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Guardion Health Sciences Announces Financial Results for the Three Months and Year Ended December 31, 2020

Company Provides Corporate Update and Overview of Growth Plans

SAN DIEGO, March 26, 2021 (GLOBE NEWSWIRE) -- Guardion Health Sciences, Inc. (Nasdaq: GHSI) ("Guardion" or the "Company"), a clinical nutrition and diagnostics company that develops science-based, clinically supported nutritional supplements, medical foods, and diagnostic products, announced financial results for the three months and year ended December 31, 2020.

Effective March 1, 2021, the Company amended its Certificate of Incorporation to effectuate a 1-for-6 reverse split of its outstanding common stock. Accordingly, all share and per share amounts included herein have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Financial highlights for the year ended December 31, 2020 include the following:

- Total revenue of \$1,889,844 for the year ended December 31, 2020, as compared to \$902,937 for the year ended December 31, 2019, an increase of approximately 109%.
- Net loss for the year ended December 31, 2020 of \$(8,571,657) or \$(0.60) per share, as compared to a net loss of \$(10,878,308) or \$(1.79) per share for the year ended December 31, 2019.
- Cash balance at December 31, 2020 of \$8,518,732.
- Pro forma cash balance at December 31, 2020 of \$45,727,241, after giving effect to the sale of common stock and the exercise of warrants during January and February 2021.

Corporate highlights for the fourth quarter ended December 31, 2020 include the following:

- The Company appointed seasoned nutritional products industry veteran Bret Scholtes as President and Chief Executive Officer, and as a member of the Board of Directors.
- The Company retained an investment banking firm to act as its exclusive financial advisor to assist management and the Board of Directors in the identification and evaluation of strategic transactions to enhance shareholder value.

- Ho Wah Genting Berhad, the Company's exclusive Malaysian distributor, advised Guardion that Astramern Astra H (formerly Astramern Nutra H), an immune support dietary supplement designed and produced by the Company, was granted product registration approval by the Malaysian National Pharmaceutical Regulatory Agency. Previously, in August 2020, the Company had announced the product registration approval of the vitamin formulation Astramern NutraV.
- New data was published in the journal *Nutrients* (published October 26, 2020) that the efficacy of the Company's Lumega-Z® compared to the current standard of care, the AREDS-2 soft gel supplement (marketed under the PreserVision® brand by Bausch + Lomb) in patients with vision problems associated with eye disease. Lumega-Z® demonstrated statistically significant vision improvements in both eyes at six months ($p < 0.001$), and a positive linear trend with treatment time ($p < 0.001$), with benefits evident after just three months. This compares to no significant change ($p > 0.05$) provided by the AREDS-2 supplement gel cap formulation.
- A trademark was issued for "NutriGuard" on October 27, 2020 by the U.S. Patent and Trademark Office under Class 5 – nutritional dietary supplements.

Bret Scholtes, Guardion's President and Chief Executive Officer, commented, "As it was for many companies, 2020 was a year of transition and challenge on multiple fronts. I joined the Company in January 2021 to lead the effort to build Guardion into a leading clinical nutrition company with the objective that it become a top performing growth company. As a start, our team has taken the first three months of 2021 to begin to assess the business, the core fundamentals, and the market opportunity for the Company's products and services. I am excited by the prospects of the business, evidenced, in part, by the increased revenue on a year-over-year basis and the critical third-party validation of our science that we received in 2020. We plan to continue such efforts in future periods."

Mr. Scholtes continued, "We have much to do in the coming months before we will be in a position to implement and accelerate our growth initiatives. We are focused on building a strong foundation by developing a business model and infrastructure that are designed for long-term commercial success. We have started this process by concentrating on certain key areas, including our business strategy, go-to-market capabilities, scientific affairs and human capital. We are also beginning the process of establishing our nascent brands and identifying core customer bases where we can accelerate our marketing efforts once our clinical support and scientific evidence is in place."

Mr. Scholtes concluded, "This process will take time, but we have already taken two important steps to build a stronger company. We have raised sufficient capital to not only fund the process -- but also to accelerate the process -- of building the Company through organic growth and carefully considered strategic acquisitions. Our recent at-the-market equity financings in 2021 generated gross proceeds of \$35,000,000 and the exercise of warrants in 2021 generated net proceeds of \$3,608,509. In addition, our recent reverse stock split enabled us to come into full compliance with Nasdaq's continued listing rules regarding minimum bid stock price. Over the long-term, the key to our success will be to create value in well-differentiated and robust brands through strong clinically proven claims that address consumer needs in growing markets, both domestically and internationally. We are committed to bringing compelling products to market under meaningful and differentiated brands supported by strong science. We appreciate the patience and support of our shareholders as we focus on the Company's evolution during 2021."

Financial Results

Years Ended December 31, 2020 and 2019

Total revenue for the year ended December 31, 2020 increased by approximately 109% to \$1,889,844, as compared total revenue for the year ended December 31, 2019 of \$902,937, primarily due to an initial order from the Company's Malaysian distributor of \$890,000 for a novel nutraceutical formulation designed to support the body's immune function.

Operating expenses for the year ended December 31, 2020 were \$8,494,940, as compared to operating expenses for the year ended December 31, 2019 of \$11,058,559. Operating expenses in 2020 included a \$615,936 reduction to expense associated with the settlement with the former Chief Executive Officer, while operating expenses in 2019 included a goodwill impairment charge of \$1,563,520.

Net loss for the year ended December 31, 2020 was \$(8,571,657), which included inventory write-downs of \$971,719, offset by a net gain from the settlement with the former Chief Executive Officer of \$615,936. Net loss for the year ended December 31, 2019 was \$(10,878,308), which included a goodwill impairment charge of \$1,563,520. Taking all of these factors into account, net loss decreased by approximately 21% in 2020 as compared to 2019.

About Guardian Health Sciences

Guardion Health Sciences, Inc. (NASDAQ: GHSI), is a clinical nutrition and diagnostics company. Guardion's portfolio of science-based, clinically supported nutrition, medical foods, and diagnostic products support healthcare professionals, their patients, and consumers in achieving health goals. Guardion's commercial and developmental initiatives are supported by equally impressive scientific and medical advisory boards, led by seasoned business executives and physicians with many years of experience. This combination of expertise and scientific knowledge forms the foundation of Guardion's growing position within the eye care industry and the clinical nutrition marketplace. 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 U. S. Securities and Exchange Commission (the "SEC") at www.sec.gov.

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). 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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Guardion Health Sciences, Inc.

Consolidated Balance Sheets

December 31,	
2020	2019
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Assets

Current assets

Cash	\$ 8,518,732	\$ 11,115,502
Accounts receivable	11,248	78,337
Inventories	384,972	310,941
Prepaid expenses	179,931	362,938

Total current assets **9,094,883** **11,867,718**

Deposits	11,751	11,751
Property and equipment, net	285,676	374,638
Operating lease right-of-use asset, net	418,590	572,714
Intangible assets, net	50,000	50,000

Total assets **\$ 9,860,900** **\$ 12,876,821**

Liabilities and Stockholders' Equity

Current liabilities

Accounts payable and accrued liabilities	\$ 608,313	\$ 129,132
Accrued expenses	127,637	116,211
Payable to former officer	148,958	-
Derivative warrant liability	25,978	13,323
Operating lease liability - current	162,845	151,568

Total current liabilities **1,073,731** **410,234**

Operating lease liability – long-term	271,903	434,747
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Total liabilities **1,345,634** **844,981**

Commitments and contingencies

Stockholders' Equity

Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2020 and December 31, 2019	-	-
Common stock, \$0.001 par value; 250,000,000 shares authorized; 15,170,628 and 12,497,094 shares issued and outstanding at December 31, 2020 and December 31, 2019	15,171	12,497
Additional paid-in capital	62,583,423	57,531,014
Accumulated deficit	(54,083,328)	(45,511,671)

Total stockholders' equity **8,515,266** **12,031,840**

Total liabilities and stockholders' equity **\$ 9,860,900** **\$ 12,876,821**

Guardion Health Sciences, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2020	2019
Revenue		
Medical foods	\$ 1,609,482	\$ 444,657
Medical devices	275,862	434,010
Other	4,500	24,270
Total revenue	1,889,844	902,937
Cost of goods sold		
Medical foods (includes inventory write-down of \$760,488 during the year ended December 31, 2020)	1,599,510	155,212
Medical devices (includes inventory write-down of \$211,231 during the year ended December 31, 2020)	344,647	178,815
Other	2,478	7,288
Total cost of goods sold	1,946,635	341,315
Gross profit (loss)	(56,791)	561,622
Operating expenses		
Research and development	160,978	194,311
Sales and marketing	1,450,205	1,874,901
General and administrative	7,450,245	7,425,827
Costs related to resignation of former officer (including the reversal of previously recognized stock compensation expense of \$965,295 during the year ended December 31, 2020)	(615,936)	-
Loss on sales of equipment	18,500	-
Equipment impairment	30,948	-
Goodwill impairment	-	1,563,520
Total operating expenses	8,494,940	11,058,559
Loss from operations	(8,551,731)	(10,496,937)
Other income (expenses):		
Interest expense	(7,271)	(258,365)
Finance cost upon issuance of warrants	-	(415,955)
Change in fair value of derivative liability	(12,655)	292,949
Total other income (expenses)	(19,926)	(381,371)
Net loss	(8,571,657)	(10,878,308)

Net loss per common share – basic and diluted	\$ (0.60)	\$ (1.79)
Weighted average common shares outstanding – basic and diluted	<u>14,256,856</u>	<u>6,078,014</u>

Guardion Health Sciences, Inc.

Operations by Segment

For the Year Ended December 31, 2020

	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Revenue	\$ 4,500	\$ 1,609,482	\$ 275,862	\$ 1,889,844
Cost of goods sold	<u>2,478</u>	<u>1,599,510</u>	<u>344,647</u>	<u>1,946,635</u>
Gross profit (loss)	2,022	9,972	(68,785)	(56,791)
Stock compensation expense	544,127	-	-	544,127
Operating expenses	<u>3,757,945</u>	<u>3,892,899</u>	<u>299,969</u>	<u>7,950,813</u>
Loss from operations	<u>\$ (4,300,050)</u>	<u>\$ (3,882,927)</u>	<u>\$ (368,754)</u>	<u>\$ (8,551,731)</u>

As of December 31, 2020

	Corporate	Medical Foods and Nutraceuticals	Medical Devices	Total
Current assets				
Cash	\$ 8,518,732	\$ -	\$ -	\$ 8,518,732
Inventories, net	-	254,879	130,093	384,972
Other	-	89,333	101,846	191,179
Total current assets	8,518,732	344,212	231,939	9,094,883
Right of use asset	-	374,447	44,143	418,590
Property and equipment, net	-	135,641	150,035	285,676
Intangible assets, net	-	50,000	-	50,000
Other	-	11,751	-	11,751
Total assets	<u>\$ 8,518,732</u>	<u>\$ 916,051</u>	<u>\$ 426,217</u>	<u>\$ 9,860,900</u>