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

FORM 8-K

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

Date of Report (Date of earliest event reported): **May 5, 2022**

CHEMBIO DIAGNOSTICS, INC.

Nevada	**0-30379**	**88-0425691**
(State or Other Jurisdiction of Incorporation or Organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

555 Wireless Blvd. Hauppauge, NY 11788
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **(631) 924-1135**

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:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	CEMI	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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 May 5, 2022, we issued a press release announcing financial results for the quarter ended March 31, 2022. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of Section 11 or Section 12(a)(2) of the Securities Act of 1933. The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this report shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by us whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit No.	Description
99.1	Press Release of Chembio Diagnostics, Inc., dated May 5, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

CHEMBIO DIAGNOSTICS, INC.

Dated: May 5, 2022

By: /s/ Richard L. Eberly
Chief Executive Officer and President

Exhibit 99.1

Chembio Diagnostics Reports First Quarter 2022 Financial Results

HAUPPAUGE, NY, May 5, 2022 -- Chembio Diagnostics, Inc. ("Chembio" or the "Company") (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today reported financial results for the quarter ended March 31, 2022.

Recent Highlights

- Achieved total revenue of $18.8 million including record quarterly product revenue of $18.5 million in the first quarter of 2022, representing growth of 116% and 360%, respectively, compared to the prior year period:
  - U.S. product revenue of $4.5 million, representing growth of 530% compared to the prior year period
  - Latin America product revenue of $12.5 million, compared to $0.3 million in the prior year period
- Completed shipments under the $28.3 million purchase order from Bio-Manguinhos for DPP SARS-COV-2 Antigen Tests in Brazil and continued shipments on the $4 million HIV test purchase order supported by The Global Fund, which are expected to be completed in the second quarter of 2022
- Improved gross product margin to 18% in the first quarter of 2022 from negative 9% in the fourth quarter of 2021
- Reduced cash usage in the first quarter of 2022 to $4.4 million, from $8.7 million in the prior year period and $7.2 million in the preceding quarter
- Expanded distributor relationships in Europe to supply the Sure Check HIV Self-tests in the UK and France
- Enhanced operations at Chembio Diagnostics Brazil by increasing low-cost manufacturing capabilities for over-the-counter packaging to support Sure Check Self-test supply for state, local and retail pharmacies

"We are pleased with our first quarter performance which included record quarterly product sales and substantial sequential gross product margin improvement," said Richard Eberly, Chembio's President and Chief Executive Officer. "In light of decreasing international demand for COVID-19 testing, we are repositioning our commercial focus toward our core products. The HIV self-testing market continues to grow across Europe, Brazil and Africa, and with renewed marketing efforts we believe our Sure Check products can address the needs of this patient population and further penetrate this market. Going forward, we will continue to prioritize use of our resources to drive more profitable growth and operational efficiency in accordance with our previously announced Global Competitiveness Program."

First Quarter 2022 Financial Results

Total revenue for the first quarter of 2022 was $18.8 million, an increase of 116% compared to the prior year period. Net product sales for the first quarter of 2022 were $18.5 million, an increase of 360% compared to the prior year period. Government grant, license and royalty, and R&D revenue for the first quarter of 2022 totaled $0.3 million, a decrease of 94% compared to the prior year period.

Gross product margin for the first quarter of 2022 was $3.3 million, compared to $0.5 million for the prior year period. Gross product margin percentage for the first quarter of 2022 was 18%, compared to 12% for the prior year period. Gross product margin in the first quarter of 2022 was driven by increased product volume sold in US and Latin America at higher average selling prices and operational productivity.

Research and development expenses decreased by $1.2 million, or 42%, in the first quarter of 2022 compared to the prior year period. Selling, general and administrative expenses increased by $0.9 million, or 14%, in the first quarter of 2022 compared to the prior year period.

Impairment, restructuring, severance and related costs for the first quarter of 2022 totaled $3.0 million, including an impairment of goodwill.

Net loss for the first quarter of 2022 was $8.8 million, or $0.29 per diluted share, compared to a net loss of $4.5 million, or $0.22 per diluted share, for the prior year period. The net loss includes impairment, restructuring, severance and related costs of $3.0 million, or $0.10 per share, for the first quarter of 2022, compared to a de minimis amount in the prior year period.

Cash and cash equivalents as of March 31, 2022 totaled $24.4 million, compared to $28.8 million at December 31, 2021.

Going Concern Considerations

The Company continued to experience market, clinical trial and regulatory complications in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty caused by COVID-19. For the three months ended March 31, 2022, the Company continued to incur significant expenses in connection with pending legal matters.

The Company performed an assessment to determine whether there were conditions or events that, considered in the aggregate, raised substantial doubt about the Company's ability to continue as a going concern within one year after the date the Company's unaudited condensed consolidated financial statements for the three months ended March 31, 2022 are being issued (the "Q1 Financials Issuance Date"). Initially, this assessment did not consider the potential mitigating effect of management's plans that had not been fully implemented. Because, as described below, substantial doubt was determined to exist as the result of this initial assessment, management then assessed the mitigating effect of its plans to determine if it is probable that the plans (1) would be effectively implemented within one year after the Q1 Financials Issuance Date and (2) when implemented, would mitigate the relevant conditions or events that raise substantial doubt about the Company's ability to continue as a going concern.

The Company achieved significant revenue growth in recent years while profitability has not been at levels as expected. It has taken steps, including investments in automation, to mitigate headwinds such as labor availability, volatile capacity planning and implementation of operational efficiency targets to proactively monitor production with the overarching goal for profitable growth. During the three months ended March 31, 2022, the Company undertook measures to increase its total revenues and improve its liquidity position by implementing the Global Competitiveness Program. The main pillars of the Global Competitiveness Program include the following:

- Focus on higher margin business in growth markets
- Lower manufacturing costs
- Reduce infrastructure costs
- Strategic review of non-core businesses and assets:

In addition, the Company will continue to focus on regulatory approvals for its DPP SARS-CoV-2 Antigen test system, DPP Respiratory Antigen Panel, and DPP HIV-Syphilis test system. These measures and other plans and initiatives have been designed to provide the Company with adequate liquidity to meet its obligations for at least the twelve-month period following the Q1 Financials Issuance Date. The Company's execution of those measures and its other plans and initiative continue to depend, however, on factors and uncertainties that are beyond the Company's control, or that may not be addressable on terms acceptable to the Company or at all.

The Company considered in particular how:

- The ongoing healthcare and economic impacts of COVID-19 on the global customer base for the Company's non-COVID-19 products continue to negatively affect the timing and rate of recovery of the Company's revenues from those products by, for example, decreasing the allocation of funding for HIV testing, thereby continuing to adversely affect the Company's liquidity.

- Although the Company has entered into agreements to distribute third-party COVID-19 products in the United States, its ability to sell those products could be constrained because of staffing and supply chain limitations affecting the suppliers of those products.

The Company further considered how these factors and uncertainties could impact its ability over the next year to meet the obligations specified in its existing Credit Agreement. Those obligations include covenants requiring: i) minimum cash balance of $3.0 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $43.8 million for the twelve months ending June 30, 2022 to$ 48.8 million for the twelve months ending March 31, 2023. Upon an event of default under the Credit Agreement, the Lender could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. In such an event, there can be no assurance that the Company would have sufficient liquidity to fund payment of the amounts that would be due under the Credit Agreement or that, if such liquidity were not available, the Company would be successful in raising additional capital on acceptable terms, or at all, or in completing any other endeavor to continue to be financially viable and continue as a going concern. The Company's inability to raise additional capital on acceptable terms in the near future, whether for purposes of funding payments required under the Credit Agreement or providing additional liquidity needed for its operations, could have a material adverse effect on its business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined the Company could not be certain that the Company's plans and initiatives would be effectively implemented within one year after the Q1 Financials Issuance Date. Without giving effect to the prospect of raising additional capital pursuant to the Company's existing At the Market Offering Agreement, increasing product revenue in the near future or executing other mitigating plans, many of which are beyond the Company's control, it is unlikely that the Company will be able to generate sufficient cash flows to meet its required financial obligations, including its debt service and other obligations due to third parties. The existence of these conditions raises substantial doubt about the Company's ability to continue as a going concern for the twelve-month period following the Q1 Financials Issuance Date.

The Company's unaudited condensed consolidated financial statements for the three months ended March 31, 2022 have been prepared assuming the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the Q1 Financials Issuance Date. As such, those unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of assets and their carrying amounts, or the amount and classification of liabilities that may result should the Company be unable to continue as a going concern.

Conference Call

Chembio will host a conference call today beginning at 4:30 pm ET to discuss its financial results and recent business highlights. Investors interested in listening to the call may do so by dialing 888-506-0062 from the United States or 973-528-0011 from outside the United States and providing entry code 898553. To listen to a live webcast of the call, please visit the Investor Relations section of Chembio's website at www.chembio.com. Following the call, a replay will be available on the Investor Relations section of Chembio's website. A telephone replay will be available until 4:30 pm ET on May 19, 2022 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 45278.

About Chembio Diagnostics

Chembio is a leading diagnostics company focused on developing and commercializing point-of-care tests used for the rapid detection and diagnosis of infectious diseases, including sexually transmitted disease, insect vector and tropical disease, COVID-19 and other viral and bacterial infections, enabling expedited treatment. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease. Chembio's products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers. Learn more at www.chembio.com.

Forward-Looking Statements

Certain statements contained in the second bulleted item under “Recent Highlights” above and in the paragraph following the bulleted items under “Recent Highlights” above are not historical facts and may be forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding the intent, belief or current expectations with respect to the Chembio’s R&D investments, development of certain products and registration of existing products in new geographies. Such statements, which are expectations only, reflect management's current views, are based on certain assumptions, and involve risks and uncertainties. Actual results, events or performance may differ materially from forward-looking statements due to a number of important factors, and will be dependent upon a variety of factors, including, but not limited to, the following, any of which could be exacerbated even further by the continuing COVID-19 outbreak in the United States and globally: the ability of Chembio to continue to generate revenue from the HIV test purchase order supported by The Global Fund or other product orders, and the margins it can realize from that revenue, or its ability to develop new products, will depend on the availability and cost of human, material and other resources required to build and deliver the tests, which factors are largely outside Chembio’s control; the ability of Chembio to maintain existing, and timely obtain additional, regulatory approvals, which approvals are subject to processes that can change recurringly without notice; the highly competitive and rapidly developing diagnostics market, which includes a number of competing companies with strong relationships with current and potential customers, including governmental authorities, and with significantly greater financial and other resources that are available to Chembio; and the risks of doing business with foreign governmental entities, including geopolitical, international and other challenges as well as potential material adverse effects of tariffs and other changes in U.S. trade policy. Chembio undertakes no obligation to publicly update forward-looking statements in this release to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to the forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's periodic public filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2021, particularly under the heading “Risk Factors.”

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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	For the three months ended (Unaudited)	
	March 31, 2022	March 31, 2021
REVENUES:		
Product revenue	**$ 18,527,456**	$ 4,024,662
R&D revenue	**18,173**	1,106,639
Government grant income	**-**	3,350,000
License and royalty revenue	**270,982**	243,058
TOTAL REVENUES	**18,816,611**	8,724,359
COSTS AND EXPENSES:		
Cost of product revenue	**15,223,861**	3,548,441
Research and development expenses	**1,653,706**	2,863,338
Selling, general and administrative expenses	**6,946,271**	6,085,067
Impairment, restructuring, severance and related costs	**3,043,179**	83,087
TOTAL COSTS AND EXPENSES	**26,867,017**	12,579,933
LOSS FROM OPERATIONS	**(8,050,406)**	(3,855,574)
OTHER EXPENSE:		
Interest expense, net	(733,561)	(712,477)
LOSS BEFORE INCOME TAXES	**(8,783,967)**	(4,568,051)
Income tax (expense)/benefit	**(6,327)**	67,888
NET LOSS	**$ (8,790,294)**	$ (4,500,163)
Basic and diluted loss per share	**$ (0.29)**	$ (0.22)
Weighted average number of shares outstanding, basic and diluted	**30,090,045**	20,163,386

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
AS OF

	March 31, 2022	December 31, 2021
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	$ 24,399,388	$ 28,772,892
Accounts receivable	9,879,954	11,441,107
Inventories, net	11,844,121	12,920,451
Prepaid expenses and other current assets	2,097,491	2,096,399
TOTAL CURRENT ASSETS	48,220,954	55,230,849
FIXED ASSETS:		
Property, plant and equipment, net	8,414,313	8,556,773
Finance lease right-of-use asset, net	190,526	191,870
TOTAL FIXED ASSETS, net	8,604,839	8,748,643
OTHER ASSETS:		
Operating lease right-of-use assets, net	5,693,482	5,891,906
Goodwill	-	3,022,787
Deposits and other assets	370,940	358,010
TOTAL ASSETS	$ 62,890,215	$ 73,252,195
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	$ 10,542,851	$ 13,127,993
Current portion of long-term debt	2,100,000	1,200,000
Operating lease liabilities	916,524	886,294
Finance lease liabilities	72,203	68,176
TOTAL CURRENT LIABILITIES	13,631,578	15,282,463
OTHER LIABILITIES:		
Long-term operating lease liabilities	5,733,214	5,976,151
Long-term finance lease liabilities	134,955	139,678
Long-term debt, less current portion, net	16,855,322	17,589,003
TOTAL LIABILITIES	36,355,069	38,987,295
STOCKHOLDERS' EQUITY:		
Common stock - $0.01 par value	302,699	301,050
Additional paid-in capital	166,483,376	165,772,636
Accumulated deficit	(139,800,154)	(131,009,860)
Treasury stock	(206,554)	(206,554)
Accumulated other comprehensive (loss)	(244,221)	(592,372)
TOTAL STOCKHOLDERS' EQUITY	26,535,146	34,264,900
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 62,890,215	$ 73,252,195

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE THREE MONTHS ENDED
(Unaudited)

	March 31, 2022	March 31, 2021
Net cash used in operating activities	**$ (4,368,959)**	$ (7,261,260)
Net cash used in investing activities	**(286,544)**	(1,239,168)
Net cash used by financing activities	**(55,444)**	(129,341)
Effect of exchange rate changes on cash	**337,442**	(85,579)
INCREASE IN CASH AND CASH EQUIVALENTS	**(4,373,504)**	(8,715,348)
Cash and cash equivalents - beginning of the period	**28,772,892**	23,066,301
Cash and cash equivalents - end of the period	**$ 24,399,388**	$ 14,350,953