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): **November 3, 2022**

CHEMBIO DIAGNOSTICS, INC.

Nevada	**001-355669**	**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 November 3, 2022, we issued a press release announcing financial results for the quarter ended September 30, 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 7.01 Regulation FD Disclosure

We held an investor conference call on November 3, 2022. The script for such call is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained in this Item 7.01 and in the script furnished as Exhibit 99.2 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 7.01 and in the script furnished as Exhibit 99.2 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 November 3, 2022
99.2	Script of conference call of Chembio Diagnostics, Inc. held on November 3, 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: November 3, 2022

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

Exhibit 99.1

Chembio Diagnostics Reports Third Quarter 2022 Financial Results

HAUPPAUGE, NY, November 3, 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 September 30, 2022.

Recent Highlights

- Achieved third quarter 2022 total revenue of $11.2 million including product revenue of $10.9 million, representing product revenue growth of 16% compared to the prior year period:
  - U.S. product revenue of $4.8 million grew 361% compared to the prior year period
- Awarded $3.2 million contract from the CDC for development and clinical validation of Dual-Path Platform (DPP) Syphilis Treponemal Nontreponemal (TNT) Assay
- Launched E-Commerce platform commercialization of Sure Check HIV Self-Test in Brazil and in the U.K. through Amazon
- Completed initial test production in the Chembio Malaysia facility

“We are pleased with our product revenue growth in the third quarter highlighted by 361% growth in the U.S. compared to the prior year period,” said Richard Eberly, Chembio’s President and Chief Executive Officer. “We have taken steps to position Chembio for future profitable growth through execution of our Global Competitiveness Program including the launch of our e-commerce platforms in Brazil and Europe for the sale of our HIV self-test, expanded manufacturing capabilities through automation and operationalizing our Malaysia facility and continued advancements with our regulatory and product pipeline.”

Third Quarter 2022 Financial Results

Total revenue for the third quarter of 2022 was $11.2 million, a decrease of 7% compared to the prior year period. Net product sales for the third quarter of 2022 were $10.8 million, an increase of 16% compared to the prior year period. Government grant, license and royalty, and R&D revenue for the third quarter of 2022 totaled $0.4 million, a decrease of 87% compared to the prior year period.

Gross product margin for the third quarter of 2022 was $1.2 million, compared to $1.5 million for the prior year period. Gross product margin percentage for the third quarter of 2022 was 11%, compared to 16% for the prior year period impacted by inventory reserves taken in the current quarter.

Research and development expenses decreased by $1.6 million, or 46%, compared to the prior year period to $1.9 million in the third quarter of 2022.

Selling, general and administrative expenses decreased by $0.4 million, or 7%, compared to the prior year period to $5.6 million in the third quarter of 2022.

Net loss for the third quarter of 2022 was ($6.7) million, or ($0.21) per diluted share, compared to a net loss of ($6.4) million, or ($0.24) per diluted share, for the prior year period.

Cash and cash equivalents as of September 30, 2022 totaled $21.1 million, compared to $22.8 million at June 30, 2022. The company received net proceeds of approximately $4 million in the third quarter of 2022 from use of its ATM program.

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 558147. 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 November 17, 2022 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 600643.

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.

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 resulting from COVID-19. For the three and nine months ended September 30, 2022, the Company also continued to incur significant expenses in connection with pending legal matters (see Note 6 – Commitments, Contingencies, and Concentrations: Litigation).

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 accompanying unaudited condensed consolidated financial statements are being issued. 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 date the accompanying unaudited condensed consolidated financial statements are issued 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 of profitable growth. The Company undertook measures to increase its total revenues and improve its liquidity position by continuing to develop 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 date the accompanying unaudited condensed consolidated financial statements are being issued. The Company's execution of its plans 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.

- 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 the Credit Agreement with the Lender (as defined in Note 7 – Long-Term Debt). 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 three quarters, the minimum total revenue requirements range from $47.4 million for the twelve months ending December 31, 2022 to $50.1 million for the twelve months ending June 30, 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 date on which the accompanying unaudited condensed consolidated financial statements are being issued. Without giving effect to the prospect of raising additional capital, 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 date on which the accompanying unaudited condensed consolidated financial statements are being issued.

The accompanying unaudited condensed consolidated financial statements 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 date the accompanying unaudited condensed consolidated financial statements are issued. As such, the accompanying 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.

Forward-Looking Statements

Certain statements contained in the third and fourth bulleted items 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 Reszon Diagnostics International’s manufacturing products and Chembio’s increasing its commercial presence in the Asia-Pacific region; Chembio’s expanding the Direct-to-Consumer e-Commerce channel for the commercialization of the Sure Check HIV Self-test in Brazil and the United Kingdom, and the third-party SCoV-2 Ag Detect Self-Test in the United States; Chembio’s continued progress with its Global Competitiveness Program, positioning it to drive adoption of its core higher margin products in high-growth markets, and expanding manufacturing capabilities through automation and a contract manufacturing agreement leveraging its facility in Malaysia; and Chembio’s advance key new product development and regulatory initiatives, all of which help define a path to more profitable growth. 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 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 on a recurrent basis 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, its Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2022 and June 30, 2022 and September 30, 2022 and in subsequent filings, particularly under the headings “Risk Factors.”

DPP is Chembio’s registered trademark, and the Chembio logo is Chembio’s trademark. For convenience, these trademarks appear in this release without ® or ™ symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademarks. All other trademarks appearing in this release are the property of their respective owners.

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

	For the three months ended		For the nine months ended	
	September 30, 2022	September 30, 2021	**September 30, 2022**	September 30, 2021
REVENUES:				
Product revenue	**$ 10,844,003**	$ 9,371,160	**$ 38,229,605**	$ 17,327,204
R&D revenue	**50,000**	441	**76,219**	1,107,808
Government grant income	**-**	2,400,000	**-**	8,030,000
License and royalty revenue	**306,145**	286,843	**872,365**	779,901
TOTAL REVENUES	**11,200,148**	12,058,444	**39,178,189**	27,244,913
COSTS AND EXPENSES:				
Cost of product revenue	**9,658,678**	7,902,819	**32,969,388**	15,490,956
Research and development expenses	**1,871,113**	3,442,044	**5,567,169**	9,102,363
Selling, general and administrative expenses	**5,551,362**	5,947,327	**17,747,613**	18,033,748
Impairment, restructuring, severance and related costs	**110,250**	396,740	**3,153,429**	2,440,983
TOTAL COSTS AND EXPENSES	**17,191,403**	17,688,930	**59,437,599**	45,068,050
LOSS FROM OPERATIONS	**(5,991,255)**	(5,630,486)	**(20,259,410)**	(17,823,137)
OTHER EXPENSE:				
Interest expense, net	**(707,549)**	(735,336)	**(2,169,525)**	(2,175,188)
LOSS BEFORE INCOME TAXES	**(6,698,804)**	(6,365,822)	**(22,428,935)**	(19,998,325)
Income tax (provision) benefit	**-**	(28)	**(6,606)**	67,928
NET LOSS	**$ (6,698,804)**	$ (6,365,850)	**$ (22,435,541)**	$ (19,930,397)
Basic and diluted loss per share	**$ (0.21)**	$ (0.24)	**$ (0.73)**	$ (0.89)
Weighted average number of shares outstanding, basic and diluted	**32,274,664**	26,701,546	**30,862,982**	22,361,899

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

	(Unaudited) September 30, 2022	December 31, 2021
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 21,055,026**	$ 28,772,892
Accounts receivable, net of allowance for doubtful accounts of $242,354 and $243,042 as of September 30, 2022 and December 31, 2021, respectively	**5,252,573**	11,441,107
Inventories, net	**8,465,210**	12,920,451
Prepaid expenses and other current assets	**12,509,604**	2,096,399
TOTAL CURRENT ASSETS	**47,282,413**	55,230,849
FIXED ASSETS:		
Property, Plant and Equipment, net	**8,813,699**	8,556,773
Finance lease right-of-use asset, net	**154,826**	191,870
TOTAL FIXED ASSETS, net	**8,968,525**	8,748,643
OTHER ASSETS:		
Operating lease right-of-use assets, net	**5,639,763**	5,891,906
Goodwill	**-**	3,022,787
Deposits and other assets	**289,203**	358,010
TOTAL ASSETS	**$ 62,179,904**	$ 73,252,195
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 18,050,498**	$ 13,127,993
Operating lease liabilities	**910,100**	886,294
Finance lease liabilities	**75,279**	68,176
Current portion of long-term debt	**18,993,535**	1,200,000
TOTAL CURRENT LIABILITIES	**38,029,412**	15,282,463
OTHER LIABILITIES:		
Long-term operating lease liabilities	**5,655,468**	5,976,151
Long-term finance lease liabilities	**96,529**	139,678
Long-term debt, net	**10,684**	17,589,003
TOTAL LIABILITIES	**43,792,093**	38,987,295
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none issued or outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 35,392,496 shares and 30,056,929 shares issued at September 30, 2022 and December 31, 2021, respectively	**354,406**	301,050
Additional paid-in capital	**171,448,870**	165,772,636
Accumulated deficit	**(153,445,401)**	(131,009,860)
Treasury stock 48,057 shares at cost as of September 30, 2022 and December 31, 2021, respectively	**(206,554)**	(206,554)
Accumulated other comprehensive loss	**(358,510)**	(592,372)
TOTAL STOCKHOLDERS' EQUITY	**17,792,811**	34,264,900
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 61,584,904**	$ 73,252,195

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

	September 30, 2022	September 30, 2021
Net cash used in operating activities	**(9,751,666)**	(24,150,484)
Net cash used in investing activities	**(1,480,662)**	(1,420,249)
Net cash provided by financing activities	**3,531,071**	38,646,767
Effect of exchange rate changes on cash	**(16,609)**	(138,335)
DECREASE IN CASH AND CASH EQUIVALENTS	**(7,717,866)**	12,937,699
Cash and cash equivalents - beginning of the period	**28,772,892**	23,066,301
Cash and cash equivalents - end of the period	**$ 21,055,026**	$ 36,004,000

Exhibit 99.2

Chembio Script
November 3, 2022

Philip Taylor, Investor Relations

Thank you, operator. Before we begin, let me remind you that the Company's remarks made during this conference call today, November 3, 2022, may include predictions, estimates or other information that might be considered forward-looking. These forward-looking statements represent Chembio's current judgment for the future. They are, however, subject to numerous assumptions, risks and uncertainties, many of which are beyond Chembio's control, including risks and uncertainties described from time to time in Chembio's SEC filings, including those under "Risk Factors" in its annual report on Form 10-K for the full year 2021, its quarterly reports on Form 10-Q for the first quarter and second quarter of 2022, and in subsequent SEC filings. Chembio's results may differ materially from those projected. Chembio undertakes no obligation to publicly revise or update any forward-looking statement made today. I encourage you to review all of the Company's filings with the SEC concerning these and other matters.

With that, I would like to turn the call over to Rick Eberly, President and Chief Executive Officer.

Richard L. Eberly, Chief Executive Officer and President

Good afternoon and thank you all for joining us. On today's call we will review our strategy and our progress scaling growth, improving operational efficiency and further developing our test portfolio. Larry will then cover the third quarter financial results and provide a detailed update on our Global Competitiveness Program. I will then conclude and open the call for questions.

First, I want to provide a brief description of the current priorities that have guided Chembio's strategic pivot over the year. Across the business, profitable growth remains the top objective. In prior quarters, we've announced several initiatives to pursue higher margin business and reduce operating expenses. Not all of these changes are reflected immediately in our financial results but we expect their impact to be significant in the coming quarters and for the Company long-term. This year we've renewed our focus on commercial efforts with our core business in higher value markets. We are now more focused on markets like the U.S. and Europe with higher ASPs for advanced technologies. These markets also represent health care systems that support reoccurring opportunities, versus large one-time government tenders. Additionally we have expanded our attention toward OTC markets which provide similar structural benefits. We believe winning business with a regular cadence of frequent, smaller orders should allow us to be more efficient with resource planning, supply chain management and product manufacturing.

To further improve our operating efficiency, we have advanced our manufacturing capabilities by leveraging both expanded automation and contract manufacturing in Malaysia. Both solutions, combined with tighter cost controls, are expected to improve our cost of product revenue. Over the medium term we plan to develop products to broaden our portfolio with differentiated tests that command premium value.

Now, I will outline our third quarter performance and growth drivers. In the third quarter we generated total revenue of $11.2 million, including product revenue of $10.8 million. Product revenue grew 16% compared to the prior year period.

Product revenue in the third quarter was primarily driven by $4.8 million of sales in the U.S. Growth here of 361%, compared to the prior year period, resulted mainly from increased, SCoV-2 Ag Detect rapid test. The self-test version of this test has received an EUA, and we have initiated a direct-to-consumer launch to service the OTC market through an e-commerce platform. One of our featured core products, the DPP HIV-Syphilis system, also contributed to sales in the U.S. We continue to believe this differentiated test will be a meaningful growth driver upon receipt of a CLIA waiver.

Third quarter Latin America sales were $2.3 million. Sales in the region transitioned back to core product sales from COVID sales, as in the prior year period sales in the region were predominantly for DPP SARS-CoV-2 Tests under the large Bio Manguinhos order. Approximately $2 million of DPP HIV tests were shipped to Bio Manguinhos in the quarter. In Brazil, we are now focused on marketing our Sure Check and HIV self-testing. We continue to believe that is the most promising commercial opportunity supported by our current product portfolio in the region. The healthcare system in Brazil is currently promoting self-testing through the Ministry of Health and awareness campaigns. As a reminder, our product resides on the shelf in three out of the five largest pharmacy chains in Brazil and we have just launched our e-commerce sales channel.

In EMEA & Asia, product revenues in the third quarter grew 43% compared to the prior year to $3.8 million. In Europe, like Brazil, we've heightened distribution efforts of the Sure Check HIV Self-Test. We continue to expand shipments to pharmacies across Europe and are now on the shelf in approximately 35,000 pharmacies through the excellent work by our distribution partner in France. Within the UK, we have launched our direct-to-consumer channel through Amazon and are also in pharmacies in the region. We continue to seek opportunities for expansion for our HIV self-test across applicable markets in Europe.

Turning to Africa, this quarter, Chembio completed its tender with Ethiopia for shipments of the HIV 1/2 STAT-PAK Assay. This tender had generated margins below our expectations and now we are actively pursuing opportunities in markets seeking higher-margin, premium solutions.

Shifting now to our product and regulatory development pipeline. On the DPP HIV-Syphilis test, we continue our work to address the FDA's request for additional data to achieve a CLIA waiver.

Our EUA submission for the DPP SARS-CoV-2 Ag test continues to be under active review by the FDA and we are encouraged by the progress made over the past quarters.

Late in the third quarter, we announced the Company was awarded a $3.2 million contract from the Centers for Disease Control for the development and clinical validation of a rapid point-of-care diagnostic test for syphilis. We are actively developing a syphilis treponemal nontreponemal (TNT) test leveraging our Dual Path Platform, or DPP, technology and proprietary DPP Micro Reader II. We expect that the assay will be able to simultaneously and separately detect treponemal and nontreponemal IgM and IgG antibodies. We anticipate that grant revenue will begin in the fourth quarter and will be milestone-based through the regulatory submission. We are excited to expand our portfolio as we endeavor to develop a highly sensitive and specific test where we anticipate a large need for physicians to quickly and accurately confirm active or prior syphilis infections.

We also announced in the third quarter development of a rapid point-of-care diagnostic test for Lyme disease. Lyme disease, caused by the bacterium Borrelia burgdorferi, is transmitted to humans via infected-tick bites. Recently, the CDC has updated its guidelines for Lyme disease diagnosis with the new algorithm termed MTTT for modified two-tier testing. These two step methods are labor intensive, take a long time to run and require trained professional laboratory personnel. The DPP Lyme IgM/IgG test is designed to be a rapid multiplex point-of-care test and combine the two-tier testing algorithm into one DPP test cassette utilizing our DPP Micro Reader II for objective test results. We are collecting preclinical data for our DPP Lyme test in development. We are hopeful this data will underpin a productive pre-submission meeting with the FDA. Our intention is to complete pre-submission meetings for both the DPP TNT and Lyme tests to discuss guidance on the structure and requirements for potential pivotal clinical trials.

I will now hand the call over to Larry to detail the third quarter financials and provide more details on our operational improvements under the Global Competitiveness Program.

Lawrence J. Steenvoorden, Executive Vice President and Chief Financial Officer

Thank you, Rick.

For the three months ended September 30, 2022, total revenue was $11.2 million, representing a decline of 7% compared to the prior year period. Product revenue for the third quarter of 2022 was $10.8 million, an increase of 16% compared to the prior year period. Government grant income, license and royalty revenues, and R&D revenues combined for the three months ended September 30, 2022, were $0.4 million compared to $2.7 million the prior year period, the decrease was due to the expiration of previous partner development agreements. Our revenues were in compliance with the quarterly twelve-month rolling Minimum Total Revenue covenant in our Credit Agreement.

Gross product margins during the three months ended September 30, 2022 decreased to $1.2 million, compared to $1.5 million in the prior year period. Gross product margin percent was 11% in the quarter compared to 16% in the third quarter of 2021 impacted by inventory reserves taken in the third quarter of this year.

R&D costs decreased by $1.6 million compared to the prior year period, to $1.9 million in the third quarter of 2022 primarily associated with completion of development work from prior partnership development agreements.

Selling, general and administrative expenses decreased by $0.4 million compared to the prior year period, to $5.6 million in the third quarter of 2022.

Net loss in the three months ended September 30, 2022, was $6.7 million, or a loss of $0.21 cents per diluted share, compared to a net loss of $6.4 million, or a loss of $0.24 cents per diluted share, in the prior-year period.

On the balance sheet, cash and cash equivalents as of September 30, 2022, totaled $21.1 million. In the third quarter of 2022, the Company received net proceeds of approximately $4 million from sales of its common stock as part of its ongoing ATM offering.

Net working capital as of September 30, 2022, was $8.7 million.

Looking forward, given the substantial nature of the COVID revenues over the past three quarters, as expected revenue for the year will be first half weighted and we anticipate challenging sales growth comparisons in the fourth quarters of 2022. Line-of-sight on orders is a major priority for the final quarter of the year, especially with regards to our large customers and markets.

I will now provide an overview of the progress we are making on our Global Competitiveness Program, which we launched in the first quarter of 2022. We continue to prioritize higher-margin options within key markets that the organization has identified as prime growth opportunities. We are focusing on both our core products and non-core products that have the potential to be profitable. We've identified a global opportunity for our Sure Check HIV Self-test and have allocated resources to support its adoption and distribution.

Additionally, we're actively lowering our manufacturing costs through increased adoption of automated manufacturing. We believe automation and labor reductions are required to improve product gross margins and scale unit volumes to support new initiatives. We have executed on our previously communicated strategy to have all our product platforms on an automated line by end of Q3. Bolstering these efforts is our contract with Reszon Diagnostics International to oversee the manufacturing efforts of our HIV 1/2 STAT-PAK Assay at our Chembio Diagnostics Malaysia facility. They are now up and running and we have initiated production in the facility.

In an effort to reduce infrastructure expenses, we conducted an internal audit of our business and external spending to reduce costs. We reduced our organizational headcount from 290 to 211 employees as of September 30th. We expect to continue to increase our automation capabilities and further reduce our headcount and dependency on manual labor.

Our path to profitability is clear. As we realign our organization to reduce cost and prioritize efficiency, we believe the company is well-positioned for long-term growth. Keeping our customers at the forefront of our vision, we believe our organization can deliver the initiatives necessary to achieve expansion both domestically and internationally. We look forward to providing more updates and are excited for the future of Chembio.

I'll now turn the call back to Rick for concluding remarks.

Richard L. Eberly, Chief Executive Officer and President

Thank you, Larry.

We are pleased with our results from the third quarter of 2022. Over the course of this year, we have improved efficiency, identified and initiated commercialization of promising market opportunities and reduced our operating infrastructure. We improved visibility on our top line and sales efforts have been refocused on our core products in key growth markets. With advancements in our pipeline supported by a new contract with the CDC, we are excited by the opportunities that lie ahead to propel Chembio to long-term profitable growth.

With that, operator, please open up the call to questions.