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**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): **August 12, 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.

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**Item 2.02. Results of Operations and Financial Condition.**

On August 12, 2020, Guardian Health Sciences, Inc. issued a press release announcing its second quarter 2020 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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1*	<a href="#">Press release, dated August 12, 2020</a>

\* Furnished herewith.

**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: August 12, 2020

**GUARDION HEALTH SCIENCES, INC.**

By: /s/ David Evans

Name: David Evans

Title: Interim Chief Executive Officer



**Guardion Health Sciences Reports Results of Operations  
for Quarter Ended June 30, 2020**

**Asian Nutraceutical Sales Drive Second Quarter Revenues**

**SAN DIEGO, California – August 12, 2020** – Guardion Health Sciences, Inc. (“Guardion” or the “Company”) (NASDAQ: GHSI), a specialty health sciences company that develops medical foods and medical devices in the ocular health space and nutraceutical products that the Company believes provide supportive health benefits to consumers, reported financial results for the three months and six months ended June 30, 2020.

**Fiscal 2020 Financial Highlights (Unaudited) (all dollar amounts rounded to the nearest ‘000)**

**Three Months Ended June 30, 2020**

- Total revenue was \$1,191,000 for the three months ended June 30, 2020, as compared to total revenue of \$261,000 for the three months ended June 30, 2019, an increase of 356%, due to shipment of a large nutraceutical initial test order to Malaysian distributor
- Completed shipment and cash collection of \$890,000 for nutraceutical initial test order to Malaysian distributor
- Medical foods sales up 26% year over year
- Medical devices sales were down 75% year over year, primarily as a result of medical facility closures due to COVID-19 “Stay at Home” orders
- Review and rationalization of product lines, resulting in the decision to wind-down the Trans-Cranial Doppler business unit at June 30, 2020
- Net loss for the three months ended June 30, 2020 was (\$707,000) or (\$0.01) per share, as compared to a net loss of (\$3,048,000) or (\$0.14) per share for the three months ended June 30, 2019
- Warrant exercises netted \$999,000 in cash during the three months ended June 30, 2020
- Ending cash balance at June 30, 2020 was \$11,600,000
- Recently published research shows an absorption rate three to four times higher, and thus similarly increased bioavailability, of Lumega-Z ® versus AREDS2 gel caps

**Six Months Ended June 30, 2020**

- Total revenue was \$1,437,000 for the six months ended June 30, 2020, as compared to total revenue of \$504,000 for the six months ended June 30, 2019, an increase of 185%, due to shipment of a large nutraceutical initial test order to Malaysian distributor
- Medical foods sales were up 33% year over year
- Medical devices sales were down 57% as a result of medical facility closures due to COVID-19 “Stay at Home” orders
- Net loss for the six months ended June 30, 2020 was (\$3,054,000) or (\$0.04) per share, as compared to a net loss of (\$4,437,000) or (\$0.21) per share for the six months ended June 30, 2019
- Warrant exercises netted \$4,549,000 in cash during the six months ended June 30, 2020

## Management Commentary

Robert N. Weingarten, Guardion's recently appointed Chairman of the Board of Directors, commented, "The last few months have seen major changes in the executive leadership of Guardion Health Sciences, Inc., changes that the board believes are necessary to focus the Company on effective deployment of its capital and maximization of shareholder value. These ongoing changes, some of which will take some time to develop and implement, include new research studies, development and roll-out of an e-commerce platform, enhanced trade promotion, and other programs and strategies that the Company expects will generate value over the long term, are being made to pave the way for a better and brighter future for Guardion and its shareholders."

Mr. Weingarten added, "The Board of Directors is working closely with Dr. David Evans, Ph.D., MBA, Guardion's Chief Science Officer and Interim President and Interim Chief Executive Officer, and with Andrew Schmidt, who was recently appointed as Chief Financial Officer of the Company, to finalize plans to take advantage of the market and commercialization opportunities for the Company's proprietary products and technologies. The Company is focusing on expanding its product lines with unique formulas under a comprehensive branding strategy that is expected, over time, to result in a sustainable improvement in the operating performance of our business units."

Dr. David Evans, Ph.D., MBA, Guardion's Chief Science Officer and Interim President and Interim Chief Executive Officer, commented, "I am encouraged by our strong second quarter revenues and the market opportunities that such sales in Asia indicate. We are engaged in a wide-ranging series of discussions with existing and potential new distributors to identify additional business opportunities, both domestically and internationally. The new leadership team and I are focused on implementing initiatives across our core product lines to continue this positive momentum through the rest of the year and beyond, particularly in light of signs that many doctors' offices are reopening and patients are beginning to return for eye health care."

Dr. Evans concluded, "From a scientific perspective, we are pleased with the newly published peer-review research demonstrating the superiority of our medical foods over the competition, as well as the commencement of new research studies to collect and publish data showing the excellent efficacy of our medical food products, which we believe will further validate the technology-based health benefits of our products."

Andrew Schmidt, Guardion's newly-appointed Chief Financial Officer, commented, "My financial team and I are focused on supporting the Company's efforts to improve revenue growth and operational performance in the near-term. I am looking forward to working with Dr. Evans and the rest of the Guardion management team to expand the distribution of our proprietary products and technologies through different channels, including by building an on-line commercial presence, as well as expanding international distribution."

### Three Months Ended June 30, 2020 Financial Results

Total revenue for the second quarter of fiscal 2020 increased 356% to \$1,191,000, as compared to \$261,000 for the second fiscal quarter of 2019. This increase was due to a large initial test order of a nutraceutical product placed by a Malaysian distributor and increased sales of medical food product lines, partially offset by a decrease in medical device sales which were affected by the impact of COVID-19 closures.

Operating expenses for the second quarter of fiscal 2020 of \$1,255,000 were significantly lower than operating expenses for the second quarter of fiscal 2019 of \$2,976,000, primarily due to a one-time gain of \$1,402,000 related to a reversal of stock-based compensation as a result of the resignation of the Company's former President and Chief Executive Officer in June 2020.

Operating loss for the second quarter of fiscal 2020 was (\$708,000), a decrease of \$2,104,000 from the operating loss of (\$2,812,000) for the second quarter of fiscal 2019. Net loss for the second quarter of fiscal 2020 was (\$707,000), or (\$0.01) per share, as compared with a net loss of (\$3,048,000), or (\$0.14) per share, for the second quarter of fiscal 2019.

### **Six Months Ended June 30, 2020 Financial Results**

Total revenue for the six months ended June 30, 2020 increased 185% to \$1,437,000, as compared to \$504,000 for the six months ended 2019. This increase was due to a large initial test order of a nutraceutical product placed by a Malaysian distributor and increased sales of medical food product lines, partially offset by a decrease in medical device sales which were affected by the impact of COVID-19 closures.

Operating expense for the six months ended June 30, 2020 of \$3,727,000 was lower than operating expense for the for the six months ended June 30, 2019 of \$4,310,000, primarily due to a reduction of \$965,000 in stock compensation expense, related to a reversal of stock-based compensation as a result of the resignation of the Company's former President and Chief Executive Officer in June 2020.

Operating loss the six months ended June 30, 2020 was (\$3,044,000), a decrease of \$953,000 from the operating loss of (\$3,997,000) for the six months ended June 30, 2019. Net loss for the six months ended June 30, 2020 was (\$3,054,000), or (\$0.04) per share, as compared with a net loss of (\$4,437,000), or (\$0.21) per share, for the six months ended June 30, 2019.

### **Earnings Conference Call**

Guardion will conduct a conference call and webcast today at 4:30 p.m. Eastern Time (1:30pm Pacific Time) to discuss its fiscal 2020 second quarter results. To access the live call, dial 800-353-6461 (United States and Canada) or +1 334-323-0501 (International) and give the participant passcode 7353998. In addition, a live and archived webcast of the conference call will be accessible on the Investor Relations section of the Company's website at [www.guardionhealth.com](http://www.guardionhealth.com). In addition, a phone replay will be available approximately two hours following the end of the call and will remain available for one week. To access the call replay dial-in information, please [click here](#).

### **About Guardion Health Sciences, Inc.**

Guardion is a specialty health sciences company that develops (i) medical foods and medical devices for the ocular health marketplace, and (ii) nutraceutical products that the Company believes provide supportive 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](http://www.sec.gov).

### **About VectorVision®**

VectorVision® specializes in the standardization of contrast sensitivity, glare sensitivity, low contrast acuity, and ETDRS acuity vision testing. Its patented standardization system provides the practitioner or researcher the ability to delineate very small changes in visual capability, either as compared to the population or from visit to visit. VectorVision's® patented technology is considered the standard of care for clinical trials. VectorVision® is a wholly owned subsidiary of Guardion.

## **About NutriGuard™**

NutriGuard™ formulates high-quality nutraceuticals which are designed to supplement consumers' diets. NutriGuard uses industry standards to establish the safety and efficacy of the products it develops and markets, maintains that commitment through prudent manufacturing and quality assurance programs, and only uses manufacturers who comply with FDA current Good Manufacturing Practices (cGMP) requirements. Guardion plans to increase NutriGuard's existing customer base and build on its product platform by making NutriGuard products available to patients directly and through recommendations by their physicians.

## **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 COVID-19 pandemic on the Company's business, operations 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](http://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.

## **Investor Relations**

MKR Investor Relations, Inc.

Todd Kehrli

[ghsi@mkr-group.com](mailto:ghsi@mkr-group.com)

**Guardion Health Sciences, Inc.**  
**Condensed Consolidated Balance Sheets**

	<u>June 30,</u> <u>2020</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
<b>Current assets</b>		
Cash	\$ 11,603,459	\$ 11,115,502
Accounts receivable	34,180	78,337
Inventories	1,235,052	310,941
Prepaid expenses	274,140	362,938
Equipment held for sale	24,500	-
<b>Total current assets</b>	<b>13,171,331</b>	<b>11,867,718</b>
Deposits	11,751	11,751
Property and equipment, net	304,534	374,638
Right of use asset, net	496,387	572,714
Intangible assets	50,000	50,000
<b>Total assets</b>	<b>\$ 14,034,003</b>	<b>\$ 12,876,821</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 332,787	\$ 70,291
Accrued expenses	162,461	175,052
Due to former officer	311,458	-
Derivative warrant liability	19,411	13,323
Lease liability – current	157,119	151,568
<b>Total current liabilities</b>	<b>983,236</b>	<b>410,234</b>
Lease liability – long term	355,127	434,747
<b>Total liabilities</b>	<b>1,338,363</b>	<b>844,981</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' Equity</b>		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, \$0.001 par value; 250,000,000 shares authorized; 88,309,962 and 74,982,562 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	88,310	74,983
Additional paid-in capital	61,173,074	57,468,528
Accumulated deficit	(48,565,744)	(45,511,671)
<b>Total stockholders' equity</b>	<b>12,695,640</b>	<b>12,031,840</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 14,034,003</b>	<b>\$ 12,876,821</b>

**Guardion Health Sciences, Inc.**  
**Condensed Consolidated Statements of Operations**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020 (Unaudited)	2019 (Unaudited)	2020 (Unaudited)	2019 (Unaudited)
<b>Revenue</b>				
Medical foods and nutraceuticals	\$ 1,152,894	\$ 104,448	\$ 1,304,028	\$ 204,382
Medical devices	35,315	150,222	126,505	292,826
Other	2,700	6,300	6,100	6,300
<b>Total revenue</b>	<b>1,190,909</b>	<b>260,970</b>	<b>1,436,633</b>	<b>503,508</b>
<b>Cost of goods sold</b>				
Medical foods and nutraceuticals	628,205	40,681	695,291	78,953
Medical devices	15,278	53,816	55,920	109,036
Other	1,096	2,559	2,477	2,559
<b>Total cost of goods sold</b>	<b>644,579</b>	<b>97,056</b>	<b>753,688</b>	<b>190,548</b>
<b>Gross profit</b>	<b>546,330</b>	<b>163,914</b>	<b>682,945</b>	<b>312,960</b>
<b>Operating expenses</b>				
Research and development	44,581	77,688	75,769	106,716
Sales and marketing	519,067	409,409	1,007,913	764,028
General and administrative	1,712,183	2,489,011	3,228,698	3,439,633
Costs related to resignation of former officer (including the reversal of previously recognized stock compensation expense of \$1,401,582 and \$965,295 during the three and six months ended June 30, 2020, respectively)	(1,052,223)	-	(615,936)	-
Impairment loss on equipment held for sale	30,948	-	30,948	-
<b>Total operating expenses</b>	<b>1,254,556</b>	<b>2,976,108</b>	<b>3,727,392</b>	<b>4,310,377</b>
<b>Loss from operations</b>	<b>(708,226)</b>	<b>(2,812,194)</b>	<b>(3,044,447)</b>	<b>(3,997,417)</b>
<b>Other (income) expense:</b>				
Interest expense	1,790	234,065	3,538	251,637
Finance cost upon issuance of warrants	-	229,921	-	415,955
Change in fair value of derivative warrants	(2,856)	(227,832)	6,088	(227,832)
<b>Total other (income) expense</b>	<b>(1,066)</b>	<b>236,154</b>	<b>9,626</b>	<b>439,760</b>
<b>Net loss</b>	<b>\$ (707,160)</b>	<b>\$ (3,048,348)</b>	<b>\$ (3,054,073)</b>	<b>\$ (4,437,177)</b>
Net loss per common share – basic and diluted	\$ (0.01)	\$ (0.14)	\$ (0.04)	\$ (0.21)
Weighted average common shares outstanding – basic and diluted	86,567,215	22,537,943	82,598,791	21,628,758

**Guardion Health Sciences, Inc.**  
**Unaudited Segment Reporting Details**

	<b>For the Three Months Ended June 30, 2020</b>			
	<b>Corporate</b>	<b>Medical Foods and Nutraceuticals</b>	<b>Medical Devices</b>	<b>Total</b>
<b>Revenue</b>	\$ 2,700	\$ 1,152,894	\$ 35,315	\$ 1,190,909
<b>Cost of goods sold</b>	<u>1,096</u>	<u>628,205</u>	<u>15,278</u>	<u>644,579</u>
<b>Gross profit</b>	1,604	524,689	20,037	546,330
<b>Operating expenses</b>	<u>88,428</u>	<u>1,072,508</u>	<u>93,620</u>	<u>1,254,556</u>
<b>Loss from operations</b>	<u>\$ (86,824)</u>	<u>\$ (547,819)</u>	<u>\$ (73,583)</u>	<u>\$ (708,226)</u>

	<b>For the Three Months Ended June 30, 2019</b>			
	<b>Corporate</b>	<b>Medical Foods and Nutraceuticals</b>	<b>Medical Devices</b>	<b>Total</b>
<b>Revenue</b>	\$ 6,300	\$ 104,448	\$ 150,222	\$ 260,970
<b>Cost of goods sold</b>	<u>2,559</u>	<u>40,681</u>	<u>53,816</u>	<u>97,056</u>
<b>Gross profit</b>	3,741	63,767	96,406	163,914
<b>Operating expenses</b>	<u>72,021</u>	<u>2,643,725</u>	<u>260,362</u>	<u>2,976,108</u>
<b>Loss from operations</b>	<u>\$ (68,280)</u>	<u>\$ (2,579,958)</u>	<u>\$ (163,956)</u>	<u>\$ (2,812,194)</u>

**For the Six Months Ended June 30, 2020**

	<u>Corporate</u>	<u>Medical Foods and Nutraceuticals</u>	<u>Medical Devices</u>	<u>Total</u>
<b>Revenue</b>	\$ 6,100	\$ 1,304,028	\$ 126,505	\$ 1,436,633
<b>Cost of goods sold</b>	<u>2,477</u>	<u>695,291</u>	<u>55,920</u>	<u>753,688</u>
<b>Gross profit</b>	3,623	608,737	70,585	682,945
<b>Operating expenses</b>	<u>172,911</u>	<u>3,344,411</u>	<u>210,070</u>	<u>3,727,392</u>
<b>Loss from operations</b>	<u>\$ (169,288)</u>	<u>\$ (2,735,674)</u>	<u>\$ (139,485)</u>	<u>\$ (3,044,447)</u>

**For the Six Months Ended June 30, 2019**

	<u>Corporate</u>	<u>Medical Foods and Nutraceuticals</u>	<u>Medical Devices</u>	<u>Total</u>
<b>Revenue</b>	\$ 6,300	\$ 204,382	\$ 292,826	\$ 503,508
<b>Cost of goods sold</b>	<u>2,559</u>	<u>78,953</u>	<u>109,036</u>	<u>190,548</u>
<b>Gross profit</b>	3,741	125,429	183,790	312,960
<b>Operating expenses</b>	<u>120,783</u>	<u>3,719,338</u>	<u>470,256</u>	<u>4,310,377</u>
<b>Loss from operations</b>	<u>\$ (117,042)</u>	<u>\$ (3,593,909)</u>	<u>\$ (286,466)</u>	<u>\$ (3,997,417)</u>