
**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, 2019**

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 August 12, 2019, Guardion Health Sciences, Inc. (the “Company”) issued a press release announcing the Company’s unaudited financial results for the quarter and six months ended June 30, 2019. A copy of the Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall 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 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, regardless of any general incorporation language in such a filing, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1*	Press release issued by Guardion Health Sciences, Inc. on August 12, 2019

*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.

GUARDION HEALTH SCIENCES, INC.

By: /s/ MICHAEL FAVISH

Name: Michael Favish

Title: Chief Executive Officer

Date: August 12, 2019



Guardion Health Sciences Reports June 30, 2019 Interim Results of Operations

Highlights Include:

**18.2% Revenue Growth for the Three Months Ended June 30, 2019 and
21.7% Revenue Growth for the Six Months Ended June 30, 2019**

San Diego, CA – August 12, 2019 – Guardion Health Sciences, Inc. (“Guardion” or the “Company”) (Nasdaq: GHSI), today announced its unaudited interim financial results for the three months and six months ended June 30, 2019.

FINANCIAL HIGHLIGHTS (Unaudited):

Second Quarter - Three Months Ended June 30, 2019:

- Total revenue increased by \$40,192 or 18.2% to \$260,970 for the three months ended June 30, 2019, as compared to \$220,778 for the three months ended June 30, 2018. The increase was primarily due to growth in the Company’s Lumega-Z customer base and in its VectorVision vision testing diagnostic products.
 - Gross profit margin was 62.8% for the three months ended June 30, 2019, as compared to 60.2% for the three months ended June 30, 2018, reflecting primarily an improved profitability in the medical foods segment.
 - Research and development costs were \$77,688 for the three months ended June 30, 2019, as compared to \$34,320 for the three months ended June 30, 2018, an increase of \$43,368 or 126.4%. The increase was due to primarily to engineering development costs associated with the development of the Company’s CSV-2000 VectorVision product.
 - Sales and marketing costs were \$409,409 for the three months ended June 30, 2019, as compared to \$378,750 for the three months ended June 30, 2018, an increase of \$30,659 or 8.1%.
 - General and administrative costs (including stock-based compensation costs) were \$2,489,011 for the three months ended June 30, 2019, as compared to \$1,034,914 for the three months ended June 30, 2018, an increase of \$1,454,097 or 140.5%, primarily as a result of an increase in stock-based compensation of approximately \$976,000, as well as increases in insurance, investor relations, labor, legal, professional fees and travel costs.
 - Loss from operations was \$2,812,194 for the three months ended June 30, 2019, as compared to \$1,314,982 for the three months ended June 30, 2018, an increase of \$1,497,212, or 113.9%, reflecting increased general and administrative costs.
 - Other (income) expense consisted of a net expense of \$236,154 for the three months ended June 30, 2019, as compared to a net expense of \$495,101 for the three months ended June 30, 2018. The components of such amounts consisted of interest expense of \$234,065, finance costs associated with the issuance of warrants of \$229,921, net of a gain on the change in the fair value of derivative warrants of \$227,832 for the three months ended June 30, 2019, as compared to interest expense of \$710 and a loss incurred on the extension of warrant expiration dates of \$494,391 for the three months ended June 30, 2018.
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- Net loss increased by \$1,238,265 or 68.4% to \$3,048,348 for the three months ended June 30, 2019, as compared to \$1,810,083 for the three months ended June 30, 2018. Basic loss per share for the three months ended June 30, 2019 was \$0.14 per share, as compared to \$0.09 per share for the three months ended June 30, 2018.

First Half - Six Months Ended June 30, 2019 (Unaudited):

- Total revenue increased by \$89,690 or 21.7% to \$503,508 for the six months ended June 30, 2019, as compared to \$413,818 for the three months ended June 30, 2018. The increase was primarily due to growth in the Company's Lumega-Z customer base and in its VectorVision vision testing diagnostic products.
 - Gross profit margin was 62.2% for the six months ended June 30, 2019, as compared to 59.6% for the six months ended June 30, 2018, reflecting primarily an improved profitability in the medical foods segment.
 - Research and development costs were \$106,716 for the six months ended June 30, 2019, as compared to \$194,708 for the six months ended June 30, 2018, a decrease of \$87,992 or 45.2%. The decrease was due to primarily to due to reduced engineering development costs associated with the Company's MapcatSF® medical device during 2019, partially offset by engineering costs associated with the development of the Company's CSV-2000 VectorVision product.
 - Sales and marketing costs were \$764,028 for the six months ended June 30, 2019, as compared to \$984,464 for the six months ended June 30, 2018, a decrease of \$220,436 or 22.4%, reflecting the Company's transition to an in-house sales organization since mid-2018, as compared to utilizing an outside party sales organization during a substantial portion of the six months ended June 30, 2018.
 - General and administrative costs (including stock-based compensation costs) were \$3,439,633 for the six months ended June 30, 2019, as compared to \$2,714,680 for the six months ended June 30, 2018, an increase of \$724,953 or 26.7%, primarily as a result of an increase in stock-based compensation of approximately \$254,000, as well as increases in insurance, investor relations, labor, legal, professional fees and travel costs.
 - Loss from operations was \$3,997,417 for the six months ended June 30, 2019, as compared to \$3,647,089 for the six months ended June 30, 2018, an increase of \$350,328, or 9.6%, reflecting increased general and administrative costs.
 - Other (income) expense consisted of a net expense of \$439,760 for the six months ended June 30, 2019, as compared to a net expense of \$495,936 for the six months ended June 30, 2018. The components of such amounts consisted of interest expense of \$251,637, finance costs associated with the issuance of warrants of \$415,955, net of a gain on the change in the fair value of derivative warrants of \$227,832 for the six months ended June 30, 2019, as compared to interest expense of \$1,545 and a loss incurred on the extension of warrant expiration dates of \$494,391 for the six months ended June 30, 2018.
 - Net loss increased by \$294,152 or 7.1% to \$4,437,177 for the six months ended June 30, 2019, as compared to \$4,143,025 for the six months ended June 30, 2018. Basic loss per share for the six months ended June 30, 2019 and 2018 was \$0.21 per share.
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Liquidity:

As of June 30, 2019, the Company had cash of \$2,368,645 and working capital of \$2,326,641. The Company is continuing its efforts to increase its working capital resources to fund the planned growth in its operations, both domestically and internationally.

BUSINESS AND OPERATIONAL HIGHLIGHTS (year-to-date):

- On August 6, 2019, the Company announced that its standardized vision testing instrument, the CSV-1000, has been selected by the *Foundation Fighting Blindness* for inclusion in a large-scale multi-center long-term clinical trial, the PRO-EYS Study. This study is being conducted to evaluate vision loss and progression in patients with degenerative retinal disease. There are expected to be about 30 sites in the study, with each site having a dedicated CSV-1000 device.
 - On July 16, 2019, the Company was notified by the Patents Registry in Hong Kong that it has received a patent from the Government of the Hong Kong Special Administrative Region (Hong Kong Patent No. HK1204758 titled “Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye”) for the MapcatSF®.
 - On June 4, 2019, the Company announced that the parent compound of the GlaucoCetin™ formula was used in an IRB-approved patient study conducted at the New York Eye and Ear Infirmary and successfully reversed mitochondrial dysfunction in the optic nerve cells in patients with glaucoma. GlaucoCetin™ is an enhanced formulation of GlaucoHealth. The Company owns both formulas and has a patent application pending on the GlaucoCetin™ formula.
 - On May 30, 2019, the Company was notified by the European Patent Office that it has received a patent from the European Union (European Patent No. 2,811,892 titled “Apparatus for Use in the Measurement of Macular Pigment Optical Density and/or Lens Optical Density of an Eye”) for the MapcatSF®.
 - On May 9, 2019, the Company announced a recent study that showed statistically significant improvement in visual function (“CSF”) of patients taking Lumega-Z who participated in the study. The study was conducted by research scientists at the Western University College of Optometry to evaluate the visual benefits of Lumega-Z in one group of patients as compared to a group of patients taking AREDS 2 soft gel supplements.
 - The results of the study were presented at the Association for Research in Vision and Ophthalmology (“ARVO”) 2019 annual meeting and showed improvements in visual function (“CSF”) in the group of patients taking Lumega-Z that were statistically significant and definitive. The patients taking AREDS 2 showed no statistical change.
 - On April 25, 2019, the Company was notified by the State Intellectual Property Office of the People’s Republic of China (“China”) that the Company has been granted trademark registrations in China for its proprietary medical food, Lumega-Z (Registration No. 27151643), and for its proprietary and patented medical device, the MapcatSF (Registration No. 27151644).
 - On April 9, 2019, the Company closed its initial public offering (the “IPO”) of 1,250,000 shares of common stock, par value \$0.001 per share, at an IPO price to the public of \$4.00 per share resulting in net proceeds to the Company of \$3,888,000 after all costs and expenses. The shares began trading on the Nasdaq Capital Market on April 5, 2019 under the symbol “GHSL.”
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MANAGEMENT COMMENTARY:

Michael Favish, Guardion's Chief Executive Officer, commented, "We are encouraged with the continuing momentum we are experiencing from our portfolio of proprietary technologies and treatments. Effective vision therapies for an aging global population are in increasing demand. As there are currently no effective treatments for age-related macular degeneration and glaucoma, the need to address these debilitating ocular diseases is all the more imperative. Guardion's products, supported by clinical data, represent an array of compelling treatment solutions for the medical profession, and we are now beginning to experience wider recognition and adoption in the industry. We are planning to expand our reach and, subject to adequate capital resources, we will be taking the initial steps to scale up our sales efforts worldwide, including in Asia, where we have been granted trademark registrations in China and Hong Kong for our products. During the remainder of 2019, our focus will remain on advancing our full line of products aimed at transformative therapies for patients living with these devastating ocular diseases."

About Guardion Health Sciences, Inc.

Guardion is an ocular health sciences company that develops, formulates and distributes condition-specific medical foods supported by evidence-based protocols, with a lead medical food product, Lumega-Z[®], that addresses a depleted macular protective pigment, a known risk factor for age-related macular degeneration ("AMD") and a significant component of functional vision performance. Guardion has also developed a proprietary medical device, the MapcatSF[®], which accurately measures the macular pigment density, thereby providing the only two-pronged evidence-based protocol for the treatment of a depleted macular protective pigment. 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 Securities and Exchange Commission ("SEC") at www.sec.gov.

About VectorVision[®]

VectorVision[®], operating through a wholly-owned subsidiary of the Company, 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 CSV-1000 device is considered the standard of care for clinical trials.

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. 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 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.

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The following tables should be read in conjunction with the footnotes accompanying the condensed consolidated financial statements contained in the Quarterly Report on Form 10-Q filed today with the Securities and Exchange Commission.
