



Guardion Health Sciences, Inc. Reports Results for the Three and Nine Months Ended September 30, 2019

Results Highlighted by 33% Increase in Revenues for Guardion's Flagship Medical Food Lumega-Z®

San Diego, CA – November 14, 2019 – Guardion Health Sciences, Inc. (“Guardion” or the “Company”) (Nasdaq: GHSI), today announced its unaudited financial results for the three months and nine months ended September 30, 2019.

RECENT HIGHLIGHTS:

- Revenue from Guardion's flagship medical food Lumega-Z increased 31% in the three months ended September 30, 2019 and 33% in the nine months ended September 30, 2019, as compared to the prior year's comparable period revenue.
- Acquired certain assets of NutriGuard Research, Inc., a 30-year old globally respected and physician-preferred nutraceuticals brand, enabling Guardion to establish a branded direct-to-consumer capability.
- Received approval from the United States Patent and Trademark Office for expanded claims for the Company's proprietary medical device, the MapcatSF®.
- Completed development of the Company's computer-generated CSV-2000™ standardized contrast sensitivity test and introduced the commercial product at Vision Expo West in September 2019.
- Announced statistically significant blood assay study results, showing 40 times higher blood concentration levels of Mesozeaxanthin from Lumega-Z, as compared to standard AREDS2 over-the-counter gel caps.
- Closed public offering August 15 consisting of 12,000,000 shares of common stock, pre-funded warrants exercisable for 1,000,000 shares of common stock, warrants to purchase up to an aggregate of 13,000,000 shares of common stock, and an additional 1,950,000 warrants upon exercise of the underwriters' over-allotment option, resulting in net proceeds of \$4,944,340 after deducting underwriting discounts, commissions, and expenses.
- Closed public offering October 30 consisting of 24,500,000 shares of common stock (including 1,700,000 pre-funded warrants to purchase common stock in lieu thereof) and warrants to purchase up to 24,500,000 shares of the Company's common stock, resulting in net proceeds of approximately \$7.2 million after deducting underwriting

discounts, commissions and expenses.

- Management believes that with net proceeds raised of approximately \$12.1 million from the August and October offerings that the Company has adequate funding to pursue its planned business initiatives and operations through at least December 31, 2020.

MANAGEMENT COMMENTARY:

Michael Favish, Guardion's Chief Executive Officer, commented, "We are pleased with the progress we made in the third-quarter, which was highlighted by revenue growth in our flagship medical food Lumega-Z. As a result of the recent commercial introduction of the VectorVision CSV-2000 device to the marketplace in September 2019, we anticipate positive momentum from this business in 2020."

"Our team's continued focus on successful patient outcomes and product excellence has already resulted in a strong start to the fourth quarter, with improving revenue in October 2019 as compared to October 2018. We are focused on expanding our position as one of the most trusted names in the ocular health care field, consistently bringing new innovations to market that can have a measurable impact on vision therapy and preservation over many years. With no direct competition in the glaucoma therapy market, and no effective treatments for age-related macular degeneration, Guardion's products represent unique, market-leading treatments, and we are beginning to see this realization through wider adoption of our products by physicians and customers."

"Furthermore, we anticipate that the NutriGuard transaction will fast-track our direct-to-consumer platform, enabling wider distribution and awareness of our products to NutriGuard's long-standing customer and doctor base. Overall, we will continue to invest in our infrastructure to ensure that we are able to properly scale operations in anticipation of the growing demand for our products. I am enthusiastic about the long-term growth prospects for our growing product portfolio and remain committed to setting the industry's bar for consistency and execution in the dynamic and rapidly growing world of ocular health," concluded Mr. Favish.

FINANCIAL HIGHLIGHTS (Unaudited):

Third Quarter - Three Months Ended September 30, 2019:

- Total consolidated revenue was \$161,162 for the three months ended September 30, 2019, as compared to \$294,230 for the three months ended September 30, 2018, reflecting a decrease of \$133,068 or 45%. This decrease was primarily due to a reduction in sales of the VectorVision CSV-1000 device in the third quarter of 2019, as the market awaited the release of the CSV-2000. The CSV-2000 will be the only computer-generated vision testing instrument available and provides the Company's proprietary, industry-standard contrast sensitivity test. While the CSV-1000 will continue to be sold, the Company will be focusing its efforts on marketing the CSV-2000, sales of which are planned to commence during the fourth quarter of 2019.
- Revenue from the Company's Medical Foods segment was \$112,957 for the three months ended September 30, 2019, as compared to \$86,082 for the three months ended September 30, 2018, reflecting an increase of \$26,875 or 31%. This increase reflects an increased customer base for Lumega-Z, the Company's flagship medical

food, which replenishes and restores the macular protective pigment, as the Company expands into new clinics. The Company plans to continue developing its medical foods segment and expects it to be a driving force for future revenue and growth.

- Revenue from the Company's Vision Testing Diagnostics segment was \$44,705 for the three months ended September 30, 2019, as compared to \$208,148 for the three months ended September 30, 2018, reflecting a decrease of \$163,443 or 79%. The decrease was primarily due to the market's anticipation of the new CSV-2000 VectorVision product discussed above.
- Gross profit for the three months ended September 30, 2019 was \$90,163, as compared to \$168,824 for the three months ended September 30, 2018, reflecting a decrease of \$78,661 or 47%, primarily due to the VectorVision product transition discussed above. Gross profit represented 56% of revenue for the three months ended September 30, 2019, as compared to 57% of revenue for the three months ended September 30, 2018.
- Research and development costs for the three months ended September 30, 2019 were \$31,897, as compared to \$4,793 for the three months ended September 30, 2018, reflecting an increase of \$27,104. This increase was primarily due to engineering development costs associated with the development of the Company's CSV-2000 product.
- Sales and marketing costs for the three months ended September 30, 2019 were \$448,387, as compared to \$240,028 for the three months ended September 30, 2018, reflecting an increase of \$208,359 or 87%, primarily due to increases in marketing, website development, professional services, and trade show expenses in the three months ended September 30, 2019.
- General and administrative costs for the three months ended September 30, 2019 were \$2,022,367, as compared to \$1,064,645 for the three months ended September 30, 2018, reflecting an increase of \$957,722 or 90%, primarily due to increases in stock-based compensation cost as well as increased consulting, professional services, investor relations, legal fees, and corporate insurance. Included in general and administrative costs were stock-based compensation costs of \$779,000 in 2019 as compared to \$350,000 in 2018.
- Net loss for the three months ended September 30, 2019 was \$2,385,371, as compared to a net loss of \$2,148,193 for the three months ended September 30, 2018, reflecting an increase of \$237,178 or 11%. The increase in net loss in 2019 as compared to 2018 was primarily due to an increase in non-cash stock compensation costs of approximately \$429,000.

Nine Months Ended September 30, 2019:

- Total consolidated revenue was \$664,669 for the nine months ended September 30, 2019, as compared to \$708,047 for the nine months ended September 30, 2018, reflecting a decrease of \$43,378 or 6%. This decrease was primarily due to a reduction in sales of the VectorVision CSV-1000 device in the third quarter of 2019, as the market awaited the release of the CVS-2000.

- Revenue from the Company's Medical Foods segment was \$317,338 for the nine months ended September 30, 2019, as compared to \$238,213 for the nine months ended September 30, 2018, reflecting an increase of \$79,125 or 33%. This increase reflects an increased customer base for Lumega-Z.
- Revenue from the Company's Vision Testing Diagnostics segment were \$337,531 for the nine months ended September 30, 2019, as compared to \$469,834 for the nine months ended September 30, 2018, reflecting a decrease of \$132,303 or 28%, primarily due to the VectorVision product transition discussed above.
- Gross Profit for the nine months ended September 30, 2019 was \$403,122, as compared to \$415,586 for the nine months ended September 30, 2018, reflecting a decrease of \$12,464 or 3%, primarily due to the VectorVision product transition discussed above. Gross profit represented 61% of revenue for the nine months ended September 30, 2019, as compared to 59% of revenue for the nine months ended September 30, 2018.
- Research and development costs for the nine months ended September 30, 2019 were \$138,613, as compared to \$199,500 for the nine months ended September 30, 2018, reflecting a decrease of \$60,887 or 31%. This decrease was due to reduced engineering development costs associated with the Company's MapcatSF[®] medical device during 2019, which was partially offset by increased engineering costs incurred with respect to the development of the Company's CSV-2000 product.
- Sales and marketing costs for the nine months ended September 30, 2019 were \$1,246,846, as compared to \$1,224,491 for the nine months ended September 30, 2018, reflecting an increase of \$22,355 or 2%.
- General and administrative costs for the nine months ended September 30, 2019 were \$5,427,573, as compared to \$3,779,325 for the nine months ended September 30, 2018, reflecting an increase of \$1,648,248 or 44%, primarily due to increases in stock-based compensation cost as well as increased consulting, professional services, investor relations, legal fees, corporate insurance, and travel. Included in general and administrative costs for the nine month periods were stock-based compensation costs of \$2,088,000 in 2019 as compared to \$1,405,000 in 2018.
- Net loss for the nine months ended September 30, 2019 was \$6,822,553, as compared to a net loss of \$6,291,217 for the nine months ended September 30, 2018, reflecting an increase of \$531,336 or 8%. The increase in net loss in 2019 as compared to 2018 was primarily due to an increase in non-cash stock compensation costs of approximately \$683,000.

Liquidity:

As of September 30, 2019, the Company had cash of \$5,554,960, working capital of \$5,672,704, and total assets of \$8,955,046. On October 30, 2019, the Company completed an underwritten public offering consisting of 24,500,000 shares of common stock (or pre-funded warrants to purchase common stock in lieu thereof) and Series B warrants to purchase up to 24,500,000 shares of the Company's common stock, which generated net proceeds to the Company of approximately \$7,200,000.

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. The Company recently completed the development of the CSV-2000, which will be the only computer-generated vision testing instrument available that can provide the Company’s proprietary, industry-standard contrast sensitivity test.

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.

Company Contact:

Michael Favish
Chief Executive Officer
Telephone: (858) 605-9055 x 201
E-mail: mfavish@guardionhealth.com

Investor Relations Contact:

Matthew Abenante
Porter, LeVay & Rose, Inc.

Telephone: (212) 564-4700
E-mail: guardion@plrinvest.com

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.

Guardion Health Sciences, Inc.
Condensed Consolidated Balance Sheets

| | <u>September 30,</u> <u>2019</u> | <u>December 31,</u> <u>2018</u> |
|--|-------------------------------------|------------------------------------|
| | (Unaudited) | |
| Assets | | |
| Current assets | | |
| Cash | \$ 5,554,960 | \$ 670,948 |
| Accounts receivable | 21,927 | 28,203 |
| Inventories | 320,355 | 357,997 |
| Prepaid expenses | 234,384 | 47,773 |
| Total current assets | 6,131,626 | 1,104,921 |
| Deposits | 11,751 | 11,751 |
| Property and equipment, net | 389,074 | 274,804 |
| Right of use asset, net | 563,948 | - |
| Deferred offering costs | - | 270,000 |
| Intangible assets, net | 295,127 | 456,104 |
| Goodwill | 1,563,520 | 1,563,520 |
| Total assets | \$ 8,955,046 | \$ 3,681,100 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | | |
| Accounts payable and accrued liabilities | \$ 218,815 | \$ 413,925 |
| Accrued expenses and deferred rent | 63,964 | 81,412 |
| Derivative warrant liability | 47,118 | - |
| Lease liability – current | 129,025 | - |
| Total current liabilities | 458,922 | 495,337 |
| Lease liability – long term | 447,292 | - |
| Total liabilities | 906,214 | 495,337 |
| Commitments and contingencies | | |
| Stockholders' Equity | | |
| Preferred stock, \$0.001 par value; 10,000,000 shares authorized | - | - |
| Common stock, \$0.001 par value; 90,000,000 shares authorized; 50,482,562 and 20,564,328 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively | 50,483 | 20,564 |
| Additional paid-in capital | 49,454,265 | 37,798,562 |
| Accumulated deficit | (41,455,916) | (34,633,363) |
| Total stockholders' equity | 8,048,832 | 3,185,763 |
| Total liabilities and stockholders' equity | \$ 8,955,046 | \$ 3,681,100 |

Guardion Health Sciences, Inc.
Condensed Consolidated Statements of Operations

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------------------|------------------------------------|-----------------------|
| | 2019 | 2018 | 2019 | 2018 |
| | (Unaudited) | (Unaudited) | (Unaudited) | (Unaudited) |
| Revenue | | | | |
| Medical foods | \$ 112,957 | \$ 86,082 | \$ 317,338 | \$ 238,213 |
| Vision testing diagnostics | 44,705 | 208,148 | 337,531 | 469,834 |
| Other | 3,500 | - | 9,800 | - |
| Total revenue | <u>161,162</u> | <u>294,230</u> | <u>664,669</u> | <u>708,047</u> |
| Cost of goods sold | | | | |
| Medical foods | 41,655 | 37,076 | 120,608 | 110,462 |
| Vision testing diagnostics | 27,922 | 88,330 | 136,958 | 181,999 |
| Other | 1,422 | - | 3,981 | - |
| Total cost of goods sold | <u>70,999</u> | <u>125,406</u> | <u>261,547</u> | <u>292,461</u> |
| Gross profit | <u>90,163</u> | <u>168,824</u> | <u>403,122</u> | <u>415,586</u> |
| Operating expenses | | | | |
| Research and development | 31,897 | 4,793 | 138,613 | 199,500 |
| Sales and marketing | 448,387 | 240,028 | 1,246,846 | 1,224,491 |
| General and administrative | 2,022,367 | 1,064,645 | 5,427,573 | 3,779,325 |
| Total operating expenses | <u>2,502,651</u> | <u>1,309,466</u> | <u>6,813,032</u> | <u>5,203,316</u> |
| Loss from operations | <u>(2,412,488)</u> | <u>(1,140,642)</u> | <u>(6,409,910)</u> | <u>(4,787,730)</u> |
| Other (income) expense: | | | | |
| Interest expense | 4,205 | 545 | 255,842 | 2,090 |
| Finance cost upon issuance of warrants | - | - | 415,955 | - |
| Change in fair value of derivative warrants | (31,322) | - | (259,154) | - |
| Costs associated with extension of warrant expiration dates | - | 1,007,006 | - | 1,501,397 |
| Total other (income) expense | <u>(27,117)</u> | <u>1,007,551</u> | <u>412,643</u> | <u>1,503,487</u> |
| Net loss | <u>\$ (2,385,371)</u> | <u>\$ (2,148,193)</u> | <u>\$ (6,822,553)</u> | <u>\$ (6,291,217)</u> |
| Net loss per common share – basic and diluted | <u>\$ (0.07)</u> | <u>\$ (0.11)</u> | <u>\$ (0.26)</u> | <u>\$ (0.31)</u> |
| Weighted average common shares outstanding – basic and diluted | <u>36,035,309</u> | <u>20,164,761</u> | <u>26,483,713</u> | <u>20,162,354</u> |

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

| | Nine Months Ended | |
|---|--------------------|--------------------|
| | September 30, | |
| | 2019 | 2018 |
| | (Unaudited) | (Unaudited) |
| Operating Activities | | |
| Net loss | \$ (6,822,553) | \$ (6,291,217) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 209,813 | 223,014 |
| Amortization of debt discount | 250,000 | - |
| Accrued interest expense included in notes payable | 788 | - |
| Amortization of right of use asset | 93,222 | - |
| Stock-based compensation | 299,684 | 1,405,222 |
| Stock-based compensation – officer and director | 1,788,751 | - |
| Non-cash financing costs – derivative liability | 415,955 | - |
| Change in fair value of warrants – derivative liability | (259,154) | - |
| Costs associated with extension of warrant expiration dates | - | 1,501,397 |
| Changes in operating assets and liabilities: | | |
| (Increase) decrease in - | | |
| Accounts receivable | 6,275 | 55,761 |
| Inventories | 37,642 | (226,537) |
| Deposits and prepaid expenses | (186,611) | 77,147 |
| Lease liability | (86,902) | - |
| Increase (decrease) in - | | |
| Accounts payable and accrued expenses | 75,439 | (43,117) |
| Accrued expenses and deferred rent | (11,399) | 10,390 |
| Net cash used in operating activities | <u>(4,189,050)</u> | <u>(3,287,940)</u> |
| Investing Activities | | |
| Purchase of property and equipment | (163,105) | (228,311) |
| Purchase of intellectual property | - | (50,000) |
| Net cash used in investing activities | <u>(163,105)</u> | <u>(278,311)</u> |
| Financing Activities | | |
| Proceeds from initial public offering | 3,888,000 | - |
| Proceeds from follow-on public offering | 4,944,340 | - |
| Proceeds from issuance of convertible notes | 250,000 | - |
| Proceeds from issuance of promissory note | 100,000 | - |
| Payments on promissory note | (100,548) | - |
| Payments on line of credit | - | (30,535) |
| Proceeds from exercise of warrants | 154,375 | 1,460 |
| Decrease in due to related parties | - | (38,114) |
| Net cash provided by (used in) financing activities | <u>9,236,167</u> | <u>(67,189)</u> |
| Cash: | | |
| Net increase (decrease) | 4,884,012 | (3,633,440) |

| | | |
|---------------------------------|---------------------|---------------------|
| Balance at beginning of period | 670,948 | 4,735,230 |
| Balance at end of period | <u>\$ 5,554,960</u> | <u>\$ 1,101,790</u> |

Supplemental disclosure of cash flow information:

| | | |
|----------------|------|------|
| Cash paid for- | | |
| Interest | \$ - | \$ - |
| Income taxes | \$ - | \$ - |

Non-cash financing activities:

| | | |
|---|------------|------|
| Fair value of warrant liability issued in connection with issuance of convertible notes | \$ 436,034 | \$ - |
| Recording of lease asset and liability upon adoption of ASU 2016-02 | \$ 663,218 | \$ - |
| Reclass of warrant liability to equity | \$ 359,683 | \$ - |
| Fair value of common stock issued upon conversion of common stock and accrued interest | \$ 250,788 | \$ - |
| Reclass of deferred offering cost to equity | \$ 270,000 | \$ - |