



Chembio Diagnostics Reports Third Quarter 2022 Financial Results

November 3, 2022

HAUPPAUGE, N.Y., Nov. 03, 2022 (GLOBE NEWSWIRE) -- 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 \$10.8 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 operations improvements at 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 and was negatively 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 \$4.0 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 600643. 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 46584.

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.

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 its unaudited condensed consolidated financial statements are being issued for the nine months ended September 30, 2022. 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 its unaudited condensed consolidated financial statements for the nine months ended September 30, 2022 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 its unaudited condensed consolidated financial statements for the nine months ended September 30, 2022 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 its lender. 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 its unaudited condensed consolidated financial statements for the nine months ended September 30, 2022 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 unaudited condensed consolidated financial statements for the nine months ended September 30, 2022 are being issued.

The Company's unaudited condensed consolidated financial statements for the nine months ended September 30, 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 date such unaudited condensed consolidated financial statements are issued. As such, the Company's unaudited condensed consolidated financial statements for the nine months ended September 30, 2022 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, 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 | \$ 18,645,498 | \$ 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 | 38,624,412 | 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 | - | 17,576,635 |
| Other long-term liabilities | 10,684 | 12,368 |
| TOTAL LIABILITIES | 44,378,093 | 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 | \$ 62,179,904 | \$ 73,252,195 |

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

| | September 30, 2022 | September 30, 2021 |
|---------------------------------------|-----------------------|-----------------------|
| Net cash used in operating activities | (9,861,916) | (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 | 93,641 | (138,335) |
| (DECREASE)/INCREASE 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 |



Source: Chembio Diagnostics, Inc.