
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 30, 2020**

GUARDION HEALTH SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38861
(Commission
File Number)

44-4428421
(I.R.S. Employer
Identification No.)

**15150 Avenue of Science, Suite 200
San Diego, CA 92128**

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: **(858) 605-9055**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

On March 30, 2020, Guardion Health Sciences, Inc. issued a press release announcing its fourth quarter and full year 2019 financial results. A copy of the press release is furnished herewith as Exhibit 99.1.

The information included herein and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (“Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 [Press Release dated March 30, 2020](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 30, 2020

GUARDION HEALTH SCIENCES, INC.

By: /s/ MICHAEL FAVISH

Name: Michael Favish

Title: Chief Executive Officer



Guardion Health Sciences Reports 2019 Year End Results and Provides Corporate Update and Overview

—*Growing portfolio of synergistic assets and proprietary technologies*

—*Focusing on scalable market opportunities to drive Company's growth initiatives*

—*Maintaining vision lifestyle and eye health with medical foods and condition-specific nutraceuticals is a key element of Company's plans*

San Diego, California - March 30, 2020 - Guardion Health Sciences, Inc. ("Guardion" or the "Company") (Nasdaq: GHSI), a company (i) that has developed medical foods and medical devices in the ocular health marketplace and (ii) that is developing condition-specific nutraceuticals that the Company believes will provide supportive health benefits to consumers, announced today its financial results for the year ended December 31, 2019. Guardion also provided a corporate update and product overview.

"Over the course of 2019, we made significant progress in expanding our business profile by adding synergistic assets to our growing portfolio. We believe our portfolio contains an array of market-leading products, and our efforts are focused on obtaining wider adoption of these unique products by physicians and their patients, and by consumers," commented Michael Favish, CEO of Guardion.

2019/2020 Corporate Highlights

- Closed \$16.2 million in underwritten public offerings during 2019, including the Company's initial public offering and listing of its common stock on the Nasdaq Capital Market in April 2019;
- Received proceeds of \$3.5 million from the exercise of warrants during March 2020;
- Selected by Malaysian company, Ho Wah Genting Berhad ("HWGB"), in February 2020, to leverage Guardion's NutriGuard business line to develop an immune-supportive formula designed to provide immuno-supportive benefits;
- Announced plans in February 2020 to develop a proprietary immuno-supportive complex, labeled acuMMUNE, designed with the objective of supporting effective immune function, under its NutriGuard business line (trademark registration pending);
- In October 2019, received approval from the United States Patent and Trademark Office for expanded claims for the Company's proprietary medical device, the MapcatSF[®]; and
- In October 2019, announced statistically significant blood assay study results evaluating Lumega-Z, demonstrating 40 times higher blood concentration levels of Mesozeaxanthin from Lumega-Z, as compared to standard AREDS2 over-the-counter gel caps.

"We are pleased with the steady growth in revenue from our flagship medical food, Lumega-Z. We have also received significant interest from customers on the recent launch of the second generation of the VectorVision[®] CSV-2000 contrast sensitivity device. We attribute the drop in sales of our legacy CSV-1000 device in 2019 to physicians delaying their orders until our second generation CSV-2000 device became available, and we expect to regain traction in the coming quarters. We believe over the past year we have set the stage to propel the Company into its next phase of growth and, importantly, to drive significant value for our shareholders," added Mr. Favish.



Product Portfolio Overview

Lumega-Z[®]: Currently distributed regulated vision-specific medical food designed to replenish and restore the macular protective pigment.

- Data presented at the Association for Research in Vision and Ophthalmology (ARVO) 2019 Annual Meeting, demonstrated that patients who used Lumega-Z for 12 consecutive months were associated with significant improvement in Frequency Doubling Technology pericentral function among patients with severe glaucoma who had previously shown degeneration despite having had excellent intraocular pressure control.
- Data from a separate study also presented at ARVO showed that patients with drusen and at risk of vision loss from macular degeneration treated with Lumega-Z for 6 months showed improvements in vision, as measured by contrast sensitivity. Similar patients treated with standard over-the-counter AREDS2 gel caps showed no change.

VectorVision[®]: Standardization system specializing in contrast sensitivity, glare sensitivity, low contrast acuity, and ETDRS acuity vision testing.

- Sales of second generation device, the CSV-2000, the only computer-generated vision testing instrument available, commenced in February 2020.

NutriGuard[™]: High-quality, condition-specific nutraceuticals, which are designed to supplement consumers' diets, allowing the Company to enter the direct-to-consumer ("DTC") marketplace.

- Developing an immune-supportive formula, acuMMUNE, designed to provide immuno-supportive benefits to its users.
- The Company is currently in the process of manufacturing and packaging acuMMUNE at contract facilities in the United States and expects that this product will be available for sale beginning in mid-April 2020.

GlaucoCetin[™]: First vision-specific product designed to support and protect the mitochondrial function of optic nerve cells in patients with glaucoma.

MapcatSF[®]: Patented device for accurate measurement of macular pigment density.

Transcranial Doppler Solutions, Inc. ("TDSI"): Ultrasound technology to assess intracerebral blood flow within the brain and eyes to help detect potential stroke risk in patients and stenosis of ophthalmic artery; utilized in the identification of early predictors of eye disease.

Mr. Favish concluded, "The safety and wellness of our employees, customers and community remains of the upmost importance to us and we are actively monitoring the evolving situation with the coronavirus. We remain vigilant and have implemented multiple risk mitigation strategies to ensure the least amount of disruption to our business as possible. Although trade shows have been cancelled or postponed, we have shifted outreach efforts to conducting webinars and video conferencing, and to other methods of reaching our target audiences. We are also focusing on new business opportunities both in the United States and internationally as a result of the impact of the coronavirus."



Summary of Financial Results for Fiscal Year 2019

For the year ended December 31, 2019, revenue from product sales was \$902,937 compared to \$942,153 for the year ended December 31, 2018, resulting in a decrease of \$39,216 or 4%. The decrease is primarily due to the transition of sales and manufacturing efforts away from our VectorVision CSV-1000 device. Although the CSV-1000 will continue to be sold, the Company intends to put a greater emphasis on sales and marketing efforts of the new CSV-2000 device. The Company commenced sales of the next generation CSV-2000 device in February 2020. For the year ended December 31, 2019, revenue from medical foods was \$444,657 compared to \$332,795 for the year ended December 31, 2018, resulting in an increase of \$111,862 or 34%.

For the year ended December 31, 2019, gross profit was \$561,622 compared to \$543,974 for the year ended December 31, 2018, resulting in an increase of \$17,648 or 3% due to pricing and product mix changes. Gross profit represented 62% of revenues for the year ended December 31, 2019, versus 58% of revenue for the year ended December 31, 2018.

For the year ended December 31, 2019, the Company incurred a net loss of \$10,878,308, compared to a net loss of \$7,767,407 for the year ended December 31, 2018. The increase in net loss compared to the prior year period was primarily due to a non-cash goodwill impairment charge of approximately \$1,564,000 related to VectorVision, as well as an increase in non-cash stock compensation costs of approximately \$1,123,000.

The Company had approximately \$11.1 million in cash and cash equivalents at December 31, 2019.

About Guardion Health Sciences, Inc.

Guardion is a specialty health sciences company (i) that has developed medical foods and medical devices in the ocular health marketplace and (ii) that is developing condition-specific nutraceuticals that the Company believes will provide medicinal and health benefits to consumers. Information and risk factors with respect to Guardion and its business, including its ability to successfully develop and commercialize its proprietary products and technologies, may be obtained in the Company's filings with the SEC at www.sec.gov.



Guardion Health Sciences, Inc.

Consolidated Balance Sheets

	December 31,	
	2019	2018
Assets		
Current assets		
Cash	\$ 11,115,502	\$ 670,948
Accounts receivable	78,337	28,203
Inventories	310,941	357,997
Prepaid expenses	362,938	47,773
Total current assets	11,867,718	1,104,921
Deposits	11,751	11,751
Property and equipment, net	374,638	274,804
Right of use asset, net	572,714	-
Deferred offering costs	-	270,000
Intangible assets, net	50,000	456,104
Goodwill	-	1,563,520
Total assets	\$ 12,876,821	\$ 3,681,100
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	\$ 129,132	\$ 413,925
Accrued expenses and deferred rent	116,211	81,412
Derivative warrant liability	13,323	-
Lease liability - current	151,568	-
Total current liabilities	410,234	495,337
Lease liability - long term	434,747	-
Total liabilities	844,981	495,337
Commitments and contingencies		
Stockholders' Equity		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2019 and December 31, 2018	-	-
Common stock, \$0.001 par value; 250,000,000 shares authorized; 74,982,562 and 20,564,328 shares issued and outstanding at December 31, 2019 and December 31, 2018	74,983	20,564
Additional paid-in capital	57,468,528	37,798,562
Accumulated deficit	(45,511,671)	(34,633,363)
Total stockholders' equity	12,031,840	3,185,763
Total liabilities and stockholders' equity	\$ 12,876,821	\$ 3,681,100



Guardion Health Sciences, Inc.

Consolidated Statements of Operations

	Years Ended December 31,	
	2019	2018
Revenue		
Medical foods	\$ 444,657	\$ 332,795
Medical Devices	434,010	609,358
Other	24,270	-
Total revenue	<u>902,937</u>	<u>942,153</u>
Cost of goods sold		
Medical foods	155,212	161,023
Medical Devices	178,815	237,156
Other	7,288	-
Total cost of goods sold	<u>341,315</u>	<u>398,179</u>
Gross profit	<u>561,622</u>	<u>543,974</u>
Operating expenses		
Research and development	194,311	231,847
Sales and marketing	1,874,901	1,520,862
General and administrative	7,425,827	4,934,986
Goodwill impairment	1,563,520	-
Total operating expenses	<u>11,058,559</u>	<u>6,687,695</u>
Loss from operations	<u>(10,496,937)</u>	<u>(6,143,721)</u>
Other (income) expenses:		
Interest expense	258,365	2,289
Finance cost upon issuance of warrants	415,955	-
Change in fair value of derivative warrants	(292,949)	-
Costs associated with extension of warrant expiration dates	-	1,621,397
Total other (income) expenses	<u>381,371</u>	<u>1,623,686</u>
Net loss	<u>(10,878,308)</u>	<u>(7,767,407)</u>
Net loss per common share – basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.38)</u>
Weighted average common shares outstanding – basic and diluted	<u>36,468,081</u>	<u>20,188,628</u>



Forward-Looking Statement Disclaimer

With the exception of the historical information contained in this news release, the matters described herein may contain 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. Statements preceded by, followed by or that otherwise include the words “believes,” “expects,” “anticipates,” “intends,” “projects,” “estimates,” “plans” and similar expressions or future or conditional verbs such as “will,” “should,” “would,” “may” and “could” are generally forward-looking in nature and not historical facts, although not all forward-looking statements include the foregoing. 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, the impact of the coronavirus (COVID-19) on the Company’s business and the economy in general, and the Company’s 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 filings with the SEC, which 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.

Guardion Health Sciences, Inc.

15150 Avenue of Science, Suite 200
San Diego, CA 92128
Ph 858-605-9055; Fax 858-630-5543
www.guardionhealth.com

Investor Contact:

Jenene Thomas
JTC Team, LLC
T: +1 (833) 475-8247
GHSI@jtcir.com

Michael Porter
Porter, LeVay & Rose, Inc
T: +1 (212) 564-4700
mike@plrinvest.com