250,000 equal to the face amount of the convertible notes and recorded a financing cost of $186,034 equal to the difference between the fair value of the warrants and the debt discount. See Note 10 for further discussion of the derivative liability.

The convertible notes and accrued interest with an aggregate balance of $250,788 were mandatorily converted into 109,038 shares of common stock based on a conversion price of $2.30 per share upon the consummation of the IPO in April 2019 and the valuation discount of $250,000 was recognized as interest cost.

9. 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 September 30, 2019, $11,751 remained on deposit under the lease agreement. The lease ("Lease 1") was renewed for an additional five years in 2018. As of September 30, 2019, remaining lease payments under the amended lease agreement average $12,959 per month through July 2023.

In connection with the VectorVision acquisition on September 29, 2017, the Company assumed a lease agreement for 5,000 square feet of office and warehouse space which commenced on October 1, 2017. The lease ("Lease 2") was renewed for an additional 65 months. As of June 30, 2019, remaining lease payments average $1,844 per month through February 2023.

In accounting for the leases, the Company adopted ASU 2016-02 - Leases, 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 $625,778 using a discount rate of 8.0%. the fair value of Lease 2 at the inception of the lease was $100,742 using a discount rate of 8%. During the nine months ended September 30, 2019, the Company made combined payments on both leases of $124,422 towards the lease liabilities. As of September 30, 2019 and December 31, 2018, the lease liability for Lease 1 was $510,496 and $586,082, respectively, and the lease liability for Lease 2 was $65,821 and $77,137, respectively. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. Combined rent expense for both leases for the nine months ended September 30, 2019 and 2018 was $130,742 and $137,600, respectively. During the nine months ended September 30, 2019 and 2018, the Company reflected amortization of right of use asset of $93,222 and $28,034 related to the leases, respectively, resulting in a net asset balance of $563,948 as of September 30, 2019.

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 September 30, 2019 with respect to such matters.

11. Stockholders' Equity (Deficit)

Common Stock

On April 9, 2019, the Company closed its initial public offering (the "IPO") and issued 1,250,000 shares of its common stock at a public offering price of $4.00 per share for total gross proceeds of $5.0 million pursuant to an underwriting agreement by and between the Company, WallachBeth Capital, LLC, and WestPark Capital, Inc., acting as the representatives. In connection with the IPO, two convertible promissory notes previously issued on March 15, 2019 and March 20, 2019 were automatically converted into 109,038 shares of common stock based on a conversion price of $2.30 per share. The Company also issued 109,038 warrants to the note holders with an exercise price of $2.88 per share. 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 upon issuance. On April 9, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the underwriters and affiliates in connection with the IPO. The Company accounted for these warrants as a derivative liability in the financial statements upon issuance because they were associated with a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. Net proceeds to the Company were $3,888,000 after deducting underwriting discounts, commissions, and other offering expenses. See Warrant Liability discussion below for additional details.

On August 15, 2019, the Company closed a second public offering consisting of (i) 12,000,000 shares of common stock, par value $0.001 per share, of the Company, (ii) pre-funded warrants exercisable for 1,000,000 shares of common stock, and (iii) warrants to purchase up to an aggregate of 13,000,000 shares of common stock pursuant to an underwriting agreement by and between the Company, Maxim Group LLC, and WallachBeth Capital LLC, acting as the representatives. On August 16, 2019, the Company sold an additional 1,950,000 Warrants upon exercise of the underwriters' over-allotment option. The public offering price was $0.44 per share of common stock, $0.43 per pre-funded warrant and $0.01 per accompanying warrant. On August 15, 2019, the Company issued 1,040,000 warrants with an exercise price of $0.50 per share to the underwriters in connection with the offering. Net proceeds to the Company were $4,944,340 after deducting underwriting discounts, commissions, and other offering expenses. See Warrants discussion below for additional details.

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, 2018	**1,265,674**	**0.71**	**0.29**
Granted	17,161,538	0.58	4.88
Forfeitures	-	-	-
Expirations	(279,424)	(1.83)	-
Exercised	(16,645,050)	(0.55)	-
September 30, 2019, all exercisable	**1,502,738**	**$ 0.92**	**4.65**

The exercise prices of warrants outstanding and exercisable as of September 30, 2019 are as follows:

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
1,040,000	$ 0.50
226,200	0.59
65,000	1.50
109,038	2.88
62,500	5.00
1,502,738	

During the nine months ended September 30, 2019, the Company granted 17,161,538 warrants to investors, consisting of (a) 171,538 warrants associated with our IPO financing in April 2019 (see Warrant Liability discussion below), and (b) 16,990,000 warrants associated with our August public offering, including pre-funded warrants exercisable for 1,000,000 shares of common stock, warrants to purchase up to an aggregate of 13,000,000 shares of common stock, warrants to purchase 1,950,000 shares of common stock upon the exercise of the underwriters' over-allotment option, and warrants to purchase 1,040,000 shares of common stock issued to the underwriters as representatives of the public offering.

The August pre-funded warrants were sold to purchasers whose purchase of shares of common stock in the offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of the Company's outstanding common stock immediately following the consummation of the offering, in lieu of shares of common stock. Each pre-funded warrant represents the right to purchase one share of common stock at an exercise price of $0.01 per share.

The August public offering price was $0.44 per share of common stock and $0.01 per accompanying warrant. Each warrant sold with the shares of common stock represents the right to purchase one share of common stock at an exercise price of $0.585 per share. The warrants are exercisable immediately, expire five years from the date of issuance and provide that, beginning on the earlier of (i) 30 days from the effective date of the Registration Statement and (ii) the date on which the Common Stock trades an aggregate of more than 40,000,000 shares after the announcement of the pricing of the offering, and ending on the twelve month anniversary thereof, each warrant may be exercised at the option of the holder on a cashless basis at a ratio of one warrant for one share of common stock, in whole or in part, if the weighted average price of the common stock on the trading day immediately prior to the exercise date fails to exceed the initial exercise price of the warrant.

During the nine months ended September 30, 2019, investors exercised a total of 16,645,050 warrants for 16,504,806 shares of common stock, consisting of (I) 15,356,300 warrants exercised on a cashless basis for 15,216,056 net common shares, and (II) 1,288,750 warrants exercised for a total of $154,375 in proceeds to the Company (1,000,000 of these warrants were exercisable for $0.01 per share, and 288,750 were exercisable for $0.50 per share).

During the nine months ended September 30, 2019, 279,424 warrants expired unexercised.

As of September 30, 2019, the Company had an aggregate of 1,502,738 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of $0.92, a weighted average remaining life of 4.65 years and an aggregate intrinsic value of $312,517, based upon a stock valuation of $0.762 per share. The intrinsic value is calculated as the difference between the market value of the underlying common stock and the exercise price of the warrants.

Warrant Liability

In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at the issuance date. 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 Company estimated that the issuance of 109,038 warrants with an exercise price of $2.88 per share would correspond to the number of shares of common stock that the holders would receive in connection with the completion of the IPO. The fair value of the warrants at issuance was determined to be $436,034, of which $250,000 was recorded as a valuation discount and $186,034 was recorded as a finance cost. Upon completion of the IPO, the exercise price and the number of warrants were fixed and the warrants are no longer accounted for as liabilities. The fair value of the warrants at the closing of the IPO was determined to be $359,683 using a Black-Scholes model with a weighted average remaining life of 4.94 years and a stock valuation of $3.30 per share, and such amount was reclassified to equity. During the period ended September 30, 2019, the Company recognized a change in warrant liability of $76,351 that was recorded in the accompanying statements of operations.

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 the date of issuance was determined to be $229,921 and was recorded as a finance cost. As of September 30, 2019, the fair value of the warrants was determined to be $47,118 and the change in fair value of $182,803 was recognized in the accompanying statements of operations.

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

	Convertible Noteholders Upon Issuance	Underwriter Upon Issuance	Warrant Liability As of September 30, 2019
Stock price	$ 4.00	$ 3.68	$ 0.76
Risk free interest rate	2.34 – 2.39%	2.29%	1.56%
Expected volatility	138%	137%	145%
Expected life in years	5.00	5.00	4.51
Expected dividend yield	0%	0%	0%
Number of warrants	109,038	62,500	62,500
Fair value of warrants	$ 436,034	$ 229,921	$ 47,118

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, 2018	**1,362,500**	**2.26**	**3.78**
Granted	1,350,000	4.11	4.56
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
September 30, 2019, outstanding	**2,712,500**	**$ 3.18**	**3.79**
September 30, 2019, exercisable	**1,520,833**	**$ 2.51**	**3.33**

The exercise prices of options outstanding and exercisable as of September 30, 2019 are as follows:

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
100,000	25,000	$ 0.54
625,000	625,000	2.00
62,500	62,500	2.30
675,000	600,000	2.50
1,250,000	208,333	4.40
2,712,500	**1,520,833**	

On April 9, 2019, the Company granted options to purchase 1,250,000 shares of common stock to the Company's Chairman and CEO with a grant date fair value of $4,122,750 and at a price per share of $4.40. The options vest on a quarterly basis over three years. On September 20, 2019, the Company granted options to purchase 100,000 shares of common stock to a consultant with a grant date fair value of $54,004 and at a price per share of $0.54. The options vest on an annual basis over three years. 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 period ended September 30, 2019, $1,807,491 of compensation expense was recognized relating the amortization of these awards.

During the nine months ended September 30, 2019, option awards were valued based upon the Black-Scholes option-pricing model, with stock prices ranging from $0.54 to $4.00 per share, volatility ranging from 115% to 145%, and an average risk-free rate ranging from 1.63% to 2.46%.

During the nine months ended September 30, 2019 and 2018, we recognized aggregate stock-compensation expense of $1,964,432 and $1,405,221, respectively, based upon stock prices ranging from $0.54 to $4.00 per share, all of which was recorded in general and administrative expense.

As of September 30, 2019, the Company had an aggregate of 1,191,667 remaining unvested options outstanding, with a total estimated fair value of $2,407,256, weighted average exercise price of $4.04, and weighted average remaining life of 4.38 years. The aggregate intrinsic value of options outstanding as of September 30, 2019 was $22,090.

12. Related Party Transactions

During the nine months ended September 30, 2019 and 2018, the Company incurred and paid $225,000 and $206,250, respectively, of salary expense to our Board Chairman and CEO, Mr. Michael Favish. In addition, compensation cost of $1,788,751 was recognized on amortization of stock option awards during the nine months ended September 30, 2019.

13. Subsequent Events

Public Offering

On October 30, 2019, the Company completed an underwritten public offering of 24,500,000 shares of its common stock (including 1,700,000 pre-funded warrants to purchase common stock in lieu thereof) and Series B warrants to purchase up to 24,500,000 shares of the Company's common stock. Each share of common stock (or pre-funded warrant) was sold together with one Series B warrant to purchase one share of common stock at a combined price to the public of $0.342 per share and Series B warrant. The shares of common stock or pre-funded warrants and the accompanying Series B warrants were sold together but will be issued separately and will be immediately separable upon issuance. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7.2 million.

As of October 30, 2019, the 1,700,000 pre-funded warrants, with an exercise price of $0.01 per warrant, have been exercised in full and the Company has received $17,000 in proceeds from exercise.

The Series B warrants are exercisable at a price of $0.342 per share of common stock and will expire five years from the date on which the Series B warrants become initially exercisable. Currently, Guardion does not have a sufficient number of authorized shares of common stock to issue the shares of common stock issuable upon the exercise of the Series B warrants. As a result, the Series B warrants will become exercisable only after Guardion effectuates an amendment to its certificate of incorporation to either (i) increase the number of authorized shares of its common stock or (ii) implement a reverse stock split with respect to the shares of its common stock. There can be no assurance that Guardion's stockholders will approve a charter amendment, or as to when, if ever, the, holders of the Series B warrants will be able to exercise the Series B warrants.

Maxim Group LLC and WallachBeth Capital, LLC are acting as joint-bookrunning managers in connection with the offering. Guardion also has granted to the underwriters a 45-day option to purchase up to an additional 3,675,000 shares of common stock and/or Series B warrants to purchase up to 3,675,000 shares of common stock, at the public offering price less discounts and commissions.

The following table sets forth the unaudited condensed consolidated balance sheet of the Company as of September 30, 2019 on an as reported basis and on an unaudited pro-forma basis giving effect to the issuance and sale of 22,800,000 shares of our common stock, pre-funded warrants to purchase 1,700,000 shares of common stock and warrants to purchase 24,500,000 shares of common stock, after deducting the underwriting discounts, commissions and offering expenses payable by us, and after all pre-funded warrants were exercised:

	Actual As Reported	**Pro Forma**
	(Unaudited)	(Unaudited)
Cash and cash equivalents	$ 5,554,960	$ 12,749,850
Other current assets	576,666	576,666
Non-current assets	2,823,420	2,823,420
Total assets	$ 8,955,046	$ 16,149,936
Current liabilities	$ 458,922	$ 458,922
Lease liability – long term	447,292	447,292
Total liabilities	906,214	906,214
Stockholders' equity:		
Common stock, $0.001 par value; 90,000,000 shares authorized; 50,482,562 issued and outstanding as reported, and 74,982,562 shares on a proforma basis	50,483	74,983
Additional paid-in capital	49,454,265	56,624,655
Accumulated deficit	(41,455,916)	(41,455,916)
Total stockholders' equity	8,048,832	15,243,722
Total liabilities and stockholders' equity	$ 8,955,046	$ 16,149,936

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, 2018, and the notes thereto, which are set forth in the 2018 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 formed to develop, formulate and distribute condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that is designed to replenish and restore the macular protective pigment. A depleted macular protective pigment is a modifiable risk factor for retina-based diseases such as age-related macular degeneration ("AMD"), computer vision syndrome ("CVS") and diabetic retinopathy. The Company believes this risk may be modified by taking Lumega-Z to maintain a healthy macular protective pigment. Additional research has also shown a depleted macular protective pigment to be a biomarker for neurodegenerative diseases such as Alzheimer's disease and dementia.

The Company invented a proprietary technology, embodied in the Company's medical device, the MapcatSF® that accurately measures the macular pigment optical density ("MPOD"). On November 8, 2016, the United States Patent and Trademark Office ("USPTO") issued patent number 9,486,136 for the MapcatSF invention. Using the MapcatSF to measure the MPOD allows one to monitor the increase in the density of the macular protective pigment after taking Lumega-Z. The MapcatSF is a non-mydriatic, non-invasive device that accurately measures the MPOD, the lens optical density and lens equivalent age, thereby creating an evidence-based protocol that is shared with the patient. A non-mydriatic device is one that does not require dilation of the pupil for it to function. The MapcatSF is the first medical device using a patented "single fixation" process and "automatic lens density correction" that produces accurate serialized data.

In September 2017, the Company, through its wholly-owned subsidiary VectorVision Ocular Health, Inc. ("VectorVision"), 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 ("ETDRS") visual acuity testing. VectorVision's standardization system is designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing for use by eye doctors in clinical trials, for real-world vision evaluation, and industrial vision testing. The acquisition expanded the Company's technical portfolio. CSV-1000 and CSV-3000 instruments offer auto-calibrated tests to ensure correct testing luminance and contrast levels for consistent, highly accurate and repeatable results. Recently issued patents the Company received for continuously calibrating the light source, an automated standardization technology the Company refers to as AcQviz™, are expected to be incorporated into the new CSV-2000, in which the proprietary standardized contrast sensitivity test patterns can be presented to the patient using a computer monitor as opposed to the current calibrated backlit system. The Company believes the acquisition of VectorVision further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). TDSI is dedicated to the pursuit of early predictors resulting in, the Company believes, valuable therapeutic intervention for practitioners and their patients, and additional revenue streams generated from the testing and sale of Company products to appropriate customers. The Company has established operations with selected clinics and is focusing on expanding its client base.

In November 2018, the Company launched a new medical food product, GlaucoCetin™, which the Company believes is the first vision-specific medical food designed to support and protect the mitochondrial function of optic nerve cells and improve blood flow in the ophthalmic artery in patients with glaucoma.

In September 2019, the Company, through its wholly owned subsidiary NutriGuard Formulations, Inc., acquired the nutraceuticals business from NutriGuard Research, Inc. See "Recent Developments" below. Pursuant to the Asset Purchase Agreement, the Company purchased specified assets of the NutriGuard brand and business, primarily consisting of inventory, trademarks, copyrights and other intellectual property. Once developed, the NutriGuard Formulations nutraceutical product line should provide the Company a new direct-to-consumer ("DTC") capability. The Company intends to build a portfolio of nutraceutical products under the NutriGuard brand by developing new formulations and marketing its products to patients directly through DTC channels and through recommendations by their physicians.

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

By combining the MapcatSF medical device, the newly acquired VectorVision standardized vision testing technology and Lumega-Z medical food, the Company has developed, based on Management's knowledge of the industry, what it believes to be the only reliable three-pronged, evidence-based protocol for replenishing and restoring the macular protective pigment, increasing overall retinal health and measuring the related improvements in visual function.

Recent Developments

Initial Public Offering

On April 9, 2019, the Company closed its initial public offering (the "IPO") of 1,250,000 shares of common stock, par value $0.001 per share, at an IPO price to the public of $4.00 per share resulting in net proceeds to the Company of $3,888,000 after all costs and expenses. The shares began trading on the NASDAQ Capital Market on April 5, 2019 under the symbol "GHSI."

Follow-On Public Offerings

On August 15, 2019, the Company completed a second public offering (the "August Offering") of (i) 12,000,000 shares of common stock, (ii) pre-funded warrants exercisable for 1,000,000 shares of common stock (the "Pre-Funded Warrants"), and (iii) warrants to purchase up to an aggregate of 13,000,000 shares of common stock (the "August Warrants"). The August Offering was conducted pursuant to an Underwriting Agreement, dated August 13, 2019 by and between the Company and Maxim Group LLC and WallachBeth Capital, LLC. On August 16, 2019, the Company sold an additional 1,950,000 August Warrants upon exercise of the underwriters' over-allotment option. The net proceeds to the Company from the August Offering, after deducting underwriting discounts and commissions and other estimated expenses were $4,944,340.

The public offering price was $0.44 per share of common stock and $0.01 per accompanying August Warrant. Each August Warrant represents the right to purchase one share of common stock at an exercise price of $0.585 per share. The August Warrants are exercisable immediately, expire five years from the date of issuance and provide that, beginning on the earlier of (i) September 11, 2019 and (ii) the date on which the common stock traded an aggregate of more than 40,000,000 shares after the announcement of the pricing of the August Offering, and ending on the twelve (12) month anniversary thereof, each August Warrant may be exercised at the option of the holder on a cashless basis at a ratio of one August Warrant for one share of common stock, in whole or in part, if the weighted average price of the Common Stock on the trading day immediately prior to the exercise date fails to exceed the initial exercise price of the August Warrant. As of November 13, 2019, 1,000,000 August Pre-Funded Warrants have been exercised for proceeds of $10,000 and 14,723,800 August Warrants have been exercised on a cashless basis, and the Company has issued an aggregate of 15,723,800 shares of common stock upon such exercises.

On October 30, 2019, the Company completed a third public offering of 24,500,000 shares of its common stock (including 1,700,000 pre-funded warrants to purchase common stock in lieu thereof) and Series B warrants to purchase up to 24,500,000 shares of the Company's common stock. Each share of common stock (or pre-funded warrant) was sold together with one Series B warrant to purchase one share of common stock at a combined price to the public of $0.342 per share and Series B warrant. The shares of common stock or pre-funded warrants and the accompanying Series B warrants were sold together but will be issued separately and will be immediately separable upon issuance. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7.2 million.

The Series B warrants are exercisable at a price of $0.342 per share of common stock and will expire five years from the date on which the Series B warrants become initially exercisable. Currently, Guardion does not have a sufficient number of authorized shares of common stock to issue the shares of common stock issuable upon the exercise of the Series B warrants. As a result, the Series B warrants will become exercisable only after Guardion effectuates an amendment to its certificate of incorporation to either (i) increase the number of authorized shares of its common stock or (ii) implement a reverse stock split with respect to the shares of its common stock. There can be no assurance that Guardion's stockholders will approve a charter amendment, or as to when, if ever, the, holders of the Series B warrants will be able to exercise the Series B warrants.

Maxim Group LLC and WallachBeth Capital, LLC are acting as joint-bookrunning managers in connection with the offering. Guardion also has granted to the underwriters a 45-day option to purchase up to an additional 3,675,000 shares of common stock and/or Series B warrants to purchase up to 3,675,000 shares of common stock, at the public offering price less discounts and commissions.

NutriGuard Acquisition

Effective September 20, 2019 (the "Effective Date"), the Company's newly-formed wholly-owned subsidiary, NutriGuard Formulations, Inc., a Delaware corporation ("Buyer"), entered into an asset purchase agreement (the "Asset Purchase Agreement") with NutriGuard Research, Inc., a California corporation ("NutriGuard"), and NutriGuard's sole shareholder, Mark McCarty (the "NutriGuard Acquisition").

Pursuant to the Asset Purchase Agreement, Buyer purchased from NutriGuard specified assets of the NutriGuard brand and business, primarily consisting of inventory, trademarks, copyrights and other intellectual property. In exchange, Buyer agreed to pay a royalty fee to NutriGuard subsequent to meeting certain financial performance metrics based on the operating results of the NutriGuard brand of products following the Effective Date. NutriGuard and Mr. McCarty also agreed, among other terms, to no longer use the "NutriGuard" name upon the Effective Date.

In addition, on the Effective Date, the Company and Mr. McCarty entered into a consulting agreement (the "Consulting Agreement") with Buyer pursuant to which Mr. McCarty will provide consulting services to, and serve as the Director of Research of, Buyer. Additionally, the Company granted to Mr. McCarty stock options to purchase 100,000 shares of the Company's common stock, exercisable at a price of $0.5411 per share (which was the closing price of the Company's common stock on the Effective Date). The options were granted under the terms of the Company's 2018 Equity Incentive Plan, which options vest as follows: 25% on the Effective Date, 25% on the first anniversary following the Effective Date, 25% on the second anniversary following the Effective Date, and 25% on the third anniversary following the Effective Date. The vested portion of the options may be exercised at any time prior to the earliest to occur of: (a) the 5th anniversary of the Effective Date; (b) 90 days following the termination of the Consulting Agreement for any reason other than "for cause"; (c) 6 months following termination of the Consulting Agreement due to Mr. McCarty's death or disability; or (iv) in the event of a termination of Mr. McCarty "for cause" under the Consulting Agreement.

Patents

On October 29, 2019, the USPTO issued US Patent No. 10,456,028 as the second patent covering inventions embodied in the MapcatSF®. Prior to the issuance of US Patent No. 9,486,136, the Company filed a continuation application, Patent Application 15/346,010, covering new embodiments around the MapcatSF®device. These new embodiments contain improvements related to the accuracy of intensity measurements made with the device, as well as new patentably distinct features around photodiode detector calibrations. This patent application has now issued as US Patent No. 10,456,028.

Going Concern

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of $6,822,553 and utilized cash in operating activities of $4,189,050 during the nine months ended September 30, 2019. 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, 2018. 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 continued commercialization activities related to Lumega-Z, the MapcatSF® medical device, VectorVision products, the TDSI business, the new NutriGuard line of nutraceuticals 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. On April 9, 2019, the Company completed the IPO, resulting in net cash proceeds of $3,888,000 to the Company. 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.

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 has been provided an initial period of 180 calendar days, or until March 18, 2020 (the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180-day period, the closing bid price of the Company's common stock is at least $1.00 for a minimum of 10 consecutive business days, the Staff will provide the Company written confirmation of compliance with the Minimum Bid Price Requirement and the matter will be closed. If the Company does not regain compliance by the Compliance Date, the Company may be eligible for an additional 180 calendar day compliance period. To qualify for such additional compliance period, the Company would have to meet the continued listing requirements of the NASDAQ Capital Market, except for the Minimum Bid Price Requirement, and the Company would need to provide written notice of its intention to cure the deficiency during the additional compliance period. If the Company is not eligible for the additional compliance period or it appears to the Staff that the Company will not be able to cure the deficiency or if the Staff exercises its discretion to not provide such additional compliance period, the Staff will provide written notice to the Company that its common stock will be subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Hearing Panel.

Reverse Stock Split

On January 30, 2019, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Amended Certificate of Incorporation, as amended (the "Amendment"), with the Secretary of State of the State of Delaware to effectuate a one-for-two (1:2) reverse stock split (the "Reverse Stock Split") of its common stock, par value $0.001 per share, without any change to its par value. The Amendment became effective on the filing date. The number of shares authorized for common and preferred 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. Proportional adjustments for the Reverse Stock Split were made to the Company's outstanding common stock, stock options, and warrants as if the split occurred at the beginning of the earliest period presented.

Recent Accounting Pronouncements

See Note 2 to the condensed consolidated financial statements for the period ended September 30, 2019 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.

Intangible Assets

In connection with the VectorVision transaction, the Company identified and allocated estimated fair values to intangible assets including goodwill and customer relationships.

In accordance with Accounting Standard Codification ("ASC") 350 – Intangibles – Goodwill and Other, the Company determined whether these assets are expected to have indefinite (such as goodwill) or limited useful lives, and for those with limited lives, the Company established an amortization period and method of amortization. The Company's goodwill and other intangible assets are subject to periodic impairment testing.

The Company utilized the services of an independent third-party valuation firm to assist it in identifying intangible assets and in estimating their fair values. The useful lives for its intangible assets other than goodwill were estimated based on Management's consideration of various factors, including assumptions that market participants might use about sales expectations as well as potential effects of obsolescence, competition, technological progress and the regulatory environment. Because the future pattern in which the economic benefits of these intangible assets may not be reliably determined, amortization expense is generally calculated on a straight-line basis.

The Company reviews all intangible assets for impairment when circumstances indicate that their carrying values may not be recoverable. If the carrying value of an asset group is not recoverable, the Company recognizes an impairment loss for the excess carrying value over the fair value in its consolidated statements of operations. As of September 30, 2019 and December 31, 2018, the Company was not aware of the existence of any indicators of impairment of its intangibles at such dates.

Goodwill

Goodwill represents the excess of the purchase consideration over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. The Company evaluates goodwill for impairment on an annual basis or whenever events and changes in circumstances suggest that the carrying amount may not be recoverable. The Company conducts its annual impairment analysis in the beginning of the fourth quarter of each fiscal year. Impairment of goodwill is tested at the reporting unit level by comparing the reporting unit's carrying amount, including goodwill, to the fair value of the reporting unit. Estimations and assumptions regarding the number of reporting units, future performances, results of the Company's operations and comparability of its market capitalization and net book value will be used. If the carrying amount of the reporting unit exceeds its fair value, goodwill is considered impaired and an impairment loss is measured by the resulting amount. As of September 30, 2019 and December 31, 2018, the Company was not aware of the existence of any indicators of impairment of its goodwill at such dates.

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, and employees, which include grants of employee stock options, are recognized in the financial statements based on their fair values. 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.

In prior periods, the Company accounted for stock option and warrant grants issued and vesting to non-employees in accordance with the authoritative guidance of the FASB whereas the value of the stock compensation is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. On January 1, 2019, the Company adopted Accounting Standards Update (ASU) 2018-07 which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Non-employee stock-based compensation charges generally are amortized over the vesting period using a graded vesting basis. In certain circumstances where there are no future performance requirements by the non-employee, grants are immediately vested and the total stock-based compensation charge is recorded in the period of the measurement date.

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. Until the Company has established a trading market for its common stock, estimated volatility is based on the average historical volatilities of comparable public companies in a similar industry. The expected dividend yield is based on the current yield at the grant date. The Company has never declared or paid dividends on its common stock and has no plans to do so for the foreseeable future.

The fair value of common stock was determined based on management's judgment. Due to the availability of historical data from the Company's recent preferred stock sales, Management used a valuation of $1.15 for accounting purposes during the first six months of 2018. Management used a valuation $4.00 for the first quarter of 2019. Management considered business and market factors affecting the Company during these periods, including capital raising efforts, its proprietary technology, and other factors. Based on this evaluation, management believes that its valuations are appropriate for accounting purposes during these periods. Closing prices of our common stock ranging from $1.26 to $3.30 were used in our fair value calculations during the second quarter of 2019.

The Company recognizes the fair value of stock-based compensation within its statements of operations with classification depending on the nature of the services rendered.

Plan of Operations

General Overview

Based on the availability of sufficient funding, the Company intends to increase its commercialization activities and:

- further the commercial production of the MapcatSF;
- expand the Company's domestic sales and marketing efforts;
- explore sales and marketing opportunities in foreign markets such as Asia and Europe;
- increase production of Lumega-Z and GlaucoCetin™ to support the additional sales resulting from the deployment of additional MapcatSF units and increased marketing and promotional activity;
- commence certain FDA electrical safety testing of the MapcatSF;
- increase focus on intellectual property protection and strategy;
- expand the sales and marketing of the VectorVision product line;
- develop the TDSI business and operations;
- explore opportunities and channels to enter the expansive market opportunity in China for non-pharmacologic treatments of macular degeneration, glaucoma and diabetic retinopathy; and
- increase the existing NutriGuard customer base through NutriGuard Formulations, Inc. and build on its product platform by making NutriGuard products available to customers directly through direct-to-consumer (DTC) channels and through recommendations by their physicians.

The FDA and other regulatory bodies require electronic medical devices to comply with IEC 60601 standards. The International Electrical Commission ("IEC") established technical standards for the safety and effectiveness of medical electrical equipment. Adherence to these standards is required for commercialization of electrical medical equipment. As a medical device powered by electricity, the MapcatSF will need to undergo testing to demonstrate compliance with the IEC 60601 standards. This testing is typically conducted by a Nationally Recognized Testing Laboratory ("NRTL"), which is an independent laboratory recognized by the Occupational Safety and Health Administration ("OSHA") to test products to the specifications of applicable product safety standards. The Company is in discussions with its contract manufacturer of the MapcatSF to engage an NRTL at the appropriate juncture prior to commercialization of the MapcatSF. The relevant predicate device for the MapcatSF is the MPS II, the applicable Class I product code for the MapcatSF is HJW and the applicable Code of Federal Regulation is 886.1050. The FDA does not require test documents to be submitted to the FDA for a Class I medical device, but that the evidence of such testing be placed in a Design History file and be kept internally at the company or manufacturer and readily available should the FDA or other regulatory bodies request to review the testing documents. While the FDA does not require that a Class I medical device have formal validation, the Company expects to complete applicable IEC 60601-1 testing prior to commercialization because the Company believes in marketing a product that has evidence that it is safe and effective.

Results of Operations

Through September 30, 2019, the Company had limited operations and 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 both medical foods and medical diagnostic equipment for the treatment of various eye diseases. The Company had limited revenue during the nine months ended September 30, 2019 and 2018.

Comparison of Three Months Ended September 30, 2019 and 2018

	Three Months Ended September 30,		Change	
	2019	**2018**	**Change**	
Revenue	$ 161,162	$ 294,230	$ (133,068)	(45)%
Cost of goods sold	70,999	125,406	(54,407)	(43)%
Gross Profit	90,163	168,824	(78,661)	(47)%
Operating Expenses:				
Research and development	31,897	4,793	27,104	566%
Sales and marketing	448,387	240,028	208,359	87%
General and administrative	2,022,367	1,064,645	957,722	90%
Total Operating Expenses	2,502,651	1,309,466	1,193,185	91%
Loss from Operations	(2,412,488)	(1,140,642)	(1,271,846)	112%
Other Expense:				
Interest expense	4,205	545	3,660	672%
Change in fair value of derivative warrants	(31,322)	-	(31,322)	100%
Costs associated with extension of warrant expiration dates	-	1,007,006	(1,007,006)	(100)%
Net Loss	$ (2,385,371)	$ (2,148,193)	$ (237,178)	11%

Revenue

For the three months ended September 30, 2019, revenue from product sales was $161,162 compared to $294,230 for the three months ended September 30, 2018, resulting in a decrease of $133,068 or 45%. The decrease can be attributed primarily to a reduction in sales of the Vector Vision CSV-1000 product in the third quarter of 2019 as compared to the prior periods 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 and anticipates sales of the next generation device to commence during the fourth quarter of 2019.

Cost of Goods Sold

For the three months ended September 30, 2019, cost of goods sold was $70,999 compared to $125,406 for the three months ended September 30, 2018, resulting in a decrease of $54,407 or 43%. The decrease reflects the VectorVision product transition noted above.

Gross Profit

For the three months ended September 30, 2019, gross profit was $90,163 compared to $168,824 for the three months ended September 30, 2018, resulting in a decrease of $78,661 or 47% due to the VectorVision product transition noted above. Gross profit represented 56% of revenues the three months ended September 30, 2019, versus 57% of revenue for the three months ended September 30, 2018.

Research and Development

For the three months ended September 30, 2019, research and development costs were $31,897 compared to $4,793 for the three months ended September 30, 2018, resulting in an increase of $27,104 or 566%. The increase was due to engineering development costs associated with the Company's CSV-2000 product in 2019.

Sales and Marketing

For the three months ended September 30, 2019, sales and marketing expenses were $448,387 compared to $240,028 for the three months ended September 30, 2018. The increase in sales and marketing expenses of $208,359 or 87% compared to the prior period was primarily due to increased labor costs of approximately $43,000 as well as an increase of approximately $143,000 due to marketing, website development, professional services, and trade show expenses in the current quarter.

General and Administrative

For the three months ended September 30, 2019, general and administrative expenses were $2,022,367 compared to $1,064,645 for the three months ended September 30, 2018. The increase of $957,722 or 90% compared to the prior period was primarily due to an increase in non-cash stock compensation costs during the current period of approximately $429,000. Consulting, professional services, and investor relations costs increased approximately $203,000 in the current period, legal fees increased approximately $259,000, and corporate insurance costs rose approximately $86,000.

Interest Expense

For the three months ended September 30, 2019, interest expense was $4,205 compared to $545 for the three months ended September 30, 2018. The increase of 3,660 compared to the prior period was due primarily to financing costs associated with corporate insurance coverage. There were no such costs for the comparable period in 2018.

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 $229,291 and was recorded as a finance cost. As of September 30, 2019, the fair value of the warrant liability was determined to be $47,118 and the Company recorded a change in fair value of derivative warrants of $31,322 in the Statements of Operations.

Costs Associated with Extension of Warrant Expiration Dates

During September 2018, the Company extended warrants to purchase shares of common stock of the Company that were scheduled to expire at dates ranging from September 30, 2018 through January 25, 2019 held by two stockholders. The Company recognized expense of $1,007,006 relating to the extension of the exercise period of the warrants using a Black-Scholes option-pricing model to estimate fair value.

Net Loss

For the three months ended September 30, 2019, the Company incurred a net loss of $2,385,371, compared to a net loss of $2,148,193 for the three months ended September 30, 2018. The increase in net loss of $237,178 or 11% compared to the prior year period was primarily due to an increase in non-cash stock compensation costs of approximately $429,000. In addition, expenses for corporate insurance, investor relations, consulting, legal and professional fees have increased versus the prior period. The increases were partially offset by warrant exercise period extension costs in 2018 that were not incurred in the current period.

Segment Information

As of September 30, 2019, Management reported its operating results in two operating segments: Medical Foods, and Vision Testing Diagnostics. As of September 30, 2019, the TDSI subsidiary does not meet the required quantitative criteria to be considered a reportable operating segment.

i. *Medical Foods* – Our Medical Foods segment develops, formulates and distributes condition-specific medical foods with an initial medical food product on the market under the brand name Lumega-Z® that replenishes and restores the macular protective pigment. We have also invented a proprietary technology, embodied in a medical device, the MapcatSF,® that accurately measures the macular pigment optical density ("MPOD"). Using the MapcatSF to measure the MPOD allows one to monitor the increase in the density of the macular protective pigment after taking Lumega-Z. The Company has also developed a new medical food product, GlaucoCetin™, which the Company believes is the first vision-specific medical food designed to support and protect the mitochondrial function of optic nerve cells and improve blood flow in the ophthalmic artery in patients with glaucoma. GlaucoCetin™ combines a unique set of ingredients, specifically designed to stop or potentially reverse the underlying cause of optic nerve loss, and ultimately vision loss, in patients with glaucoma.

ii. *Vision Testing Diagnostics* – Our Vision Testing Diagnostics segment, under the brand name VectorVision, specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and early treatment diabetic retinopathy study ("ETDRS") visual acuity testing. VectorVision's standardization system is designed to provide the practitioner or researcher with the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing for use by eye doctors in clinical trials, for real-world vision evaluation, and industrial vision testing.

The following tables set forth our results of operations by segment (results allocated to Other consist of non-cash stock compensation expense, depreciation and amortization, corporate legal fees, and the TDSI operations):

	For the Three Months Ended September 30, 2019			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ 3,500	$ 112,957	$ 44,705	$ 161,162
Cost of goods sold	1,422	41,655	27,922	70,999
Gross profit	2,078	71,302	16,783	90,163
Operating expenses	1,235,389	1,124,462	142,800	2,502,651
Loss from operations	**$ (1,233,311)**	**$ (1,053,160)**	**$ (126,017)**	**$ (2,412,488)**

	For the Three Months Ended September 30, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 86,082	$ 208,148	$ 294,230
Cost of goods sold	-	37,076	88,330	125,406
Gross profit	-	49,006	119,818	168,824
Operating expenses	623,791	574,974	110,701	1,309,466
Loss from operations	**$ (623,791)**	**$ (525,968)**	**$ 9,117**	**$ (1,140,642)**

Revenue

For the three months ended September 30, 2019, revenue from our Medical Foods segment was $112,957 compared to $86,082 for the three months ended September 30, 2018, resulting in an increase of $26,875 or 31%. The increase reflects an increased customer base for Lumega-Z as the Company expands into new clinics. For the three months ended September 30, 2019, revenue from our Vision Testing Diagnostics segment was $44,705 compared to $208,148 for the three months ended September 30, 2018, resulting in a decrease of $163,443 or 79%. The decrease is due to the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device. The Company anticipates sales of the next generation CSV-2000 device to commence during the fourth quarter of 2019. The Company also earned $3,500 in diagnostic imaging services revenue from its TDSI business during the three months ended June 30, 2019, as shown in the Other category above.

Cost of Goods Sold

For the three months ended September 30, 2019, cost of goods sold from our Medical Foods segment was $41,655 compared to $37,076 for the three months ended September 30, 2018, resulting in an increase of $4,579 or 12% that corresponds to the increase in Medical Foods revenue. For the three months ended September 30, 2019, cost of goods sold from our Vision Testing Diagnostics segment was $27,922 compared to $88,330 for the three months ended September 30, 2018, resulting in a decrease of $60,408 or 68%. The decrease reflects the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device.

Gross Profit

For the three months ended September 30, 2019, gross profit from the Medical Foods segment was $71,302 compared to $49,006 for the three months ended September 30, 2018, resulting in an increase of $22,296 or 45%. For the three months ended September 30, 2019, gross profit from the Vision Testing Diagnostics segment was $16,783 compared to $119,818 for the three months ended September 30, 2018, resulting in a decrease of $103,035 or 86%. The overall decrease is due primarily to the transition of sales efforts away from our VectorVision CSV-1000 device. Gross profit overall represented 56% of revenues for the three months ended September 30, 2019, versus 57% of revenue for the three months ended June 30, 2018.

Comparison of Nine Months Ended September 30, 2019 and 2018

	Nine Months Ended September 30,			
	2019	**2018**	**Change**	
Revenue	$ 664,669	$ 708,047	$ (43,378)	(6)%
Cost of goods sold	261,547	292,461	(30,914)	(11)%
Gross Profit	403,122	415,586	(12,464)	(3)%
Operating Expenses:				
Research and development	138,613	199,500	(60,887)	(31)%
Sales and marketing	1,246,846	1,224,491	22,355	2%
General and administrative	5,427,573	3,779,325	1,648,248	44%
Total Operating Expenses	6,813,032	5,203,316	1,609,716	31%
Loss from Operations	(6,409,910)	(4,787,730)	(1,622,180)	34%
Other Expense:				
Interest expense	255,842	2,090	253,752	12,141%
Finance cost upon issuance of warrants	415,955	-	415,955	100%
Change in fair value of derivative warrants	(259,154)	-	(259,154)	(100)%
Costs associated with extension of warrant expiration dates	-	1,501,397	(1,501,397)	(100)%
Net Loss	$ (6,822,553)	$ (6,291,217)	$ (531,336)	8%

Revenue

For the nine months ended September 30, 2019, revenue from product sales was $664,669 compared to $708,047 for the nine months ended September 30, 2018, resulting in a decrease of $43,378 or 6%. The decrease is primarily 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 and anticipates sales of the next generation CSV-2000 device to commence during the fourth quarter of 2019.

Cost of Goods Sold

For the nine months ended September 30, 2019, cost of goods sold was $261,547 compared to $292,461 for the nine months ended September 30, 2018, resulting in a decrease of $30,914 or 11%. The decrease reflects the VectorVision product transition noted above.

Gross Profit

For the nine months ended September 30, 2019, gross profit was $403,122 compared to $415,586 for the nine months ended September 30, 2018, resulting in a decrease of $12,464 or 3% due to the VectorVision product transition noted above. Gross profit represented 61% of revenues for the nine months ended September 30, 2019, versus 59% of revenue for the nine months ended September 30, 2018.

Research and Development

For the nine months ended September 30, 2019, research and development costs were $138,613 compared to $199,500 for the nine months ended September 30, 2018, resulting in a decrease of $60,887 or 31%. The decrease was due to reduced engineering development costs associated with the Company's MapcatSF medical device during 2019 partially offset by engineering costs associated with the Company's CSV-2000 product.

Sales and Marketing

For the nine months ended September 30, 2019, sales and marketing expenses were $1,246,846 compared to $1,224,491 for the nine months ended September 30, 2018. The increase in sales and marketing expenses of $22,355 or 2% compared to the prior period was primarily due to increased labor costs of approximately $123,000, trade show costs of approximately $94,000 as well as increases in professional services and website development of approximately $77,000. The increases were largely offset by the cancellation of a third-party contract sales agreement in the second quarter of 2018.

General and Administrative

For the nine months ended September 30, 2019, general and administrative expenses were $5,427,573 compared to $3,779,325 for the nine months ended September 30, 2018. The increase of $1,648,248 or 44% compared to the prior period was primarily due to an increase in non-cash stock compensation costs during the current period of approximately $683,000. Consulting, professional services, and investor relations costs increased approximately $348,000 in the current period, legal fees increased approximately $220,000, corporate insurance costs rose approximately $178,000, and travel costs increased approximately $154,000.

Interest Expense

For the nine months ended September 30, 2019, interest expense was $255,842 compared to $2,090 for the nine months ended September 30, 2018. The increase of $253,752 compared to the prior period was due primarily to the amortization of the debt discount associated with March 2019 convertible notes for $250,000 that were converted to equity in April of 2019. There were no such costs for the comparable period in 2018.

Finance Cost Upon Issuance of Warrants

Finance costs for the nine months ended September 30, 2019 of $415,955 include the following; (a) In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at March 31, 2019. The fair value of the warrants at the closing of the IPO was determined to be $436,034, of which $250,000 was recorded as a valuation discount, and $186,034 was recorded as a finance cost. (b) On April 4, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants at the date of issuance was determined to be $229,921 and was recorded as a finance cost. There were no such costs for the comparable period in 2018.

Change in Fair Value of Derivative Warrants

The change in fair value of the derivative warrant liability was a decrease of $259,154 for the nine months ended September 30, 2019 and includes the following:

(I) In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at March 31, 2019 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. As such the fair value of the warrant liability of $359,683 was reclassified to equity and the remaining liability of $76,351 was recorded as a change in fair value of derivative liabilities in the Statements of Operations.

(II) On April 4, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements 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. As of September 30, 2019, the fair value of the warrant liability was determined to be $47,118 and the Company recorded a change in fair value of derivative warrants of $182,803 in the Statements of Operations. There were no such costs for the comparable period in 2018.

Costs Associated with Extension of Warrant Expiration Dates

During April, May and September of 2018, the Company and certain stockholders who held warrants to purchase shares of common stock of the Company that were scheduled to expire at various dates in 2018 and early 2019 extended the termination dates of such warrants. The Company recognized expense of $1,501,397 relating to the extension of the exercise period of the warrants using a Black-Scholes option-pricing model to estimate fair value.

Net Loss

For the nine months ended September 30, 2019, the Company incurred a net loss of $6,822,553, compared to a net loss of $6,291,217 for the nine months ended September 30, 2018. The increase in net loss of $531,336 or 8% compared to the prior year period was primarily due to an increase in non-cash stock compensation costs of approximately $683,000. In addition, expenses for corporate insurance, investor relations, labor, legal and professional fees, and travel have increased versus the prior period but were offset by the elimination of costs associated with engagement of a third-party contract sales organization in 2018 as well as non-cash costs associated with the extension of warrant expiration dates in 2018.

Segment Information

The following tables set forth our results of operations by segment (results allocated to Other consist of non-cash stock compensation expense, depreciation and amortization, corporate legal fees, and the TDSI operations):

	For the Nine Months Ended September 30, 2019			
	Other	**Medical Foods**	**Vision Testing Diagnostics**	**Total**
Revenue	$ 9,800	$ 317,338	$ 337,531	$ 664,669
Cost of goods sold	3,981	120,608	136,958	261,547
Gross profit	5,819	196,730	200,573	403,122
Operating expenses	3,195,227	3,127,782	490,023	6,813,032
Loss from operations	**$ (3,189,408)**	**$ (2,931,052)**	**$ (289,450)**	**$ (6,409,910)**

	For the Nine Months Ended September 30, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 238,213	$ 469,834	$ 708,047
Cost of goods sold	-	110,462	181,999	292,461
Gross profit	-	127,751	287,835	415,586
Operating expenses	2,126,939	2,801,924	274,453	5,203,316
Loss from operations	**$ (2,126,939)**	**$ (2,674,173)**	**$ 13,382**	**$ (4,787,730)**

Revenue

For the nine months ended September 30, 2019, revenue from our Medical Foods segment was $317,338 compared to $238,213 for the nine months ended September 30, 2018, resulting in an increase of $79,125 or 33%. The increase reflects an increased customer base for Lumega-Z as the Company expands into new clinics. For the nine months ended September 30, 2019, revenue from our Vision Testing Diagnostics segment was $337,531 compared to $469,834 for the nine months ended September 30, 2018, resulting in a decrease of $132,303 or 28%. The decrease was due to the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device. The Company anticipates sales of the next generation CSV-2000 device to commence during the fourth quarter of 2019. The Company also earned $9,800 in diagnostic imaging services revenue from its TDSI business during the nine months ended September 30, 2019, as shown in the Other category above.

Cost of Goods Sold

For the nine months ended September 30, 2019, cost of goods sold from our Medical Foods segment was $120,608 compared to $110,462 for the nine months ended September 30, 2018, resulting in an increase of $10,146 or 9% that corresponds to the increase in Medical Foods revenue. For the nine months ended September 30, 2019, cost of goods sold from our Vision Testing Diagnostics segment was $136,958 compared to $181,999 for the nine months ended September 30, 2018, resulting in a decrease of $45,041 or 25%. The decrease reflects the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device.

Gross Profit

For the nine months ended September 30, 2019, gross profit from the Medical Foods segment was $196,730 compared to $127,751 for the nine months ended September 30, 2018, resulting in an increase of $68,979 or 54%. The increase reflects an increased customer base for Lumega-Z. For the nine months ended September 30, 2019, gross profit from the Vision Testing Diagnostics segment was $200,573 compared to $287,835 for the nine months ended September 30, 2018, resulting in a decrease of $87,262 or 30%. The decrease is due to the transition of sales efforts away from our VectorVision CSV-1000 device. Gross profit overall represented 61% of revenues for the nine months ended September 30, 2019, versus 59% of revenue for the nine months ended September 30, 2018.

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 lead product Lumega-Z, its MapcatSF medical device, its new medical food, GlaucoCetin™, and VectorVision's new CSV-2000 and AcQviz™ devices. As a result of these and other activities, the Company utilized cash in operating activities of $4,189,050 during the nine months ended September 30, 2019. The Company had working capital of $5,672,704 at September 30, 2019. As of September 30, 2019, the Company had cash in the amount of $5,554,960 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 stocks.

On October 30, 2019, the Company completed an underwritten public offering of 24,500,000 shares of its common stock (including 1,700,000 pre-funded warrants to purchase common stock in lieu thereof) and Series B warrants to purchase up to 24,500,000 shares of the Company's common stock. Net proceeds, after deducting underwriting discounts, commissions and offering expenses, were approximately $7.2 million. The Company's pro-form cash balance as of September 30, 2019, after including this offering on a net basis, would have been approximately $12.7 million.

The financial statements have been prepared assuming the Company will continue as a going concern. 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, 2018. 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 continued commercialization activities related to Lumega-Z, the MapcatSF medical device, VectorVision products, 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. 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 approximately $7.2 million. 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 with net proceeds raised of approximately $12.1 million from the August and October offerings 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:

	Nine Months Ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (4,189,050)	$ (3,287,940)
Net cash used in investing activities	(163,105)	(278,311)
Net cash provided by (used in) financing activities	9,236,167	(67,189)
Net increase (decrease) in cash	$ 4,884,012	$ (3,633,440)

Operating Activities

Net cash used in operating activities was $4,189,050 during the nine months ended September 30, 2019, versus $3,287,940 used during the comparable prior year period. Cash in both periods was used for used for engineering, corporate insurance, investor relations, labor, legal and professional fees, travel and other operating costs.

Investing Activities

Net cash used in investing activities was $163,105 for the nine months ended September 30, 2019 and $278,311 for the nine months ended September 30, 2018. In June 2019, we purchased medical imaging equipment for use in our TDSI business. In January 2018, we acquired the rights to a trademark portfolio for $50,000. In addition, we purchased a trade show booth in February 2018 and have invested in MapCatSF equipment and internal-use software development.

Financing Activities

Net cash provided by financing activities was $9,236,167 for the nine months ended September 30, 2019 was due primarily to the completion of our IPO, which resulted in net proceeds of $3,888,000, and our follow-on offering in August which resulted in net proceeds of $4,944,340. In addition, in March 2019, the Company issued $350,000 in promissory and convertible promissory notes and received cash of $154,375 from the exercise of warrants. These proceeds were partially offset by payment of $100,000 to settle a promissory note. Net cash used in financing activities was $67,189 for the nine months ended September 30, 2018 was due primarily to our payoff of a line of credit balance that had been assumed during our 2017 VectorVision acquisition.

Off-Balance Sheet Arrangements

At September 30, 2019 and December 31, 2018, 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.

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 third quarter ended in 2019 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 September 30, 2019 with respect to such matters.

ITEM 1A. RISK FACTORS

The Company is not required to provide the information required by this Item as it is a "smaller reporting company," as defined in Rule 229.10(f)(1).

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

The following securities were sold pursuant to the exemption afforded under Sections 4(a)(2) and 3(a)(9) of the Securities Act of 1933. There were no placement agents or underwriters for any of the following issuances.

On August 24, 2019, warrants were exercised for 25,000 shares of common stock. The warrants were exercisable for $0.50 per share, and the Company received $12,500 in cash.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

A list of exhibits required to be filed as part of this report is set forth in the Index to Exhibits, which is presented elsewhere in this document, and is incorporated herein 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 13th day of November, 2019.

Signature	Title	Date
/s/ Michael Favish Michael Favish	CEO, President and Chairman of the Board (Principal Executive Officer)	November 13, 2019
/s/ John Townsend John Townsend	Controller and Chief Accounting Officer (Principal Accounting Officer)	November 13, 2019

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Warrant Agreement, including form of Warrant, made as of August 15, 2019, between the Company and VStock. (Filed as Exhibit 10.1 to our Current Report on Form 8-K, filed on August 19, 2019 and incorporated herein by reference)
10.2	Asset Purchase Agreement, effective September 20, 2019 (Filed as Exhibit 10.1 to our Current Report on Form 8-K, filed on September 24, 2019 and incorporated herein by reference)
4.1	Form of Underwriters' Warrant from August Offering (Filed as Exhibit 4.4 to the registration statement on Form S-1, filed on August 7, 2019 and incorporated herein by reference)
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 June 30, 2019, 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.

Exhibit 31.1

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: November 13, 2019

/s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: November 13, 2019

/s/ John Townsend

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

Exhibit 32.1

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 September 30, 2019 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.

November 13, 2019 *  *

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

November 13, 2019 */s/ John Townsend*

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