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

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

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)

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of November 9, 2018, there were 40,329,475 shares of the Registrant's common stock, par value $0.001 per share, issued and outstanding. Registrant's common stock is not publicly traded.

TABLE OF CONTENTS

		Page No.
PART I – FINANCIAL INFORMATION		
ITEM 1.	CONDENSED CONSOLIDATED FINANCIAL STATEMENTS	4
	Balance Sheets – As of September 30, 2018 (Unaudited) and December 31, 2017	4
	Statements of Operations (Unaudited) – Three and Nine Months Ended September 30, 2018 and 2017	5
	Statement of Stockholders' Equity (Unaudited) – Nine Months Ended September 30, 2018	6
	Statements of Cash Flows (Unaudited) – Nine Months Ended September 30, 2018 and 2017	7
	Notes to Condensed Consolidated Financial Statements (Unaudited)	8
ITEM 2.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	18
ITEM 3.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	27
ITEM 4.	CONTROLS AND PROCEDURES	27
PART II – OTHER INFORMATION		
ITEM 1.	LEGAL PROCEEDINGS	28
ITEM 1A.	RISK FACTORS	28
ITEM 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	28
ITEM 3.	DEFAULTS UPON SENIOR SECURITIES	28
ITEM 4.	MINE SAFETY DISCLOSURES	28
ITEM 5.	OTHER INFORMATION	28
ITEM 6.	EXHIBITS	28
SIGNATURES		29

Introductory Comment

Throughout this Quarterly Report on Form 10-Q, the terms "we," "us," "our," "our company," "Guardion," the "Company" and the "Registrant" refer to Guardion Health Sciences, Inc.

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 statements relate to future events or future predictions, including events or predictions relating to the Company's future financial performance, and are based on current expectations, estimates, forecasts and projections about the Company, its future performance, its beliefs and management's assumptions. They are generally identifiable by use of the words "may," "will," "should," "expect," "plan," "anticipate," "believe," "feel," "confident," "estimate," "intend," "predict," "forecast," "potential" or "continue" or the negative of such terms or other variations on these words or comparable terminology. These statements involve unknown risks and uncertainties that may individually or materially impact the matters discussed herein for a variety of reasons that are outside the control of the Company, including, but not limited to, the Company's ability to raise sufficient financing to implement its business plan and its ability to successfully develop and commercialize its proprietary products and technologies. Readers are cautioned not to place undue reliance on these forward-looking statements, as actual results could differ materially from those described in the forward-looking statements contained herein. 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, 2017 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.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance or achievements. The Company will not update or revise the forward-looking statements except to the extent required by applicable law.

PART I – FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Guardion Health Sciences, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets		
Cash	$ 1,101,790	$ 4,735,230
Accounts receivable	17,011	72,771
Inventories	381,268	154,730
Prepaid expenses	38,736	117,164
Total current assets	**1,538,805**	**5,079,895**
Deposits	11,751	10,470
Property and equipment, net	261,871	95,597
Intangible assets, net	509,763	620,741
Goodwill	1,563,520	1,563,520
Total assets	**$ 3,885,710**	**$ 7,370,223**
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 268,121	$ 311,236
Accrued expenses and deferred rent	22,433	12,043
Line of credit	-	30,535
Due to related parties	108,018	146,133
Total current liabilities	**398,572**	**499,947**
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized	-	-
Common stock, $0.001 par value; 90,000,000 shares authorized; 40,329,475 and 40,183,475 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	40,329	40,183
Additional paid-in capital	36,603,982	33,696,049
Accumulated deficit	(33,157,173)	(26,865,956)
Total stockholders' equity	**3,487,138**	**6,870,276**
Total liabilities and stockholders' equity	**$ 3,885,710**	**$ 7,370,223**

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue	$ 294,230	$ 62,698	$ 708,047	$ 178,610
Cost of goods sold	125,406	30,094	292,461	82,420
Gross profit	168,824	32,604	415,586	96,190
Operating expenses				
Research and development	4,793	105,561	199,500	131,330
Sales and marketing	240,028	116,440	1,224,491	294,774
General and administrative	1,064,645	1,392,524	3,779,325	2,758,331
Total operating expenses	1,309,466	1,614,525	5,203,316	3,184,435
Loss from operations	(1,140,642)	(1,581,921)	(4,787,730)	(3,088,245)
Other expenses:				
Interest expense	545	2,462	2,090	20,817
Warrants - extension of expiration dates	1,007,006	-	1,501,397	-
Total other expenses	1,007,551	2,462	1,503,487	20,817
Net loss	(2,148,193)	(1,584,383)	(6,291,217)	(3,109,062)
Adjustments related to Series A and Series B convertible preferred stock:				
Accretion of deemed dividend	-	(249,820)	-	(335,337)
Dividend declared	-	(78,616)	-	(159,798)
Net loss attributable to common shareholders	**$ (2,148,193)**	**$ (1,912,819)**	**$ (6,291,217)**	**$ (3,604,197)**
Net loss per common share – basic and diluted	$ (0.05)	$ (0.07)	$ (0.16)	$ (0.14)
Weighted average common shares outstanding – basic and diluted	40,329,475	25,825,907	40,324,662	25,469,112

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2017	40,183,475	$ 40,183	$ 33,696,049	$ (26,865,956)	$ 6,870,276
Fair value of vested stock options	-	-	1,405,222	-	1,405,222
Issuance of common stock – warrant exercises	146,000	146	1,314	-	1,460
Warrants - extension of expiration dates	-	-	1,501,397	-	1,501,397
Net loss	-	-	-	(6,291,217)	(6,291,217)
Balance at September 30, 2018	40,329,475	$ 40,329	$ 36,603,982	$ (33,157,173)	$ 3,487,138

See accompanying notes to condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	**2017**
	(Unaudited)	**(Unaudited)**
Operating Activities		
Net loss	$ (6,291,217)	$ (3,109,062)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	223,014	47,869
Accrued interest expense included in notes payable	-	14,792
Stock-based compensation	1,405,222	987,932
Stock-based compensation – related parties	-	196,051
Warrants – extension of expiration dates	1,501,397	-
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Accounts receivable	55,761	(1,831)
Inventories	(226,537)	(40,741)
Deposits and prepaid expenses	77,147	2,169
Increase (decrease) in -		
Accounts payable and accrued expenses	(43,117)	51,626
Accrued and deferred rent costs	10,390	(63,550)
Net cash used in operating activities	(3,287,940)	(1,914,745)
Investing Activities		
Purchase of property and equipment	(228,311)	(25,203)
Purchase of intellectual property	(50,000)	-
Cash assumed upon acquisition	-	4,895
Net cash used in investing activities	(278,311)	(20,308)
Financing Activities		
Proceeds from issuance of promissory notes	-	100,000
Payments on promissory notes	-	(124,000)
Payments on line of credit	(30,535)	-
Proceeds from issuance of preferred stock	-	3,105,000
Proceeds from exercise of warrants	1,460	-
(Decrease) increase in due to related parties	(38,114)	61,288
Net cash (used in) provided by financing activities	(67,189)	3,142,288
Cash:		
Net (decrease) increase	(3,633,440)	1,207,235
Balance at beginning of period	4,735,230	62,520
Balance at end of period	$ 1,101,790	$ 1,269,755
Supplemental disclosure of cash flow information:		
Cash paid for-		
Interest	$ -	$ 1,965
Income taxes	$ -	$ -
Non-cash financing activities:		
Issuance of common stock dividends on preferred stock	$ -	$ 159,798
Fair Value of common shares issued for acquisition allocated to:		
Intangible assets	$ -	$ 674,400
Goodwill	$ -	$ 1,563,520
Other assets	$ -	$ 49,580

See accompanying notes to condensed consolidated financial statements.

Guardion Health Sciences, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)
Nine Months Ended September 30, 2018 and 2017

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.

The Company also developed a proprietary medical device called the MapcatSF® that accurately measures the macular pigment optical density.

On September 29, 2017, the Company completed its acquisition of substantially all of the assets and certain liabilities of VectorVision, Inc., a company that specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and ETDRS visual acuity testing. VectorVision develops, manufactures and sells equipment and supplies for standardized vision testing.

In August 2018, the Company created a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"). TDSI will be 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 is currently setting up the operations of TDSI and hopes to launch its services in upcoming quarters.

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 $6,291,217 and utilized cash in operating activities of $3,287,940 during the nine months ended September 30, 2018. 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, 2017. 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, and VectorVision products. Development and commercialization of medical foods and medical devices involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines. The Company is continuing to attempt 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.

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, 2017 filed with the SEC. The condensed consolidated balance sheet as of December 31, 2017 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, 2018.

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

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

Intangible Assets

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

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

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

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

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, identifiable intangible assets, and goodwill for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell and are no longer depreciated. The Company has not historically recorded any impairment to its long-lived assets. In the future, if events or market conditions affect the estimated fair value to the extent that a long-lived asset is impaired, the Company will adjust the carrying value of these long-lived assets in the period in which the impairment occurs. As of September 30, 2018 and December 31, 2017, 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.

Segment Information

The Company operates and manages its business as one reporting and operating segment, which is 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, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

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.

In September 2014, the Financial Accounting Standards Board issued Accounting Standards Update No. 2014-09 (ASU No. 2014-09) regarding revenue recognition. The new 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. The ASU became effective January 1, 2018.

Due to the nature of the products sold by the Company, the adoption of the new standard has had no quantitative effect on the financial statements. However, the guidance requires additional disclosures to help readers of financial statements better understand the nature, amount, timing, and uncertainty of revenue that is recognized.

The Company previously recognized revenue when risk of loss transferred to its customers and collection of the receivable was reasonably assured, which generally occurs when the product is shipped. A product is not shipped without an order from the customer and credit acceptance procedures performed. The Company allows for returns within 30 days of purchase, although for all periods presented, returns have been insignificant.

Under the new 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 product type:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Lumega-Z and supplements	$ 86,082	$ 62,698	$ 238,213	$ 178,610
VectorVision medical devices and supplies	208,148	-	469,834	-
	$ 294,230	$ 62,698	$ 708,047	$ 178,610

Research and Development Costs

Research and development costs consist primarily of fees paid to consultants and outside service providers and other expenses relating to the acquisition, design, development and testing of the Company's medical foods and related products. Research and development expenditures, which include stock compensation expense, are expensed as incurred and totaled $199,500 and $131,330 for the nine months ended September 30, 2018 and 2017, respectively.

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, consultants, contractors, 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.

The Company accounts 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. 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 Company recognizes stock compensation expense, on stock purchases at a price less than fair value, and for fully-vested stock issued to consultants and other service providers, for the excess of fair value of the stock over the price paid for the stock. 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 Company will issue new shares to satisfy stock option exercises.

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, if applicable. 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 of common stock issuable upon conversion of convertible debt and convertible preferred stock 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 of common stock issuable upon exercise of warrants, options, and conversion of convertible debt and convertible preferred stock outstanding are anti-dilutive as they decrease loss per share.

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

	September 30,	
	2018	**2017**
Warrants	2,521,348	2,983,666
Options	2,725,000	650,000
Estimated shares issuable upon conversion of convertible notes payable	-	31,250
Shares issuable upon conversion of convertible preferred stock	-	6,981,938
	5,246,348	10,646,854

Recent Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), Leases (Topic 842). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. 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. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The adoption of ASU 2016-02 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11, Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). ASU 2017-11 allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted for as derivative liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, an entity will treat the value of the effect of the down round as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted. The guidance in ASU 2017-11 is to be applied using a full or modified retrospective approach. The adoption of ASU 2017-11 is not currently expected to have any impact on the Company's financial statement presentation or disclosures.

In June 2018, the FASB issued Accounting Standards Update 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Revenue from Contracts with Customers (Topic 606). ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company will adopt the provisions of ASU 2018-07 in the quarter beginning January 1, 2019. The adoption of ASU 2018-07 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In August 2018, the FASB issued Accounting Standards Update 2018-13, Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). ASU 2018-13 provides guidance on modifying the disclosure requirements on fair value measurements as part of the disclosure framework project. The guidance modifies, among other things, the disclosures required for Level 3 fair value measurements, including the range and weighted average of significant unobservable inputs. The guidance removes, among other things, the disclosure requirement to disclose transfers between Levels 1 and 2. The guidance will be effective for the Company on January 1, 2020, including interim periods, with early adoption permitted. The adoption of ASU 2018-13 is not expected to have any impact on the Company's financial statement presentation or disclosures.

The Company's management does not believe that any other 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. VectorVision Acquisition

On September 29, 2017, the Company, through a wholly-owned subsidiary, completed the acquisition of substantially all of the assets and certain liabilities of VectorVision, Inc., an Ohio corporation ("VectorVision"), in exchange for 3,050,000 shares of the Company's common stock, valued at $2,287,500, pursuant to the terms of an Asset Purchase and Reorganization Agreement dated September 29, 2017 (the "VectorVision Agreement"). The VectorVision Agreement was entered into on an arm's-length basis. The wholly-owned subsidiary that acquired the business is called VectorVision Ocular Health, Inc., a Delaware corporation, doing business as VectorVision. With respect to the 3,050,000 shares of common stock, 250,000 shares are held back by the Company through November 28, 2019 as security for VectorVision's indemnification obligations to the Company and the remaining 2,800,000 shares were issued to VectorVision at the closing of the transaction. Per the VectorVision Agreement, the 2,800,000 shares were subsequently distributed to the two VectorVision shareholders in proportion to their shareholdings in VectorVision. The shares represented approximately 11% of the Company's issued and outstanding common stock immediately following consummation of the transaction. The shares held back as security are included in the Company's weighted average common shares outstanding for per-share calculations.

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. VectorVision specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and ETDRS (Early Treatment Diabetic Retinopathy Study) visual acuity testing. VectorVision developed and commercialized its CSV-1000 medical device to conduct contrast sensitivity testing and it developed and commercialized its ESV-3000 medical device to conduct ETDRS visual acuity testing. The patented standardization system provides 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. The Company believes VectorVision's CSV-1000 device to be the standard of care for clinical trials. The VectorVision transaction expanded the Company's technical portfolio and the Company believes it further established the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

In accordance with ASC 805, the Company utilized the acquisition method of accounting, whereby the purchase consideration is allocated to specific tangible and intangible assets at their estimated fair values on the date of acquisition. The following table summarizes the allocation of preliminary fair values of the purchase consideration to the assets and liabilities assumed:

	Fair Values
Common stock consideration	$ 2,287,500
Liabilities assumed	108,722
Total purchase consideration	**2,396,222**
Cash	(4,895)
Accounts receivable	(50,105)
Inventory	(93,293)
Prepaid assets	(551)
Property and equipment	(9,458)
Intangible assets	(674,400)
Goodwill	**$ 1,563,520**

Goodwill is calculated as the excess of the consideration transferred over the net assets recognized and represents the expected revenue and benefits of the combined company.

The following unaudited pro forma financial information gives effect to the Company's acquisition of VectorVision as if the acquisition had occurred on January 1, 2017 and had been included in the Company's consolidated statements of operations during the three and nine-month periods ended September 30, 2017:

	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2017
Pro forma net revenues	$ 198,496	$ 565,289
Pro forma net loss attributable to common shareholders	$ (1,879,947)	$ (3,705,586)
Pro forma net loss per share	$ (0.07)	$ (0.13)

4. Inventories

Inventories consisted of the following:

	September 30, 2018	December 31, 2017
Raw materials	$ 312,981	$ 133,354
Finished goods	68,287	21,376
	$ 381,268	$ 154,730

5. Property and Equipment, net

Property and equipment consisted of the following:

	September 30, 2018	December 31, 2017
Leasehold improvements	$ 98,357	$ 98,357
Testing equipment	249,447	150,603
Furniture and fixtures	148,754	50,300
Computer equipment	47,476	16,464
Office equipment	8,193	8,193
	552,227	323,917
Less accumulated depreciation and amortization	(290,356)	(228,320)
	$ 261,871	$ 95,597

For the nine months ended September 30, 2018 and 2017, depreciation expense was $62,036 and $47,869, respectively, of which $23,854 and $22,044 were included in research and development expense, $7,242 and $0 were included in sales and marketing expense, and $30,940 and $25,825 were included in general and administrative expense, respectively.

6. Acquisition of Intellectual Property

On January 26, 2018, the Company acquired the rights to the trademark GLAUCO-HEALTH as well as the name “International Eye Wellness Institute” (together, the “IP Assets”) from an unrelated third party. The purchase included all rights, title, and interest in and to the IP Assets, including (a) the right to register and use the IP Assets; (b) all goodwill associated with the IP Assets; (c) all income, royalties, and damages hereafter due or payable with respect to the IP Assets; (d) all rights to sue for past, present, and future infringements or misappropriations of the IP Assets; and (e) and all other intellectual property rights owned or claimed by the seller or embodied in the IP Assets. In exchange for these rights, the Company paid the seller $50,000 in cash.

ASC 350-30-20 defines a defensive intangible asset as an acquired intangible asset in a situation in which an entity does not intend to actively use the asset but intends to hold (lock up) the asset to prevent others from obtaining access to the asset. The Company determined that the acquired intangible asset met the definition of a defensive intangible asset. The Company accounted for the $50,000 payment as an acquired intangible asset as of the closing of the agreement. As the Company can renew the underlying rights to the IP Assets indefinitely at nominal cost, the assets have been classified as a non-amortizable intangible asset on the Company’s balance sheet at September 30, 2018. The Company will evaluate the status of the assets for impairment annually or more frequently if warranted.

On January 26, 2018 the Company entered into a consulting agreement with the principal of the seller to assist with the development of the IP Assets and other assets acquired by the Company in the transaction. In conjunction with the consulting agreement, the Company granted a stock option on January 26, 2018 to the consultant to purchase a total of 500,000 shares of the common stock of the Company (see Note 8).

7. Related Party Transactions

Due to and from related parties represents unreimbursed expenses and compensation incurred on behalf of, and amounts loaned to the Company by, Michael Favish, the Company’s Chief Executive Officer, as well as other stockholders. The advances are unsecured, non-interest bearing and are due on demand. As of September 30, 2018 and December 31, 2017, the Company had $108,018 and $146,133, respectively, due to related parties.

8. Stockholders’ Equity

Preferred Stock

Series A

During 2016, the Company sold 1,170,000 shares of the Company's Series A Senior Convertible Preferred Stock (the "Series A Preferred Stock") to various investors. The purchase price of the Series A Preferred Stock was $1.00 per share, for an aggregate purchase price of $1,170,000. In addition, during 2016, the Company issued 535,154 shares of its Series A Preferred Stock with a fair value of $784,888 upon conversion of $535,149 of notes payable and accrued interest. The Series A Preferred Stock had a stated value of $1.00 per share and accrued an annual dividend at the rate of 8% of the stated value, calculated quarterly, paid in shares of common stock at the rate of $0.60 per share.

During the nine months ended September 30, 2017, the Company declared dividends of $102,029 on its Series A Preferred Stock which were satisfied in full through the issuance of an aggregate of 170,075 shares of common stock.

Series B

Beginning in March 2017 and through September 30, 2017, the Company sold 3,105,000 shares of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock") to various investors. The purchase price of the Series B Preferred Stock was $1.00 per share, for an aggregate purchase price of $3,105,000. The Series B Preferred Stock had a stated value of $1.00 per share and accrued an annual dividend at the rate of 6% of the stated value, calculated quarterly, paid in shares of common stock at the rate of $0.75 per share.

During the nine months ended September 30, 2017, the Company declared dividends of $57,769 on its Series B Preferred Stock which were satisfied in full through the issuance of an aggregate of 77,045 shares of common stock.

On November 3, 2017, the Company completed the issuance and sale of an aggregate of 4,347,827 shares of common stock (see below). The completion of the private placement triggered, at the Company's election, the automatic conversion of the Series A Preferred Stock and the Series B Preferred Stock into shares of common stock. Accordingly, immediately following the completion of the private placement, the Company effected the conversion of all outstanding shares of Series A Preferred Stock and the Series B Preferred Stock into 6,981,938 shares of common stock (excluding accrued but unpaid dividends) effective November 3, 2017. On April 26, 2018, the Company filed a Certificate of Elimination with the Secretary of the State of Delaware, withdrawing the respective Certificates of Designation that established the right, privileges and preferences of the Series A Preferred Stock and Series B Preferred Stock, thereby making all 10,000,000 authorized shares of preferred stock available for issuance.

Common Stock

On November 3, 2017, the Company completed the issuance and sale of an aggregate of 4,347,827 shares of common stock, par value $0.001 per share, at a purchase price of $1.15 per share. Total gross proceeds were $5,000,001. These shares were sold in a private placement to certain purchasers pursuant to a Stock Purchase Agreement dated as of November 3, 2017. Pursuant to the agreement, the purchasers have customary preemptive rights to participate in future equity and equity-linked issuances by the Company up to the extent necessary to maintain such purchaser's pro rata ownership percentage in the Company's securities, subject to customary exceptions. The preemptive rights terminate at the earlier of (i) May 3, 2019, (ii) such time as the Purchasers hold less than five percent (5%) of the issued and outstanding shares of the Company's common stock, or (iii) such time as the shares of common stock of the Company shall become listed or approved for listing on a national securities exchange.

Warrants

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

	Shares
December 31, 2017	**2,983,666**
Granted	-
Forfeitures	-
Expirations	(316,318)
Exercised	(146,000)
September 30, 2018, all exercisable	**2,521,348**

In January 2018, an investor exercised warrants for 146,000 shares of common stock. The warrants were exercisable for $0.01 per share, and the Company received $1,460 in cash. The Company issued the shares and recorded the cash received as additional equity.

On April 30, 2018, The Company offered a one-month exercise period extension to stockholders who held warrants to purchase shares of common stock of the Company that were scheduled to expire on May 1, 2018. Pursuant to the terms of a Note and Warrant Purchase Agreement entered into by the Company and such holders, such warrants were issued upon the conversion of certain promissory notes into common stock on May 1, 2015. Four of the warrant holders did not extend their warrants, resulting in the expiration of 151,006 warrants on May 1, 2018. Six warrant holders extended the term of an aggregate of 403,085 warrants by one month to June 1, 2018. The exercise price of such warrants is $1.00 per share.

On May 31, 2018, the six warrant holders noted above were offered a further extension of the exercise period for their warrants. One holder did not extend, resulting in the expiration of 30,237 warrants on June 1, 2018. The Company and five warrant holders extended the term of an aggregate of 372,848 warrants. These warrants are now scheduled to expire on the earlier of (a) May 31, 2019 or (b) sixty days following the date on which the common stock of the Company becomes listed or approved for listing on a national securities exchange. The exercise price of such warrants remains unchanged at $1.00 per share, but cashless exercise provisions have been eliminated from such warrants.

On September 21, 2018, the Company extended warrants to purchase shares of common stock of the Company that were scheduled to expire at dates ranging from September 30, 2018 through January 25, 2019 held by two stockholders. Pursuant to the terms of a Promissory Note and Loan Agreements entered into by the Company and such holders, the warrants were originally issued as inducement to lend money to the Company. The warrant holders extended the expiration dates of an aggregate of 600,000 warrants. These warrants are now scheduled to expire on February 15, 2019. The exercise price of $0.25 per share and all other terms of the warrants remain unchanged.

Management applied the guidance in ASC 718 – Compensation-Stock Compensation which indicates that a modification to the terms of an award should be treated as an exchange of the original award for a new award with the resulting total compensation cost equal to the grant-date fair value of the original award plus the incremental value of the modification to the award. Under ASC 718, the calculation of the incremental value is based on the excess of the fair value of the new (modified) award based on current circumstances over the fair value of the original award measured immediately before its terms are modified based on current circumstances. The Company recognized expense of $1,501,397 during the nine months ended September 30, 2018 relating to the extension of the exercise periods of the warrants based upon a Black-Scholes option-pricing model using stock prices of $1.15 and $1.80, volatility of 118% and 119%, and average risk-free rates of 2.61 and 2.89. The expense is reflected as Warrants - extension of expiration dates in the Company's statements of operations.

As of September 30, 2018, the Company had an aggregate of 2,521,348 outstanding warrants to purchase shares of its common stock with a weighted average exercise price of $0.43, weighted average remaining life of 0.5 years and aggregate intrinsic value of $3,461,453, based upon a stock valuation of $1.80 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.

Stock Options

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

	Shares
December 31, 2017	**2,125,000**
Granted	600,000
Forfeitures	-
Exercised	-
September 30, 2018, outstanding	**2,725,000**
September 30, 2018, exercisable	**2,400,000**

On September 30, 2017, the Company entered into a consulting agreement pursuant to which the Company granted a total of 1,250,000 common stock options. 650,000 of the options with a fair value of $486,070 vested immediately, and the remaining 600,000 options vested ratably over twelve months on a quarterly basis with compensation cost measured as the fair value at the end of each reporting period. The options are non-qualified, have an exercise price of $1.00 per share, and will expire 5 years from the grant date. As of December 31, 2017, the Company had recognized compensation cost of $658,383 relating to the vesting of 800,000 options. During the nine months ended September 30, 2018, the Company recognized stock compensation costs of $394,239 related to the vesting of 450,000 options based upon a graded vesting schedule. As of September 30, 2018, the 1,250,000 options were fully vested and exercisable.

On December 30, 2017, the Company entered into a consulting agreement pursuant to which the Company granted a total of 750,000 common stock options. 250,000 of the options with a fair value of $312,275 vested immediately, and the remaining 500,000 options vested ratably over six months on a quarterly basis with compensation cost measured as the fair value at the end of each reporting period, using a Black Scholes option-pricing model and a graded vesting schedule. The options are non-qualified, have an exercise price of $1.25 per share, and will expire 5 years from the grant date. During the nine months ended September 30, 2018, the Company recognized stock compensation costs of $413,877 related to the vesting of 500,000 options. As of September 30, 2018, the 750,000 options were fully vested and exercisable.

On January 26, 2018, the Company entered into an agreement with a consultant to develop products based on certain intellectual property owned by the Company (see Note 6). In conjunction with the consulting agreement, the Company granted a stock option to the consultant to purchase a total of 500,000 shares of the common stock of the Company. 250,000 shares of the option with a fair value of $287,500 vested immediately, 125,000 shares vest on December 31, 2018 and the remaining 125,000 shares vest on December 31, 2019 provided the consultant is still an active service provider. As of September 30, 2018, the 250,000 options that remain to vest were valued in total at $449,863 based upon a Black-Scholes option-pricing model. Compensation cost is measured as the fair value at the end of each reporting period and cost is amortized based upon a graded vesting schedule. The options are non-qualified, have an exercise price of $1.25 per share, and will expire 5 years from the grant date. During the nine months ended September 30, 2018, the Company recognized stock compensation costs of $529,323 related to the 500,000 options.

On July 25, 2018, the Company entered into an agreement with a consultant to develop products based on certain intellectual property owned by the Company. In conjunction with the consulting agreement, the Company granted a stock option to the consultant to purchase a total of 100,000 shares of the common stock of the Company. 25,000 shares of the option with a fair value of $44,994 vested immediately, while the remaining 75,000 shares vest on completion of certain performance conditions to the reasonable satisfaction of the Company. Specifically, 50,000 shares vest upon completion of design and construction of the AcQviz device, and the remaining 25,000 shares vest upon integration of the AcQviz send/receive functionality with vision testing software platform. As of September 30, 2018, the 75,000 options that remain to vest were valued in total at $134,983 based upon a Black-Scholes option-pricing model. As of September 30, 2018, the completion of all performance conditions was considered probable. Because completion of the performance conditions is considered probable, compensation cost is measured as the fair value at the end of each reporting period and cost is amortized based upon an accelerated attribution model using Management's estimates of anticipated timing for completion of the conditions. The options are non-qualified, have an exercise price of $1.25 per share, and will expire 5 years from the grant date. During the nine months ended September 30, 2018, the Company recognized stock compensation costs of $67,783 related to the 100,000 options.

As of September 30, 2018, options were valued based upon the Black-Scholes option-pricing model, with a stock price of $1.80, volatility of 121%, and an average risk-free rate of 2.88%.

As of September 30, 2018, the Company had an aggregate of 325,000 remaining unvested options outstanding, with estimated fair value of $584,846. The Company remeasures unvested options for non-employees to fair value at the end of each reporting period. The aggregate intrinsic value of options outstanding as of September 30, 2018 was $1,823,750.

9. Commitments and Contingencies

The Company is periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. In the opinion of management of the Company, adequate provision has been made in the Company's condensed financial statements at September 30, 2018 with respect to such matters, including the matter noted below.

On or about July 26, 2017, the Company received a payment demand from a former consultant to the Company alleging that the consultant was owed approximately $192,000 for services rendered. On January 29, 2018, the Company filed a lawsuit against the consultant and its related entities in the United States District Court for the Southern District of California (Case No. 18CV200-W-KSC) seeking declaratory relief regarding advisory fees and ownership interest in the Company. On March 6, 2018, the consultant and its related entities filed counterclaims against the Company, seeking payment for services rendered and seeking declaratory relief regarding ownership interest in the Company. The parties subsequently settled the disputes in their entirety. The Case was dismissed with prejudice on August 29, 2018.

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, 2017, and the notes thereto, which are set forth in the 2017 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. 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.

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 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 acquisition expands the Company's technical portfolio. The Company believes the acquisition of VectorVision, adding the CSV-1000 and ESV-3000 to its product portfolio, further establishes its position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

The Company has had limited operations to date and has been primarily engaged in research and development, product commercialization and capital raising activities.

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.

Lumega-Z is a medical food product that has a patent-pending formula that replenishes and restores the macular protective pigment simultaneously delivering critical and essential nutrients to the eye. Management believes, based on review of products on the market and knowledge of the industry, that Lumega-Z is the first liquid ocular health formula to be classified as a medical food (as defined in Section 5(b) of the "Orphan Drug Act"). However, the FDA has not monitored nor approved Lumega-Z as a medical food. Formulated by Dr. Sheldon Hendler in 2010, modifications were made over a two-year period to improve the taste and method of delivery. The current formulation has been delivered to patients and used in clinics since 2014.

Medical foods are not considered to be either dietary or nutritional supplements. The Company believes that there is an increasing level of acceptance of medical foods as a primary therapy by patients and healthcare providers to treat pain syndromes, sleep and cognitive disorders, obesity, hypertension, and viral infection. In clinical practice, medical foods are being prescribed as both a standalone therapy and as an adjunct therapy to low doses of commonly prescribed drugs. The Company believes that medical foods will continue to grow in importance over the coming years.

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

Patents

On July 10, 2018, the USPTO issued US Patent No. 10,016,128, titled Method and Apparatus for Visual Acuity Testing. This patent describes an invention pertaining to automatic light calibration of the display screens used for vision testing. The Company owns this patent, and its VectorVision CSV-1000 and ESV-3000 devices each embody this invention.

On July 17, 2018, the USPTO issued US Patent No. 10,022,045, also titled Method and Apparatus for Visual Acuity Testing, which describes a methodology to continuously calibrate display monitors to automatically hold display luminance constant for vision testing. This second patent also covers a methodology to compensate for other testing factors, such as room illumination and when patients view the vision test through a mirror, which is a common practice in eye doctors' offices worldwide. The Company also owns this patent, and its VectorVision CSV-1000 and ESV-3000 devices each embody this invention.

These patents serve as the basis for developing follow-on products to the CSV-1000, including the 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 also anticipates commercializing these proprietary methodologies for use with other types of vision tests so that other tests can be properly calibrated to adhere to recognized government vision test lighting standards.

Prior to the issuance of US Patent No. 9,486,136, the Company filed a continuation application, Patent Application 15/346,010, covering new embodiments around the MapcatSF® device. These new embodiments contain improvements related to the accuracy of intensity measurements made with the device, as well as updated features around photodiode detector calibrations.

Transcranial Doppler Solutions

In August 2018, the Company formed a wholly owned subsidiary, Transcranial Doppler Solutions, Inc. ("TDSI"), to further the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases. TDSI will be dedicated to the pursuit of early predictors resulting in, the Company believes valuable therapeutic intervention for practitioners and their patients, and additional revenues stream generated from the testing and sale of Company products to appropriate customers. TDSI will provide a service that makes TCD (as defined below) testing convenient by being in various medical facilities. A Transcranial Doppler ultrasound ("TCD") has been accepted as a safe, non-invasive, and lower-cost technique that uses a low-frequency transducer probe to assess intracerebral blood flow, within the brain and to the eyes. Studies have shown the ability of TCD to predict stroke risks as well as other potential cardiovascular events. TCD also plays an important role in detecting changes in the ophthalmic artery blood flow, which is important to help evaluate the course of common eye disorders. Blood velocities and intensities can be measured using TCD, which provides an effective way to determine more accurately the state of pathology in early stages of common eye disorders such as glaucoma and other eye diseases that cause visual field defects. Published medical resources indicate a strong relationship between ocular circulation and visual function in patients with glaucoma, diabetes, and macular disease, which are the three leading causes of acquired irreversible blindness throughout the world. A TCD is also highly repeatable, the results of which provide an effective tool for ophthalmologists to treat their patients. Through the monitoring of blood flow in the intracranial vessels, including the ophthalmic artery, the TCD results will in turn provide an evidence-based protocol for Guardion's medical foods, including the Company's soon to be released new GlaucoCetin product. The Company is currently setting up the operations of TDSI and hopes to launch its services in upcoming quarters.

GlaucoCetin

The Company has 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 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. During the glaucomatous disease process, the metabolism for the optic nerve cells start to fail because of dysfunctional mitochondria. Mitochondria is responsible for energy production in these cells. When mitochondria are unable to function, the nerve cells do not have enough energy to operate, and they eventually die, causing vision loss.

The precursor formula of GlaucoCetin (previously known as GlaucoHealth) has been under development for many years and has been proven in clinical studies to reverse mitochondrial damage in glaucoma patients. In an IRB-approved, IND registered study conducted at the New York Eye and Ear Infirmary, GlaucoHealth reversed mitochondrial metabolic dysfunction as determined by the Retinal Metabolic Analyzer, which measures retinal flavoprotein activity, a direct measure of mitochondrial activity.

The Company's GlaucoCetin product was developed in collaboration with Dr. Robert Ritch, a world-renowned glaucoma specialist from Manhattan Eye and Ear Infirmary and Mount Sinai Medical Center in New York City. Dr. Ritch has also been a member of the Company's Medical Advisory Board for the past three years. The Company is preparing to launch GlaucoCetin in the fourth quarter of 2018.

Going Concern

The financial statements have been prepared assuming the Company will continue as a going concern. The Company had a net loss of $6,291,217 and utilized cash in operating activities of $3,287,940 during the nine months ended September 30, 2018. 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, 2017. 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, and VectorVision products. Development and commercialization of medical foods and medical devices involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines. The Company is continuing to attempt to raise additional debt and/or equity capital to fund future operations, but there can be no assurances that the Company will be able to secure such additional financing in the amounts necessary to fully fund its operating requirements on acceptable terms or at all. If the Company is unable to access sufficient capital resources on a timely basis, the Company may be forced to reduce or discontinue its technology and product development programs and curtail or cease operations.

Recent Accounting Pronouncements

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

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 its 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.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, identifiable intangible assets, and goodwill for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell and are no longer depreciated. The Company has not historically recorded any impairment to its long-lived assets. In the future, if events or market conditions affect the estimated fair value to the extent that a long-lived asset is impaired, the Company will adjust the carrying value of these long-lived assets in the period in which the impairment occurs. As of September 30, 2018 and December 31, 2017, 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.

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, consultants, contractors, 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.

The Company accounts 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. 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. In order to assist management in calculating such fair value, the Company retained a third-party valuation firm in determining the value of the Company. The third-party valuation firm's input was utilized in determining the related per unit or share valuations of the Company's equity used during 2017. Management used a valuation of $0.88 per share for the six months ended June 30, 2017. Internal valuations are based on various inputs, including valuation reports prepared by third-party valuation firms and are impacted by the dilutive effect of the issuance of common shares as compensation during the periods. There are numerous acceptable ways to estimate company value, including using net tangible assets, a market-based approach, or discounted cash flows. The Company considered alternative methods and concluded that due to the lack of suitably comparable market data, the discounted cash flows method was the most appropriate. A discounted cash flows (i.e. free cash flows to equity) methodology was applied by the third-party valuation firm to assist management in their determination of the $0.88 used during 2017. This methodology used multiple years of balance sheet and income statement projections along with the following primary assumptions:

	Six Months Ended June 30, 2017
Discount rate	16%
Risk free rate	2.48%
Rate of return	16%
Sustainable growth rate	5%
Company survival probability	65%
Liquidation value	$ 0

Due to the availability of historical data from the Company's recent preferred stock sales, Management used a valuation of $0.75 for accounting purposes during the third quarter of 2017. Management used a valuation of $1.80 for the nine months ended September 30, 2018. Management considered business and market factors affecting the Company during 2018, including capital raising efforts, its proprietary technology, and other factors. Based on this evaluation, management believes that its valuations are appropriate for accounting purposes at September 30, 2018 and 2017, respectively.

The Company recognizes stock compensation expense, on stock purchases at a price less than fair value, and for fully-vested stock issued to consultants and other service providers, for the excess of fair value of the stock over the price paid for the stock. 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 Company will issue new shares to satisfy stock option exercises.

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, starting with the manufacture of at least 15 new units for sale or lease;
- expand the Company's domestic sales and marketing efforts, which include revamping its web site and new promotional materials;
- explore sales and marketing opportunities in foreign markets such as Asia and Europe;
- increase production of Lumega-Z as is necessary 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 TCDS 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

In November 2017, the Company received gross proceeds of $5,000,001 pursuant to the issuance and sale of 4,347,827 shares of common stock. During 2018, the Company has deployed significant efforts and capital resources to focus on development and commercialization activities related to its medical foods, the MapcatSF® medical device, the VectorVision CSV-1000 and ESV-3000 medical devices, and its newly incorporated subsidiary, Transcranial Doppler Solutions, Inc., which was formed to provide Transcranial Doppler ultrasound services on patients at medical facilities to further the Company's position at the forefront of early detection, intervention and monitoring of a range of eye diseases.

Substantial resources were devoted in 2018 to the redesign and improvement of the sales and marketing infrastructure. The Company now has dedicated sales personnel located in and responsible for key strategic sales territories in the United States. In conjunction with hiring sales staff, the Company procured equipment and supplies to support the sales staff and incurs travel expenses related to their sales activities. The Company developed an ecommerce platform and has upgraded and added new website access for products and information. The Company's first targeted marketing campaign for Lumega-Z began in the second quarter of 2018. The Company also dedicated resources to attend certain trade shows to increase the presence of the Company and VectorVision in pertinent industries. Engineering and product development efforts in 2018 have resulted in the first group of commercially available upgraded MapcatSF® devices. The acquisition and development of intellectual property has enabled both the improvement of existing products and the development of new ones. Specifically, the Company believes that VectorVision's CSV-2000, an upgraded, digital version of the CSV-1000 device, will contribute to the Company's revenue beginning in 2019. Additionally, the development of the GlaucoCetin medical food product has led to an expected product launch in the fourth quarter of 2018. Once fully operational, the Company believes that the Transcranial Doppler subsidiary will provide ultrasound services for the monitoring of blood flow in intracranial vessels, which results the Company hopes will in turn provide an evidence-based protocol for the new GlaucoCetin medical food product.

Through September 30, 2018, the Company had limited operations and has primarily been engaged in product development, commercialization, and raising capital. The Company has incurred and will continue to incur significant expenditures for the development of its products and intellectual property, which includes both medical foods and medical diagnostic equipment for the treatment of various eye diseases. The Company had limited revenue during the nine-month periods ended September 30, 2018 and 2017. In the fourth quarter of 2017, the Company began recognizing product revenue from the sale of VectorVision products in addition to sales of its proprietary product, Lumega-Z.

Comparison of Three Months Ended September 30, 2018 and 2017

	Three Months Ended September 30,			
	2018	2017	Change	
Revenue	$ 294,230	$ 62,698	$ 231,532	369%
Cost of goods sold	125,406	30,094	95,312	317%
Gross Profit	168,824	32,604	136,220	418%
Operating Expenses:				
Research and development	4,793	105,561	(100,768)	(95)%
Sales and marketing	240,028	116,440	123,588	106%
General and administrative	1,064,645	1,392,524	(327,879)	(24)%
Total Operating Expenses	1,309,466	1,614,525	(305,059)	(19)%
Loss from Operations	(1,140,642)	(1,581,921)	441,279	(28)%
Other Expense:				
Interest expense	545	2,462	(1,917)	(78)%
Warrants - extension of expiration dates	1,007,006	-	1,007,006	-%
Net Loss	$ (2,148,193)	$ (1,584,383)	$ (563,810)	36%

Revenue

For the three months ended September 30, 2018, revenue from product sales was $294,230 compared to $62,698 for the three months ended September 30, 2017, resulting in an increase of $231,532 or 369%. The increase reflects both an increased customer base for Lumega-Z as the Company expands into new clinics and sales of VectorVision products. $86,082, or 29% of revenue in the third quarter of 2018 was generated by sales of Lumega-Z products, representing a 37% increase in Lumega-Z sales over the prior period. Management expects continued growth in prescribing clinics and Lumega-Z revenue going forward. As of September 30, 2018, the Company had a sales backlog of approximately $87,000 in VectorVision products that are expected to be delivered during the fourth quarter of 2018.

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

	Three Months Ended September 30,	
	2018	2017
Lumega-Z and supplements	$ 86,082	$ 62,698
VectorVision medical devices and supplies	208,148	-
	$ 294,230	$ 62,698

Cost of Goods Sold

For the three months ended September 30, 2018, cost of goods sold was $125,406 compared to $30,094 for the three months ended September 30, 2017, resulting in an increase of $95,312 or 317%. The increase reflects the additional sales recorded in 2018.

Gross Profit

For the three months ended September 30, 2018, gross profit was $168,824 compared to $32,604 for the three months ended September 30, 2017, resulting in an increase of $136,220 or 418%. The increase is primarily due to the sales of VectorVision products, which did not occur in the prior period.

Research and Development

For the three months ended September 30, 2018, research and development costs were $4,793 compared to $105,561 for the three months ended September 30, 2017, resulting in a decrease of $100,768 or 95%. The decrease was due to development costs associated with the Company's MapcatSF® medical device that were incurred in the prior period.

Sales and Marketing

For the three months ended September 30, 2018, sales and marketing expenses were $240,028 compared to $116,440 for the three months ended September 30, 2017. The increase in sales and marketing expenses of $123,588 or 106% compared to the prior period was primarily due to increases for amortization expense and costs associated with trade shows.

General and Administrative

For the three months ended September 30, 2018, general and administrative expenses were $1,064,645 compared to $1,392,524 for the three months ended September 30, 2017. The decrease of $327,879 or 24% compared to the prior period was primarily due to a decrease in stock compensation expense during the current period. Legal and travel costs also decreased during the current period but were substantially offset by increases in labor and consulting.

Interest Expense

For the three months ended September 30, 2018, interest expense was $545 compared to $2,462 for the three months ended September 30, 2017. The decrease of $1,917, or 78%, was due to the repayment or conversion of promissory notes and convertible debt that had been outstanding during 2017.

Warrants – Extension of Expiration Dates

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

Net Loss

For the three months ended September 30, 2018, the Company incurred a net loss of $2,148,193, compared to a net loss of $1,584,383 for the three months ended September 30, 2017. The increase in net loss of $563,810 or 36% compared to the prior year period was due to the $1,007,006 non-cash expense related to the extension of warrant expiration dates, partially offset by a $320,000 decrease in stock compensation expense decrease as well as reduced development costs associated with the Company's MapcatSF® medical device.

Comparison of Nine Months Ended September 30, 2018 and 2017

	Nine Months Ended September 30,			
	2018	2017	Change	
Revenue	$ 708,047	$ 178,610	$ 529,437	296%
Cost of goods sold	292,461	82,420	210,041	255%
Gross Profit	415,586	96,190	319,396	332%
Operating Expenses:				
Research and development	199,500	131,330	68,170	52%
Sales and marketing	1,224,491	294,774	929,717	315%
General and administrative	3,779,325	2,758,331	1,020,994	37%
Total Operating Expenses	5,203,316	3,184,435	2,018,881	63%
Loss from Operations	(4,787,730)	(3,088,245)	(1,699,485)	55%
Other Expense:				
Interest expense	2,090	20,817	(18,727)	(90)%
Warrants - extension of expiration dates	1,501,397	-	1,501,397	-%
Net Loss	$ (6,291,217)	$ (3,109,062)	$ (3,182,155)	102%

Revenue

For the nine months ended September 30, 2018, revenue from product sales was $708,047 compared to $178,610 for the nine months ended September 30, 2017, resulting in an increase of $529,437 or 296%. The increase reflects both an increased customer base for Lumega-Z as the Company expands into new clinics and sales of VectorVision products. $238,213, or 34% of revenue in 2018 was generated by sales of Lumega-Z products, representing a 33% increase in Lumega-Z sales over the prior period. Management expects continued growth in prescribing clinics and Lumega-Z revenue going forward. As of September 30, 2018, the Company had a sales backlog of approximately $87,000 in VectorVision products that are expected to be delivered during the fourth quarter of 2018.

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

	Nine Months Ended September 30,	
	2018	2017
Lumega-Z and supplements	$ 238,213	$ 178,610
VectorVision medical devices and supplies	469,834	-
	$ 708,047	$ 178,610

Cost of Goods Sold

For the nine months ended September 30, 2018, cost of goods sold was $292,461 compared to $82,420 for the nine months ended September 30, 2017, resulting in an increase of $210,041 or 255%. The increase reflects the additional sales recorded in 2018.

Gross Profit

For the nine months ended September 30, 2018, gross profit was $415,586 compared to $96,190 for the nine months ended September 30, 2017, resulting in an increase of $319,396 or 332%. The increase is primarily due to the sales of VectorVision products, which did not occur in the prior period.

Research and Development

For the nine months ended September 30, 2018, research and development costs were $199,500 compared to $131,330 for the nine months ended September 30, 2017, resulting in an increase of $68,170 or 52%. The increase was due to engineering development costs associated with the Company's MapcatSF® medical device during the first quarter of 2018.

Sales and Marketing

For the nine months ended September 30, 2018, sales and marketing expenses were $1,224,491 compared to $294,774 for the nine months ended September 30, 2017. The increase in sales and marketing expenses of $929,717 or 315% compared to the prior period was primarily due to costs associated with engagement of a third party contract sales organization, increased amortization expense, and increased costs associated with trade shows and marketing.

General and Administrative

For the nine months ended September 30, 2018, general and administrative expenses were $3,779,325 compared to $2,758,331 for the nine months ended September 30, 2017. The increase of $1,020,994 or 37% compared to the prior period was primarily due to increased labor costs related to new employees, benefits expenses, and the inclusion of the VectorVision employees in our consolidated financials. Stock compensation and professional services costs also increased during the period.

Interest Expense

For the nine months ended September 30, 2018, interest expense was $2,090 compared to $20,817 for the nine months ended September 30, 2017. The decrease of $18,727, or 90%, was due to the repayment or conversion of promissory notes and convertible debt that had been outstanding during 2017.

Warrants – Extension of Expiration Dates

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

Net Loss

For the nine months ended September 30, 2018, the Company incurred a net loss of $6,291,217, compared to a net loss of $3,109,062 for the nine months ended September 30, 2017. The increase in net loss of $3,182,155 or 102% compared to the prior year period was due to the non-cash expenses related to stock compensation, amortization expense, and to the extension of warrant expiration dates, as well as to the increased costs associated with the sales team, professional services, marketing and promotional activities, trade show visibility, and the internal labor force. Expenses were offset in part by increased revenue and gross profit.

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 $3,287,940 during the nine months ended September 30, 2018. The Company had positive working capital of $1,140,233 at September 30, 2018 due primarily to the sale of its common stock in November 2017. As of September 30, 2018, the Company had cash in the amount of $1,101,790 and no available borrowings. The Company's financing has historically come from the issuance of convertible notes, promissory notes and from the sale of common and preferred stock and exercise of warrants.

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, 2017. 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, and VectorVision products. Development and commercialization of medical foods and medical devices involves a lengthy and complex process. Additionally, the Company's long-term viability and growth may depend upon the successful development and commercialization of new complementary products or product lines. The Company is continuing attempts 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:

	Nine Months Ended September 30,	
	2018	**2017**
Net cash used in operating activities	$ (3,287,940)	$ (1,914,745)
Net cash used in investing activities	(278,311)	(20,308)
Net cash (used in) provided by financing activities	(67,189)	3,142,288
Net (decrease) increase in cash	$ (3,633,440)	$ 1,207,235

Operating Activities

Net cash used in operating activities was $3,287,940 during the nine months ended September 30, 2018, versus $1,914,745 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 $278,311 for the nine months ended September 30, 2018 and $20,308 for the nine months ended September 30, 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 and have invested in MapCat equipment and internal-use software development.

Financing Activities

Net cash used in financing activities was $67,189 for the nine months ended September 30, 2018 was due to the Company payoff of a $30,535 line of credit balance that had been assumed from the VectorVision transaction as well as payment of 38,114 due to related parties. Financing activities for the comparable prior year period provided proceeds of $100,000 from the issuance of short-term loans, offset by payments of principal and interest on loans of $124,000, $3,105,000 in proceeds from the issuance of Series B Preferred Stock, and an increase of $61,288 in amounts due to related parties.

Off-Balance Sheet Arrangements

At September 30, 2018 and December 31, 2017, we 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. There have been no changes in the Company's internal control over financial reporting identified in connection with the evaluation that occurred during the third quarter ended in 2018 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 periodically the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on the Company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained. In the opinion of management of the Company, adequate provision has been made in the Company's condensed consolidated financial statements at September 30, 2018 with respect to such matters, including the matter noted below.

On or about July 26, 2017, the Company received a payment demand from a former consultant to the Company alleging that the consultant is owed approximately $192,000 for services rendered. The parties settled the disputes in their entirety and the case was dismissed with prejudice on August 29, 2018.

ITEM 1A. RISK FACTORS

Not required for smaller reporting companies.

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

On January 26, 2018, the Company entered into an agreement with a consultant to develop products based on certain intellectual property owned by the Company (see Note 6). In conjunction with the consulting agreement, the Company granted a stock option to the consultant to purchase a total of 500,000 shares of the common stock of the Company. 250,000 shares of the option with a fair value of $287,500 vested immediately, 125,000 shares vest on December 31, 2018 and the remaining 125,000 shares vest on December 31, 2019 provided the consultant is still an active service provider. As of September 30, 2018, the 250,000 options that remain to vest were valued in total at $449,863 based upon a Black-Scholes option-pricing model. Compensation cost is measured as the fair value at the end of each reporting period and cost is amortized based upon a graded vesting schedule. The options are non-qualified, have an exercise price of $1.25 per share, and will expire 5 years from the grant date. During the nine months ended September 30, 2018, the Company recognized stock compensation costs of $529,323 related to the 500,000 options.

On July 25, 2018, the Company entered into an agreement with a consultant to develop products based on certain intellectual property owned by the Company. In conjunction with the consulting agreement, the Company granted a stock option to the consultant to purchase a total of 100,000 shares of the common stock of the Company. 25,000 shares of the option with a fair value of $44,994 vested immediately, while the remaining 75,000 shares vest on completion of certain performance conditions to the reasonable satisfaction of the Company. Specifically, 50,000 shares vest upon completion of design and construction of the AcQviz device, and the remaining 25,000 shares vest upon integration of the AcQviz send/receive functionality with vision testing software platform. As of September 30, 2018, the 75,000 options that remain to vest were valued in total at $134,983 based upon a Black-Scholes option-pricing model. As of September 30, 2018, the completion of all performance conditions was considered probable. Because completion of the performance conditions is considered probable, compensation cost is measured as the fair value at the end of each reporting period and cost is amortized based upon an accelerated attribution model using Management's estimates of anticipated timing for completion of the conditions. The options are non-qualified, have an exercise price of $1.25 per share, and will expire 5 years from the grant date. During the nine months ended September 30, 2018, the Company recognized stock compensation costs of $67,784 related to the 100,000 options.

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 14th day of November, 2018.

Signature	Title	Date
/s/ Michael Favish Michael Favish	CEO, President and Chairman of the Board (Principal Executive Officer)	November 14, 2018
/s/ John Townsend John Townsend	Controller and Chief Accounting Officer (Principal Accounting Officer)	November 14, 2018

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 September 30, 2018, formatted in XBRL (eXtensible Business Reporting Language), (i) Balance Sheets, (ii) Statements of Income, (iii) Statements of Comprehensive Income, (iv) Statements of Cash Flows, (v) Statement of Stockholders' Equity and (vi) Notes to Financial Statements

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

Exhibit 31.1

CERTIFICATION

I, Michael Favish, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Guardion Health Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2018

/s/ Michael Favish

Michael Favish
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, John Townsend, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Guardion Health Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2018

/s/ John Townsend

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

Exhibit 32.1

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

In connection with the Quarterly Report of Guardion Health Sciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Michael Favish, Chief Executive Officer of the Company, and John Townsend, Controller and Chief Accounting Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as enacted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 14, 2018

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

November 14, 2018

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