Chembio Diagnostics Reports Second Quarter 2022 Financial Results

August 4, 2022

HAUPPAUGE, N.Y., Aug. 04, 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 June 30, 2022.

Recent Highlights

- Achieved second quarter 2022 total revenue of $9.2 million including product revenue of $8.9 million, representing growth of 42% and 125%, respectively, compared to the prior year period:
  - U.S. product revenue of $3.4 million, representing growth of 208% compared to the prior year period
  - Africa product revenue of $3.1 million, representing growth of 114% compared to the prior year period
- Completed manufacturing and most of the shipments under the $4 million HIV test purchase order supported by The Global Fund
- Broadened relationship with Reszon Diagnostics International to manufacture HIV1/2 STAT-PAK in the Chembio Diagnostics Malaysia facility and to increase commercial presence in the Asia-Pacific region
- Expanded Direct-to-Consumer 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
- Improved cash usage in the second quarter of 2022 to $1.6 million, from $8.8 million in the prior year period and $4.4 million in the preceding quarter, with a cash and cash equivalents balance as of June 30, 2022 of $22.8 million

“We are pleased with our performance in the second quarter including strong sales growth driven by contributions from our core products and a significant improvement in cash burn,” said Richard Eberly, Chembio’s President and Chief Executive Officer. “During the quarter we made continued progress with our Global Competitiveness Program – positioning the team to drive adoption of our core higher margin products in high-growth markets, and expanding manufacturing capabilities through automation and a contract manufacturing agreement leveraging our facility in Malaysia. Additionally, we are excited to advance key new product development and regulatory initiatives, all of which help define a path to more profitable growth.”

Second Quarter 2022 Financial Results

Total revenue for the second quarter of 2022 was $9.2 million, an increase of 42% compared to the prior year period. Net product sales for the second quarter of 2022 were $8.9 million, an increase of 125% compared to the prior year period. Government grant, license and royalty, and R&D revenue for the second quarter of 2022 totaled $0.3 million, a decrease of 88% compared to the prior year period.

Gross product margin for the second quarter of 2022 was $0.8 million, compared to negative $0.1 million for the prior year period. Gross product margin percentage for the second quarter of 2022 was 9%, compared to negative 3% for the prior year period. Gross product margin improvement in the second quarter of 2022 was driven by product mix and operational productivity.

Research and development expenses decreased by $0.8 million, or 27%, compared to the prior year period to $2.0 million in the second quarter of 2022.

Selling, general and administrative expenses decreased by $0.8 million, or 13%, compared to the prior year period to $5.2 million in the second quarter of 2022.

Net loss for the second quarter of 2022 was ($6.9) million, or ($0.23) per diluted share, compared to a net loss of ($9.1) million, or ($0.45) per diluted share, for the prior year period.

Cash and cash equivalents as of June 30, 2022 totaled $22.8 million, compared to $24.4 million at March 31, 2022.

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 August 18, 2022 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 45932.

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 six months ended June 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 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 its Credit Agreement with the Perceptive Credit Holdings II, LP. 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 four quarters, the minimum total revenue requirements range from $45.6 million for the twelve months ending September 30, 2022 to $50.1 million for the twelve months ending June 30, 2023. Upon an event of default under the Credit Agreement, Perceptive Credit Holdings II, LP 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 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 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 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 Report on Form 10-Q for the fiscal quarter ended June 30, 2022 and in subsequent filings, particularly under the headings "Risk Factors."*

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

	For the three months ended (Unaudited)		For the six months ended (Unaudited)	
	June 30, 2022	June 30, 2021	**June 30, 2022**	June 30, 2021
REVENUES:				
Product revenue	**$ 8,858,146**	$ 3,931,383	**$ 27,385,602**	$ 7,956,045
R&D revenue	**8,046**	727	**26,219**	1,107,366
Government grant income	**-**	2,280,000	**-**	5,630,000
License and royalty revenue	**295,238**	250,000	**566,220**	493,058
TOTAL REVENUES	**9,161,430**	6,462,110	**27,978,041**	15,186,469
COSTS AND EXPENSES:				
Cost of product revenue	**8,086,849**	4,039,696	**23,310,710**	7,588,137
Research and development expenses	**2,042,351**	2,796,981	**3,696,057**	5,660,319
Selling, general and administrative expenses	**5,249,980**	6,001,353	**12,196,250**	12,086,422
Impairment, restructuring, severance and related costs	**-**	1,961,156	**3,043,179**	2,044,243
TOTAL COSTS AND EXPENSES	**15,379,180**	14,799,186	**42,246,196**	27,379,121
LOSS FROM OPERATIONS	**(6,217,750)**	(8,337,076)	**(14,268,155)**	(12,192,652)
OTHER EXPENSE:				
Interest expense, net	**(728,414)**	(727,374)	**(1,461,976)**	(1,439,851)
LOSS BEFORE INCOME TAXES	**(6,946,164)**	(9,064,450)	**(15,730,131)**	(13,632,503)
Income tax (provision) benefit	**(279)**	65	**(6,606)**	67,955
NET LOSS	**$ (6,946,443)**	$ (9,064,385)	**$ (15,736,737)**	$ (13,564,548)
Basic and diluted loss per share	**$ (0.23)**	$ (0.45)	**$ (0.52)**	$ (0.67)
Weighted average number of shares outstanding, basic and diluted	**30,222,758**	20,219,617	**30,156,768**	20,191,657

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

	(Unaudited) June 30, 2022	December 31, 2021
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 22,837,453**	$ 28,772,892
Accounts receivable, net of allowance for doubtful accounts of $242,671 and $243,042 as of June 30, 2022 and December 31, 2021, respectively	**4,255,944**	11,441,107
Inventories, net	**11,308,660**	12,920,451
Prepaid expenses and other current assets	**2,498,447**	2,096,399
TOTAL CURRENT ASSETS	**40,900,504**	55,230,849
FIXED ASSETS:		
Property, Plant and Equipment, net	**8,843,954**	8,556,773
Finance lease right-of-use asset, net	**172,676**	191,870
TOTAL FIXED ASSETS, net	**9,016,630**	8,748,643
OTHER ASSETS:		
Operating lease right-of-use assets, net	**5,841,382**	5,891,906
Intangible assets, net		
Goodwill		3,022,787
Deposits and other assets	**297,024**	358,010
TOTAL ASSETS	**$ 56,055,540**	$ 73,252,195
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 10,051,649**	$ 13,127,993
Deferred revenue		
Operating lease liabilities	**905,516**	886,294
Finance lease liabilities	**73,724**	68,176
Current portion of long-term debt	**3,000,000**	1,200,000
TOTAL CURRENT LIABILITIES	**14,030,889**	15,282,463
OTHER LIABILITIES:		
Long-term operating lease liabilities	**5,877,063**	5,976,151
Long-term finance lease liabilities	**115,943**	139,678
Long-term debt, net	**16,126,833**	17,589,003
TOTAL LIABILITIES	**36,150,728**	38,987,295
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none issued or outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 30,086,283 shares and 20,223,498 shares issued at June 30, 2022 and December 31, 2021, respectively	**302,727**	301,050
Additional paid-in capital	**167,041,203**	165,772,636
Accumulated deficit	**(146,746,597)**	(131,009,860)
Treasury stock 41,141 shares at cost as of June 30, 2022 and December 31, 2021, respectively	**(206,554)**	(206,554)
Accumulated other comprehensive loss	**(485,967)**	(592,372)
TOTAL STOCKHOLDERS' EQUITY	**19,904,812**	34,264,900
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 56,055,540**	$ 73,252,195

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

	June 30 2022	June 30 2021
Net cash used in operating activities	**(4,802,145)**	(15,908,660)
Net cash used in investing activities	**(1,135,332)**	(1,299,012)
Net cash provided by financing activities	**(74,089)**	(69,488)
Effect of exchange rate changes on cash	**76,127**	(144,947)
DECREASE IN CASH AND CASH EQUIVALENTS	**(5,935,439)**	(17,422,107)
Cash and cash equivalents - beginning of the period	**28,772,892**	23,066,301
Cash and cash equivalents - end of the period	**$ 22,837,453**	**$** 5,644,194

Source: Chembio Diagnostics, Inc.