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 June 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 August 9, 2019, there were 22,733,762 shares of the Company's common stock, par value $0.001 per share, issued and outstanding. The Company's common stock began trading on the NASDAQ Capital Market on April 5, 2019, under the symbol "GHSI."

TABLE OF CONTENTS

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

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets		
Cash	$ 2,368,645	$ 670,948
Accounts receivable	35,920	28,203
Inventories	318,686	357,997
Prepaid expenses	132,306	47,773
Total current assets	**2,855,557**	**1,104,921**
Deposits	11,751	11,751
Property and equipment, net	303,929	274,804
Right of use asset, net	595,598	-
Deferred offering costs	19,000	270,000
Intangible assets, net	348,786	456,104
Goodwill	1,563,520	1,563,520
Total assets	**$ 5,698,141**	**$ 3,681,100**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 300,239	$ 413,925
Accrued expenses and deferred rent	25,000	81,412
Derivative warrant liability	78,440	-
Lease liability – current	125,237	-
Total current liabilities	528,916	495,337
Lease liability – long term	481,137	-
Total liabilities	1,010,053	495,337
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized	-	-
Common stock, $0.001 par value; 90,000,000 shares authorized; 22,733,762 and 20,564,328 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	22,734	20,564
Additional paid-in capital	43,735,894	37,798,562
Accumulated deficit	(39,070,540)	(34,633,363)
Total stockholders' equity	**4,688,088**	**3,185,763**
Total liabilities and stockholders' equity	**$ 5,698,141**	**$ 3,681,100**

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
	(Unaudited)	**(Unaudited)**	**(Unaudited)**	**(Unaudited)**
Revenue				
Medical foods	$ 104,448	$ 79,993	$ 204,382	$ 154,294
Vision testing diagnostics	150,222	140,785	292,826	259,524
Other	6,300	-	6,300	-
Total revenue	260,970	220,778	503,508	413,818
Cost of goods sold				
Medical foods	40,681	40,959	78,953	72,238
Vision testing diagnostics	53,816	46,817	109,036	94,817
Other	2,559	-	2,559	-
Total cost of goods sold	97,056	87,776	190,548	167,055
Gross profit	163,914	133,002	312,960	246,763
Operating expenses				
Research and development	77,688	34,320	106,716	194,708
Sales and marketing	409,409	378,750	764,028	984,464
General and administrative	2,489,011	1,034,914	3,439,633	2,714,680
Total operating expenses	2,976,108	1,447,984	4,310,377	3,893,852
Loss from operations	(2,812,194)	(1,314,982)	(3,997,417)	(3,647,089)
Other (income) expense:				
Interest expense	234,065	710	251,637	1,545
Finance cost upon issuance of warrants	229,921	-	415,955	-
Change in fair value of derivative warrants	(227,832)	-	(227,832)	-
Costs associated with extension of warrant expiration dates	-	494,391	-	494,391
Total other (income) expense	236,154	495,101	439,760	495,936
Net loss	**$ (3,048,348)**	**$ (1,810,083)**	**$ (4,437,177)**	**$ (4,143,025)**
Net loss per common share – basic and diluted	$ (0.14)	$ (0.09)	$ (0.21)	$ (0.21)
Weighted average common shares outstanding – basic and diluted	22,537,943	20,164,761	21,628,758	20,161,131

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 and Six Months Ended June 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
			Three and Six Months Ended June 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

See accompanying notes to condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2019	**2018**
	(Unaudited)	**(Unaudited)**
Operating Activities		
Net loss	$ (4,437,177)	$ (4,143,025)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	137,128	148,560
Amortization of debt discount	250,000	-
Accrued interest expense included in notes payable	788	-
Amortization of right of use asset	61,571	-
Stock-based compensation	242,996	1,054,885
Stock-based compensation – officer and director	1,066,159	-
Non-cash financing costs – derivative liability	415,955	-
Change in fair value of warrants – derivative liability	(227,832)	-
Costs associated with extension of warrant expiration dates	-	494,391
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	(7,718)	42,928
Inventories	39,311	(257,627)
Deposits and prepaid expenses	(84,533)	90,053
Lease liability	(56,844)	-
Increase (decrease) in -		
Accounts payable and accrued expenses	156,314	146,202
Accrued expenses and deferred rent	(49,814)	(425)
Net cash used in operating activities	(2,493,696)	(2,424,058)
Investing Activities		
Purchase of property and equipment	(58,934)	(137,073)
Purchase of intellectual property	-	(50,000)
Net cash used in investing activities	(58,934)	(187,073)
Financing Activities		
Proceeds from initial public offering	3,888,000	-
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	131,875	1,460
Deferred financing costs of IPO	(19,000)	-
Decrease in due to related parties	-	(28,659)
Net cash provided by (used in) financing activities	4,250,327	(57,734)
Cash:		
Net decrease	1,697,697	(2,668,865)
Balance at beginning of period	670,948	4,735,230
Balance at end of period	$ 2,368,645	$ 2,066,365
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)
Six Months Ended June 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 that 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. Lumega-Z has been used in IRB-approved patient studies to examine its effectiveness. On May 9, 2019, the Company announced in a press release a recent study that showed statistically significant improvement in visual function ("CSF") of patients taking Lumega-Z who participated in the study. The study was conducted by research scientists at the Western University College of Optometry to evaluate the visual benefits of Lumega-Z in one group of patients as compared to a group of patients taking AREDS 2 soft gel supplements. Each patient has retinal drusen and is at risk of developing AMD. The results of the study were presented at the Association for Research in Vision and Ophthalmology ("ARVO") 2019 annual meeting and showed improvements in visual function ("CSF") in the group of patients taking Lumega-Z that were statistically significant and definitive. The patients taking AREDS 2 showed no statistical change.

The Company also developed a proprietary medical device called the MapcatSF® that accurately measures the macular pigment optical density. On July 16, 2019, the Company was notified by the Patents Registry in Hong Kong that it has received a patent from the Government of the Hong Kong Special Administrative Region (Hong Kong Patent No. HK1204758 titled "Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye") for the MapcatSF®. On May 30, 2019, the Company was notified by the European Patent Office that it has received a patent from the European Union (European Patent No. 2,811,892 titled "Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye") for the MapcatSF®.

On September 29, 2017, the Company, through its wholly owned subsidiary VectorVision Ocular Health, Inc. ("VectorVision"), completed its acquisition of substantially all of the assets and certain liabilities of VectorVision, Inc. (an Ohio corporation), 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 develops, manufactures and sells equipment and supplies for standardized vision testing. The acquisition expands the Company's technical portfolio. CSV-1000 and CSV-2000 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 will 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.

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. The Company believes GlaucoCetin™ 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. The parent compound of GlaucoCetin™, called "GlaucoHealth," was designed by Robert Ritch, M.D., one of the Company's Medical Advisory Board members. Dr. Robert Ritch holds the Shelley and Steven Einhorn Distinguished Chair in Ophthalmology and is surgeon Director Emeritus and Chief of Glaucoma Services at the New York Eye and Ear Infirmary. Dr. Ritch has devoted his career to broadening the understanding of the underlying etiologies and mechanisms of glaucoma. The Company now owns the GlaucoHealth formula. On June 4, 2019, the Company announced in a press release that the formula was used in an IRB-approved patient study conducted at the New York Eye and Ear Infirmary and successfully reversed mitochondrial dysfunction in the optic nerve cells in patients with glaucoma. GlaucoCetin™ is an enhanced formulation of GlaucoHealth. The Company owns both formulas and has a patent application pending on the GlaucoCetin™ formula. The application describes an invention that provides a micro-nutrient composition for a human subject suffering from a glaucomatous disease, wherein the micro-nutrient composition comprises a formulation for reversing mitochondrial dysfunction in glaucomatous disease.

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, resulting in net proceeds to the Company of $3,888,000 after deducting underwriting discounts and commissions and other offering costs and expenses payable by Guardion. The shares began trading on the Nasdaq Capital Market on April 5, 2019, under the symbol "GHSI." In connection with the IPO, the 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 has had limited operations to date and 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 $4,437,177 and utilized cash in operating activities of $2,493,696 during the six months ended June 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 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 products other than Lumega-Z and the MapcatSF.

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.

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.

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 June 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 June 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 the equity financings. These deferred offering costs will be 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 June 30, 2019, $19,000 of costs have been deferred relating to offerings in process.

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.

Tthe 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:

	Six Months Ended June 30,	
	2019	2018
Medical foods	$ 204,382	$ 154,294
Vision testing diagnostics	292,826	259,524
Other	6,300	-
	$ 503,508	$ 413,818

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 $106,716 and $194,708 for the six months ended June 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 six months ended June 30, 2019 and 2018, patent costs were $61,482 and $34,298, 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 $626,667, lease liabilities for operating leases of $635,131, 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:

	June 30,	
	2019	**2018**
Warrants	261,538	2,656,423
Options	2,612,500	2,625,000
	2,874,038	5,281,423

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. 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 food 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 June 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 $6,300 of service revenue during the quarter ended June 30, 2019 and incurred approximately $121,000 of operating costs during the six months ended June 30, 2019. As of June 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 June 30, 2019			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ 6,300	$ 104,448	$ 150,222	$ 260,970
Cost of goods sold	2,559	40,681	53,816	97,056
Gross profit	3,741	63,767	96,406	163,914
Operating expenses	1,594,719	1,175,027	206,362	2,976,108
Loss from operations	**$ (1,590,978)**	**$ (1,111,260)**	**$ (109,956)**	**$ (2,812,194)**

	For the Three Months Ended June 30, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 79,993	$ 140,785	$ 220,778
Cost of goods sold	-	40,959	46,817	87,776
Gross profit	-	39,034	93,968	133,002
Operating expenses	468,630	893,925	85,429	1,447,984
Loss from operations	**$ (468,630)**	**$ (854,891)**	**$ 8,539**	**$ (1,314,982)**

	For the Six Months Ended June 30, 2019			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ 6,300	$ 204,382	$ 292,826	$ 503,508
Cost of goods sold	2,559	78,953	109,036	190,548
Gross profit	3,741	125,429	183,790	312,960
Operating expenses	1,959,838	2,003,320	347,219	4,310,377
Loss from operations	**$ (1,956,097)**	**$ (1,877,891)**	**$ (163,429)**	**$ (3,997,417)**

	For the Six Months Ended June 30, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 154,294	$ 259,524	$ 413,818
Cost of goods sold	-	72,238	94,817	167,055
Gross profit	-	82,056	164,707	246,763
Operating expenses	1,523,133	2,206,967	163,752	3,893,852
Loss from operations	**$ (1,523,133)**	**$ (2,124,911)**	**$ 955**	**$ (3,647,089)**

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

	As of June 30, 2019			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Current assets				
Cash	$ 13,355	$ 2,300,973	$ 54,317	$ 2,368,645
Inventories	-	206,876	111,810	318,686
Other	6,300	129,983	31,943	168,226
Total current assets	**19,655**	**2,637,832**	**198,070**	**2,855,557**
Right to use asset	595,598	-	-	595,598
Property and equipment, net	-	294,829	9,100	303,929
Deferred offering	19,000	-	-	19,000
Intangible assets, net	348,786	-	-	348,786
Goodwill	1,563,520	-	-	1,563,520
Other	-	11,751	-	11,751
Total assets	**$ 2,546,559**	**$ 2,944,412**	**$ 207,170**	**$ 5,698,141**

	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**

4. Inventories

Inventories consisted of the following:

	June 30, 2019	December 31, 2018
Raw materials	$ 248,021	$ 282,574
Finished goods	70,665	75,423
	$ 318,686	$ 357,997

5. Property and Equipment, net

Property and equipment consisted of the following:

	June 30, 2019	December 31, 2018
Leasehold improvements	$ 98,357	$ 98,357
Testing equipment	300,448	249,447
Furniture and fixtures	171,121	163,186
Computer equipment	64,976	64,976
Office equipment	8,193	8,193
	643,095	584,159
Less accumulated depreciation and amortization	(339,166)	(309,355)
	$ 303,929	$ 274,804

For the six months ended June 30, 2019 and 2018, depreciation and amortization expense was $29,810 and $41,243, respectively, of which $0 and $15,376 was included in research and development expense, $19,065 and $4,138 was included in sales and marketing expense, and $10,745 and $21,729 was included in general and administrative expense, respectively.

6. 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	(375,614)	(268,296)
	$ 348,786	$ 456,104

The Company’s amortization expense on its finite-lived intangible assets was $107,318 and $107,318 for the six months ended June 30, 2019 and 2018, respectively.

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

For Years Ended December 31,		
2019	$	107,318
2020		165,320
2021		16,307
2022		9,840
	$	298,785

7. 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 derivative liabilities at March 31, 2019. 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.

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.

8. Lease Liabilities

In October 2012, the Company entered into a lease agreement for 9,605 square feet of office and warehouse space commencing March 1, 2013. Upon entering into the agreement, the Company paid a deposit of $47,449, of which $36,979 represented prepaid rent. As of June 30, 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 June 30, 2019, remaining average monthly lease payments under the amended lease agreement were $12,915 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 average monthly lease payments are $1,838 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 six months ended June 30, 2019, the Company made combined payments on both leases of $82,434 towards the lease liabilities. As of June 30, 2019 and December 31, 2018, the lease liability for Lease 1 was $536,672 and $586,082, respectively, and the lease liability for Lease 2 was $69,703 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 six months ended June 30, 2019 and 2018 was $87,161 and $10,671, respectively. During the six months ended June 30, 2019 and 2018, the Company reflected amortization of right of use asset of $61,571 and $7,152 related to the leases, respectively, resulting in a net asset balance of $595,598 as of June 30, 2019.

9. 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 June 30, 2019 with respect to such matters.

10. Stockholders' Equity (Deficit)

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	171,538	2.39	3.11
Forfeitures	-	-	-
Expirations	(279,424)	(1.96)	-
Exercised	(896,250)	(1.88)	-
June 30, 2019, all exercisable	**261,538**	**$ 2.81**	**3.35**

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

Warrants Outstanding and Exercisable (Shares)	Exercise Prices
25,000	$ 0.50
65,000	1.50
109,038	2.88
62,500	5.00
261,538	

Between February 11, 2019 and May 21, 2019, investors net exercised a total of 632,500 warrants for 492,256 shares of common stock on a cashless basis.

Between February 11, 2019 and May 21, 2019, investors exercised warrants for 263,750 shares of common stock. The warrants were exercisable for $0.50 per share, and the Company received $131,875 in cash.

As of June 30, 2019, the Company had an aggregate of 261,538 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of $2.81, a weighted average remaining life of 3.35 years and an aggregate intrinsic value of $19,000, based upon a stock valuation of $1.26 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 March 31, 2019. At March 31, 2019, 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 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. Upon completion of the IPO, the exercise price and the number of warrants were fixed and the warrants no longer accounted for as liabilities. As such the fair value of the warrant liability of $359,683 was reclassified to equity.

On April 4, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the underwriter (the "Underwriter") in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants 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 $229,291 and was recorded as a finance cost. As of June 30, 2019, the fair value of the warrants was determined to $78,440.

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 June 30, 2019
Stock price	$ 4.00	$ 3.68	$ 1.26
Risk free interest rate	2.34 – 2.39%	2.29%	1.71%
Expected volatility	138%	137%	145%
Expected life in years	5.00	5.00	4.76
Expected dividend yield	0%	0%	0%
Number of warrants	109,038	62,500	62,500
Fair value of warrants	$ 436,034	$ 229,921	$ 78,440

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	1,250,000	2.11	2.29
Forfeitures	-	-	-
Expirations	-	-	-
Exercised	-	-	-
June 30, 2019, outstanding	**2,612,500**	**$ 3.28**	**4.00**
June 30, 2019, exercisable	**1,391,667**	**$ 2.41**	**3.46**

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

Options Outstanding (Shares)	Options Exercisable (Shares)	Exercise Prices
625,000	625,000	$ 2.00
62,500	62,500	2.30
675,000	600,000	2.50
1,250,000	104,167	4.40
2,612,500	**1,391,667**	

During the six months ended June 30, 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 of $4,122,750. The options will vest on a quarterly basis over three years. The Company accounts share-based payments to employees in accordance with ASC 718 wherein grants are measured at the grant date fair value and charged to operations over the vesting period. During the period ended June 30, 2019, compensation cost of $1, 066,159 was recognized during the period relating the amortization of this award.

During the period ended June 30, 2019, option awards were valued based upon the Black-Scholes option-pricing model, with stock price ranging from $3.30 to $4.00 per share, volatility ranging from 115% to 138%, and an average risk-free rate ranging from 2.31% to 2.46%.

During the six months ended June 30, 2019 and 2018, we recognized aggregate stock-compensation expense of $1,309,155 and $1,054,885, respectively, based upon stock prices ranging from $3.30 to $4.00 per share, all of which was recorded in general and administrative expense.

As of June 30, 2019, the Company had an aggregate of 1,220,833 remaining unvested options outstanding, with a total estimated fair value of $3,132,532, weighted average exercise price of $4.28, and weighted average remaining life of 4.61 years. The aggregate intrinsic value of options outstanding as of June 30, 2019 was $0.

11. Related Party Transactions

During the six months ended June 30, 2019 and 2018, the Company incurred and paid $150,000 and 137,500, respectively, of salary expense to our Board Chairman and CEO, Mr. Michael Favish. In addition, compensation cost of $1,066,159 was recognized on amortization of stock option awards during the period ended June 30, 2019.

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 replenishes and restores 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 will 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. The Company believes GlaucoCetin™ 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. The parent compound of GlaucoCetin™, called "GlaucoHealth," was designed by Robert Ritch, M.D., one of the Company's Medical Advisory Board members. Dr. Robert Ritch holds the Shelley and Steven Einhorn Distinguished Chair in Ophthalmology and is surgeon Director Emeritus and Chief of Glaucoma Services at the New York Eye and Ear Infirmary. Dr. Ritch has devoted his career to broadening the understanding of the underlying etiologies and mechanisms of glaucoma. The Company now owns the GlaucoHealth formula.

The Company has had limited operations to date and 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."

Products

Lumega-Z has been used in IRB-approved patient studies to examine its effectiveness. On May 9, 2019, the Company announced in a press release a recent study that showed statistically significant improvement in visual function ("CSF") of patients taking Lumega-Z who participated in the study. The study was conducted by research scientists at the Western University College of Optometry to evaluate the visual benefits of Lumega-Z in one group of patients as compared to a group of patients taking AREDS 2 soft gel supplements. Each patient has retinal drusen and is at risk of developing AMD. The results of the study were presented at the Association for Research in Vision and Ophthalmology ("ARVO") 2019 annual meeting and showed improvements in visual function ("CSF") in the group of patients taking Lumega-Z that were statistically significant and definitive. The patients taking AREDS 2 showed no statistical change.

On June 4, 2019, the Company announced in a press release that the parent compound of the GlaucoCetin™ formula was used in an IRB-approved patient study conducted at the New York Eye and Ear Infirmary and successfully reversed mitochondrial dysfunction in the optic nerve cells in patients with glaucoma. GlaucoCetin™ is an enhanced formulation of GlaucoHealth. The Company owns both formulas and has a patent application pending on the GlaucoCetin™ formula. The application describes an invention that provides a micro-nutrient composition for a human subject suffering from a glaucomatous disease, wherein the micro-nutrient composition comprises a formulation for reversing mitochondrial dysfunction in glaucomatous disease.

Patents

On July 16, 2019, the Company was notified by the Patents Registry in Hong Kong that it has received a patent from the Government of the Hong Kong Special Administrative Region (Hong Kong Patent No. HK1204758 titled "Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye") for the MapcatSF®.

On May 30, 2019, the Company was notified by the European Patent Office that it has received a patent from the European Union (European Patent No. 2,811,892 titled "Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye") for the MapcatSF®.

Trademarks

On April 25, 2019, the Company was notified by the State Intellectual Property Office of the People's Republic of China ("China") that the Company has been granted trademark registrations in China for its proprietary medical food, Lumega-Z (Registration No. 27151643), and for its proprietary and patented medical device, the MapcatSF (Registration No. 27151644). The trademark registration for the mark LUMEGA-Z is effective from November 7, 2018 to November 6, 2028. The trademark registration for the mark MAPCAT SF is effective from October 28, 2018 to October 27, 2028.

Going Concern

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of $4,437,177 and utilized cash in operating activities of $2,493,696 during the six months ended June 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 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.

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 June 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 June 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 June 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; and
- explore opportunities and channels to enter the expansive market opportunity in China for non-pharmacologic treatments of macular degeneration, glaucoma and diabetic retinopathy.

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 June 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 six months ended June 30, 2019 and 2018.

Comparison of Three Months Ended June 30, 2019 and 2018

	Three Months Ended June 30,			
	2019	2018	Change	
Revenue	$ 260,970	$ 220,778	$ 40,192	18%
Cost of goods sold	97,056	87,776	9,280	11%
Gross Profit	163,914	133,002	30,912	23%
Operating Expenses:				
Research and development	77,688	34,320	43,368	126%
Sales and marketing	409,409	378,750	30,659	8%
General and administrative	2,489,011	1,034,914	1,454,097	141%
Total Operating Expenses	2,976,108	1,447,984	1,528,124	106%
Loss from Operations	(2,812,194)	(1,314,982)	(1,497,212)	114%
Other Expense:				
Interest expense	234,065	710	233,355	32,867%
Finance cost upon issuance of warrants	229,921	-	229,921	100%
Change in fair value of derivative warrants	(227,832)	-	(227,832)	100%
Costs associated with extension of warrant expiration dates	-	494,391	(494,391)	(100)%
Net Loss	$ (3,048,348)	$ (1,810,083)	$ (1,238,265)	68%

Revenue

For the three months ended June 30, 2019, revenue from product sales was $260,970 compared to $220,788 for the three months ended June 30, 2018, resulting in an increase of $40,192 or 18%. The increase reflects both an increased customer base for Lumega-Z as the Company expands into new clinics and increased sales of VectorVision products. The Company also earned $6,300 in revenue from its TDSI business during the three months ended June 30, 2019.

Cost of Goods Sold

For the three months ended June 30, 2019, cost of goods sold was $97,056 compared to $87,776 for the three months ended June 30, 2018, resulting in an increase of $9,280 or 11%. The increase reflects the additional sales recorded in 2018.

Gross Profit

For the three months ended June 30, 2019, gross profit was $163,914 compared to $133,002 for the three months ended June 30, 2018, resulting in an increase of $30,912 or 23%. Gross profit represented 63% of revenues the three months ended June 30, 2019, versus 60% of revenue for the three months ended June 30, 2018. The increase in gross profit in 2019 was due primarily to pricing and product mix changes in 2019.

Research and Development

For the three months ended June 30, 2019, research and development costs were $77,688 compared to $34,320 for the three months ended June 30, 2018, resulting in an increase of $43,368 or 126%. 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 June 30, 2019, sales and marketing expenses were $409,409 compared to $378,750 for the three months ended June 30, 2018. The increase in sales and marketing expenses of $30,659 or 8% compared to the prior period was primarily due to increased trade show costs and consulting fees in the current quarter.

General and Administrative

For the three months ended June 30, 2019, general and administrative expenses were $2,489,011 compared to $1,034,914 for the three months ended June 30, 2018. The increase of $1,454,097 or 141% compared to the prior period was primarily due to an increase in non-cash stock compensation costs during the current period of approximately $976,000. Additionally, expenses for corporate insurance, investor relations, labor, legal and professional fees, and travel have increased versus the prior period.

Interest Expense

For the three months ended June 30, 2019, interest expense was $234,065 compared to $710 for the three months ended June 30, 2018. The increase of 233,355 compared to the prior period was due primarily to the amortization of the valuation discount of the March 2019 convertible notes of $233,455 that was reflected as an expense when the notes were converted. There were no such costs for the comparable period in 2018.

Finance Cost Upon Issuance of Warrants

Finance costs for the three months ended June 30, 2019 were $229,921. There were no such costs for the comparable period in 2018. On April 4, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the underwriter (the "Underwriter") in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants at the date of issuance was determined to be $229,291 and was recorded as a finance cost.

Change in Fair Value of Derivative Warrants

The change in fair value of the derivative warrant liability was a decrease of $227,832 for the three months ended June 30, 2019. There were no such costs for the comparable period in 2018. 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 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.

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 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 June 30, 2019, the fair value of the warrant liability was determined to be $78,440 and the Company recorded a change in fair value of derivative warrants of $151,481 in the Statements of Operations.

Costs associated with extension of warrant expiration dates

During April and May of 2018, the Company offered exercise period extensions to stockholders who held warrants to purchase shares of common stock of the Company that were scheduled to expire on May 1, 2018. The Company recognized expense of $494,391 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 June 30, 2019, the Company incurred a net loss of $3,048,348, compared to a net loss of $1,810,083 for the three months ended June 30, 2018. The increase in net loss of $1,238,265 or 68% compared to the prior year period was primarily due to an increase in non-cash stock compensation costs of approximately $976,000. In addition, engineering costs as well as corporate operating expenses increased during the current period.

Segment Information

As of June 30, 2019, Management reported its operating results in two operating segments: Medical Foods, and Vision Testing Diagnostics. As of June 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 June 30, 2019			
	Other	**Medical Foods**	**Vision Testing Diagnostics**	**Total**
Revenue	$ 6,300	$ 104,448	$ 150,222	$ 260,970
Cost of goods sold	2,559	40,681	53,816	97,056
Gross profit	3,741	63,767	96,406	163,914
Operating expenses	1,594,719	1,175,027	206,362	2,976,108
Loss from operations	**$ (1,590,978)**	**$ (1,111,260)**	**$ (109,956)**	**$ (2,812,194)**

	For the Three Months Ended June 30, 2018			
	Other	Medical Foods	Vision Testing Diagnostics	Total
Revenue	$ -	$ 79,993	$ 140,785	$ 220,778
Cost of goods sold	-	40,959	46,817	87,776
Gross profit	-	39,034	93,968	133,002
Operating expenses	468,630	893,925	85,429	1,447,984
Loss from operations	**$ (468,630)**	**$ (854,891)**	**$ 8,539**	**$ (1,314,982)**

For the three months ended June 30, 2019, revenue from our Medical Foods segment was $104,448 compared to $79,993 for the three months ended June 30, 2018, resulting in an increase of $24,455 or 31%. The increase reflects an increased customer base for Lumega-Z as the Company expands into new clinics. For the three months ended June 30, 2019, revenue from our Vision Testing Diagnostics segment was $150,222 compared to $140,785 for the three months ended June 30, 2018, resulting in an increase of $9,437 or 7%. The increase was due to increased distributor sales in 2019. The Company also earned $6,300 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 June 30, 2019, cost of goods sold from our Medical Foods segment was $40,681 compared to $40,959 for the three months ended June 30, 2018, resulting in a decrease of $278 or 1%. For the three months ended June 30, 2019, cost of goods sold from our Vision Testing Diagnostics segment was $53,816 compared to $46,817 for the three months ended June 30, 2018, resulting in an increase of $6,999 or 15%. The increase for both segments reflects the additional sales recorded in 2018.

Gross Profit

For the three months ended June 30, 2019, gross profit from the Medical Foods segment was $63,767 compared to $39,034 for the three months ended June 30, 2018, resulting in an increase of $24,733 or 63%. For the three months ended June 30, 2019, gross profit from the Vision Testing Diagnostics segment was $96,406 compared to $93,968 for the three months ended June 30, 2018, resulting in an increase of $2,438 or 3%. The increase is due to the additional sales recorded for both segments in the current year. Gross profit overall represented 63% of revenues for the three months ended June 30, 2019, versus 60% of revenue for the three months ended June 30, 2018. The increase in 2019 was due increased sales and to pricing and product mix changes in 2019.

Comparison of Six Months Ended June 30, 2019 and 2018

	Six Months Ended June 30,			
	2019	2018	Change	
Revenue	$ 503,508	$ 413,818	$ 89,690	22%
Cost of goods sold	190,548	167,055	23,493	14%
Gross Profit	312,960	246,763	66,197	27%
Operating Expenses:				
Research and development	106,716	194,708	(87,992)	(45)%
Sales and marketing	764,028	984,464	(220,436)	(22)%
General and administrative	3,439,633	2,714,680	724,953	27%
Total Operating Expenses	4,310,377	3,893,852	416,525	11%
Loss from Operations	(3,997,417)	(3,647,089)	(350,328)	10%
Other Expense:				
Interest expense	251,637	1,545	250,092	16,187%
Finance cost upon issuance of warrants	415,955	-	415,955	100%
Change in fair value of derivative warrants	(227,832)	-	(227,832)	100%
Costs associated with extension of warrant expiration dates	-	494,391	(494,391)	(100)%
Net Loss	$ (4,437,177)	$ (4,143,025)	$ (294,152)	7%

Revenue

For the six months ended June 30, 2019, revenue from product sales was $503,508 compared to $413,818 for the six months ended June 30, 2018, resulting in an increase of $86,690 or 22%. The increase reflects both an increased customer base for Lumega-Z as the Company expands into new clinics and increased sales of VectorVision products. The Company also earned $6,300 in revenue from its TDSI business during the three months ended June 30, 2019.

Cost of Goods Sold

For the six months ended June 30, 2019, cost of goods sold was $190,548 compared to $167,055 for the six months ended June 30, 2018, resulting in an increase of $23,493 or 14%. The increase results primarily from costs associated with the additional sales recorded in 2019 as compared to 2018.

Gross Profit

For the six months ended June 30, 2019, gross profit was $312,960 compared to $246,763 for the six months ended June 30, 2018, resulting in an increase of $66,197 or 27%. Gross profit represented 62% of revenues for the six months ended June 30, 2019, versus 60% of revenue for the six months ended June 30, 2018. The increase in gross profit in 2019 was due primarily to pricing and product mix changes in 2019.

Research and Development

For the six months ended June 30, 2019, research and development costs were $106,716 compared to $194,708 for the six months ended June 30, 2018, resulting in a decrease of $87,992 or 45%. 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 six months ended June 30, 2019, sales and marketing expenses were $764,028 compared to $984,464 for the six months ended June 30, 2018. The decrease in sales and marketing expenses of $220,436 or 22% compared to the prior period was primarily due to costs associated with engagement of a third-party contract sales organization in 2018. The contract sales agreement was cancelled during the second quarter of 2018.

General and Administrative

For the six months ended June 30, 2019, general and administrative expenses were $3,439,633 compared to $2,714,680 for the six months ended June 30, 2018. The increase of $724,953 or 27% compared to the prior period was primarily due to an increase in non-cash stock compensation costs during the current period of approximately $254,000. Additionally, expenses for corporate insurance, investor relations, labor, legal and professional fees, and travel have increased versus the prior period.

Interest Expense

For the six months ended June 30, 2019, interest expense was $251,637 compared to $1,545 for the six months ended June 30, 2018. The increase of $250,092 compared to the prior period was due primarily to the amortization of the valuation of the March 2019 convertible notes of $250,000 that was reflected as an expense when the notes were converted. There were no such costs for the comparable period in 2018.

Finance Cost Upon Issuance of Warrants

Finance costs for the six months ended June 30, 2019 of $415,955 include the following; (I) In March 2019, the Company issued warrants to two convertible note holders pursuant to the anticipated completion of the Company's IPO (the IPO was completed on April 9, 2019). Due to the variable terms of both the exercise price and the number of warrants to be issued, the warrants were accounted for as derivative liabilities at March 31, 2019. The fair value of the warrants at the closing of the IPO was determined to be $436,034, of which $250,000 was recorded as a valuation discount, and $186,034 was recorded as a finance cost. (II) On April 4, 2019, the Company issued 62,500 warrants with an exercise price of $5.00 per share to the Underwriter in connection with the Company's IPO. The Company accounted for these warrants as a derivative liability in the financial statements at June 30, 2019 because they were associated with the IPO, a registered offering, and the settlement provisions contained language that the shares underlying the warrants are required to be registered. The fair value of the warrants at the date of issuance was determined to be $229,291 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 $227,832 for the six months ended June 30, 2019. There were no such costs for the comparable period in 2018. 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 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.

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 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 June 30, 2019, the fair value of the warrant liability was determined to be $78,440 and the Company recorded a change in fair value of derivative warrants of $151,481 in the Statements of Operations.

Costs associated with extension of warrant expiration dates

During April and May of 2018, the Company offered exercise period extensions to stockholders who held warrants to purchase shares of common stock of the Company that were scheduled to expire on May 1, 2018. The Company recognized expense of $494,391 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 six months ended June 30, 2019, the Company incurred a net loss of $4,437,177, compared to a net loss of $4,143,025 for the six months ended June 30, 2018. The increase in net loss of $294,152 or 7% compared to the prior year period was primarily due to an increase in non-cash stock compensation costs of approximately $254,000. 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.

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 Six Months Ended June 30, 2019			
	Other	**Medical Foods**	**Vision Testing Diagnostics**	**Total**
Revenue	$ 6,300	$ 204,382	$ 292,826	$ 503,508
Cost of goods sold	2,559	78,953	109,036	190,548
Gross profit	3,741	125,429	183,790	312,960
Operating expenses	1,959,838	2,003,320	347,219	4,310,377
Loss from operations	**$ (1,956,097)**	**$ (1,877,891)**	**$ (163,429)**	**$ (3,997,417)**

	For the Six Months Ended June 30, 2018			
	Other	**Medical Foods**	**Vision Testing Diagnostics**	**Total**
Revenue	$ -	$ 154,294	$ 259,524	$ 413,818
Cost of goods sold	-	72,238	94,817	167,055
Gross profit	-	82,056	164,707	246,763
Operating expenses	1,523,133	2,206,967	163,752	3,893,852
Loss from operations	**$ (1,523,133)**	**$ (2,124,911)**	**$ 955**	**$ (3,647,089)**

For the six months ended June 30, 2019, revenue from our Medical Foods segment was $204,382 compared to $154,294 for the six months ended June 30, 2018, resulting in an increase of $50,088 or 32%. The increase reflects an increased customer base for Lumega-Z as the Company expands into new clinics. For the six months ended June 30, 2019, revenue from our Vision Testing Diagnostics segment was $292,826 compared to $259,524 for the six months ended June 30, 2018, resulting in an increase of $33,302 or 13%. The increase was due to increased distributor sales in 2019. The Company also earned $6,300 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 six months ended June 30, 2019, cost of goods sold from our Medical Foods segment was $78,953 compared to $72,238 for the six months ended June 30, 2018, resulting in an increase of $6,715 or 9%. For the six months ended June 30, 2019, cost of goods sold from our Vision Testing Diagnostics segment was $109,036 compared to $94,817 for the six months ended June 30, 2018, resulting in an increase of $14,219 or 15%. The increase for both segments results primarily from costs associated with the additional sales recorded in 2019 as compared to 2018.

Gross Profit

For the six months ended June 30, 2019, gross profit from the Medical Foods segment was $125,429 compared to $82,056 for the six months ended June 30, 2018, resulting in an increase of $43,373 or 53%. For the six months ended June 30, 2019, gross profit from the Vision Testing Diagnostics segment was $183,790 compared to $164,707 for the six months ended June 30, 2018, resulting in an increase of $19,083 or 12%. The increase is due to the additional sales recorded for both segments in the current year. Gross profit overall represented 62% of revenues for the six months ended June 30, 2019, versus 60% of revenue for the six months ended June 30, 2018. The increase in 2019 was due increased sales and to pricing and product mix changes in 2019.

Liquidity and Capital Resources

Since its formation in 2009, the Company has devoted substantial effort and capital resources to the development and commercialization activities related to its lead product Lumega-Z and its MapcatSF medical device. As a result of these and other activities, the Company utilized cash in operating activities of $2,493,696 during the six months ended June 30, 2019. The Company had working capital of $2,326,641 at June 30, 2019. As of June 30, 2019, the Company had cash in the amount of $2,368,645 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.

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. 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.

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:

	Six Months Ended June 30,	
	2019	**2018**
Net cash used in operating activities	$ (2,493,696)	$ (2,424,058)
Net cash used in investing activities	(58,934)	(187,073)
Net cash provided by (used in) financing activities	4,250,327	(57,734)
Net increase (decrease) in cash	$ 1,697,697	$ (2,668,865)

Operating Activities

Net cash used in operating activities was $2,493,696 during the six months ended June 30, 2019, versus $2,424,058 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 $58,934 for the six months ended June 30, 2019 and $187,073 for the six months ended June 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 $4,250,327 for the six months ended June 30, 2019 was due primarily to the completion of our IPO, which resulted in net proceeds of $3,888,000. In addition, in March 2019, the Company issued $350,000 in promissory and convertible promissory notes and received cash of $131,875 from the exercise of warrants. These proceeds were partially offset by payment of $100,000 to settle a promissory note. Net cash used in financing activities was $57,734 for the six months ended June 30, 2018 was due primarily to our payoff of a line of credit balance that had been assumed during our 2017 VectorVision acquisition.

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

	Years Ended December 31,	
	2018	**2017**
Net cash used in operating activities	$ (4,173,831)	$ (3,403,696)
Net cash used in investing activities	(310,243)	(32,385)
Net cash provided by financing activities	419,792	8,108,791
Net (decrease) increase in cash	$ (4,064,282)	$ 4,672,710

Operating Activities

Net cash used in operating activities was $4,173,831 during the year ended December 31, 2018, versus $3,403,696 used during the comparable prior year period. The increase in 2018 was due primarily to higher sales, marketing, professional services, and labor costs.

Investing Activities

Net cash used in investing activities was $310,243 for the year ended December 31, 2018 and $32,385 for the year ended December 31, 2017. 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 MapCat equipment and internal-use software development.

Financing Activities

Net cash provided by financing activities was $419,792 for the year ended December 31, 2018 was due to the sale in November and December of $850,000 in common stock and the exercise of warrants for proceeds of $16,460. These proceeds were partially offset by the payoff of a $30,535 line of credit balance that had been assumed from the VectorVision transaction as well as payment of $146,133 due to related parties. Net cash provided by financing activities was $8,108,791 for the year ended December 31, 2017, consisting of $5,000,001 in proceeds from the issuance of common stock, $3,105,000 in proceeds from the issuance of preferred stock, and proceeds of $100,000 from the issuance of a note payable. Partially offsetting proceeds received were $150,860 of payments on notes payable and $54,650 of payments due to related parties.

Off-Balance Sheet Arrangements

At June 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 second 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 June 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 private placements.

On April 9, 2019, the Company granted our CEO, Michael Favish, 1,250,000 common stock shares issuable upon the exercise of a common stock purchase option with a per share exercise price of $4.40 per share and a five-year term. The option vests ratably on the last day of each calendar quarter following the date of grant over a period of three (3) years and is subject to Mr. Favish remaining employed with the Company on the applicable vesting dates.

On April 9, 2019, the Company issued 109,038 shares of common stock upon the conversion of promissory notes of $250,000 that were mandatorily convertible upon the completion of the IPO.

On April 12, 2019, an investor exercised warrants for 26,250 shares of common stock. The warrants were exercisable for $0.50 per share, and the Company received $13,125 in cash.

On April 5 and 17, 2019, investors exercised a total of 275,000 warrants on a cashless basis resulting in the issuance of 229,365 shares of common stock. The warrants were exercisable for $0.50 and $2.00 per share.

As compensation for services rendered, the Company issued a total of 54,390 shares of common stock in April, May, and June 2019.

On May 6, 2019, an investor exercised warrants for 125,000 shares of common stock. The warrants were exercisable for $0.50 per share, and the Company received $62,500 in cash.

On May 20, 2019, an investor exercised a total of 50,000 warrants on a cashless basis resulting in the issuance of 33,108 shares of common stock. The warrants were exercisable for $0.50 per share.

On May 21, 2019, an investor exercised warrants for 50,000 shares of common stock. The warrants were exercisable for $0.50 per share, and the Company received $25,000 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 12th day of August, 2019.

Signature	Title	Date
/s/ Michael Favish Michael Favish	CEO, President and Chairman of the Board (Principal Executive Officer)	August 12, 2019
/s/ John Townsend John Townsend	Controller and Chief Accounting Officer (Principal Accounting Officer)	August 12, 2019

INDEX TO EXHIBITS

Exhibit No.	Description
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: August 12, 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: August 12, 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 June 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.

August 12, 2019

/s/ Michael Favish
Michael Favish
Chief Executive Officer
(Principal Executive Officer)

August 12, 2019

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