Chembio Diagnostics Reports Third Quarter 2021 Financial Results

November 4, 2021

HAUPPAUGE, N.Y., Nov. 04, 2021 (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, 2021.

Recent Highlights

- Achieved third quarter 2021 total revenue of $12.1 million and product revenue of $9.4 million, representing growth of 17% and 12%, respectively, compared to the prior year period. After reflecting the deferred recognition to the third quarter of 2020 of revenue associated with shipments from the second quarter of 2020, total revenues in the third quarter of 2021 increased by $4.5 million, or 59.2%, compared to the prior year period.
- Awarded substantial purchase orders in July 2021 from Bio-Manguinhos for DPP SARS-COV-2 Antigen tests and the Partnership for Supply Chain Management, supported by The Global Fund, for STAT-PAK 1/2 HIV tests.
- Launched US commercial distribution of a third-party COVID-19 Antigen Assay.
- Raised $38.8 million in net proceeds from at-the-market offerings of common stock launched in July.

“Product revenue growth is being driven by the largest purchase order in company history, received from Bio-Manguinhos in Brazil in July, for our DPP SARS-CoV-2 Antigen tests,” said Richard Eberly, Chembio’s President and Chief Executive Officer. “Operationally we continue to take steps to address the tight labor market and global supply chain issues for certain test components to ramp production. We are increasing our production and are delighted that our strong revenue growth was achieved in the face of these challenges. Notwithstanding the team’s hard work to increase capacity over the past few months, we currently anticipate that at least $11.5 million of the purchase order from Bio-Manguinhos will not be fulfilled by December 31, 2021, the end of the existing shipment schedule under the order. We continue to discuss with Bio-Manguinhos the possibility of fulfilling a portion of the order in early 2022, and in addition, are doing everything we can to minimize the impact of the continuing market challenges on all of our customers.”

Mr. Eberly continued, “We continue to make progress on our other commercial and regulatory initiatives. In the United States, our commercial team is gaining traction with customers interested in the third-party COVID-19 tests we are distributing. Also, we are hopeful for a straightforward review of the EUA submission for our DPP Respiratory Antigen Panel.”

Third Quarter 2021 Financial Results

Total revenue for the third quarter of 2021 was $12.1 million, an increase of 17.4% compared to the prior year period. Net product sales for the third quarter of 2021 were $9.4 million, an increase of 11.5% compared to the prior year period, including $5.4 million and $1.2 million of product revenue under the purchase orders received from Bio-Manguinhos and the Partnership for Supply Chain Management, respectively. After reflecting the deferred recognition to the third quarter of 2020 of revenue associated with shipments from the second quarter of 2020, net product sales during the third quarter of 2021 increased by $4.5 million, or 59.2%, compared to the prior year period. Government grant, license and royalty, and R&D revenue for the third quarter of 2021 totaled $2.7 million, an increase of 44.0% compared to the prior year period.

Gross product margin for the third quarter of 2021 was $1.5 million, compared to $0.9 million for the prior year period. Gross product margin percentage for the third quarter of 2021 was 15.7%, compared to 11.2% for the prior year period. Gross product margin in the third quarter of 2021 was favorably impacted from higher product margins due to higher average selling prices and higher product sales volume. Gross product margin in the prior year period was impacted by several factors, including the revocation by the U.S. Food and Drug Administration (the “FDA”) of the emergency uses authorization (“EUA”) for DPP COVID-19 IgM/IgG Systems in June 2020, which precluded planned sales of COVID-19 IgM/IgG Systems to customers in the United States as well as operational inefficiencies it triggered, offset by the recognition of $2.7 million net revenue from product shipments outside the United States that had been deferred from the second quarter of 2020.

Research and development expenses increased by $1.1 million, or 46.3%, in the third quarter of 2021 compared to the prior year period. The increase in research and development costs was primarily associated with clinical and regulatory affairs costs related to pursuing an EUA and 510(k) from the FDA for the DPP SARS-CoV-2 Antigen test system and an EUA for the DPP Respiratory Panel, each pursuant to awards from the Biomedical Advanced Research and Development Authority (part of the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response) (“BARDA”). Selling, general and administrative expenses increased by $0.6 million, or 11.2%, in the third quarter of 2021 compared to the prior year period, primarily due to increased costs associated with compensation costs related to Chembio’s expanded U.S. commercial team; commissions; and insurance; offset by a decrease in legal fees.

During the third quarter of 2021, Chembio recognized $0.4 million of restructuring costs related to professional fees.

Net loss for the third quarter of 2021 was $6.4 million, or $0.24 per diluted share, compared to a net loss of $5.4 million, or $0.28 per diluted share, for the prior year period. The net losses reflected asset impairment, restructuring, severance, and related costs of $0.4 million, or $0.01 per share, for the third quarter of 2021, compared to $0 million, or $0 per diluted share, for the prior year period.

Cash and cash equivalents as of September 30, 2021 totaled $36.0 million. During the three months ended September 30, 2021, Chembio issued and sold in at-the-market offerings a total of 9,709,328 shares of common stock at a volume-weighted average price of $4.2011 per share for gross proceeds of $40.8 million and net proceeds, after giving effect to placement fees and other transaction costs, of $38.8 million.

Going Concern Considerations

Revenues during the three months ended September 30, 2021 did not meet the Company's expectations. The Company's increase in cash and cash equivalents over the first nine months of 2021 reflected its issuance of common stock in at-the-market offerings for net proceeds of $38.8 million. 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 of the COVID-19 pandemic. In the three months ended September 30, 2021, the Company continued to incur significant expenses in connection with pending legal matters, delayed achievement of milestones associated with government grant income, investments in inventory, and the continuing automation of manufacturing.

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 on which its unaudited condensed consolidated financial statements will be issued (the "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 Issuance Date and (2) when implemented, would mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern.

During the three months ended September 30, 2021, the Company undertook measures to increase its total revenues and improve its liquidity position. The Company received significant purchase orders from two customers (the "July Purchase Orders"). The Company had pursued the July Purchase Orders for an extended period of time. The July Purchase Orders consist of the following:

- On July 20, 2021, the Company received a $28.3 million purchase order from Bio-Manguinhos for the purchase of DPP SARS-CoV-2 Antigen tests for delivery during 2021 to support the urgent needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic.
- On July 22, 2021, the Company received a $4 million purchase order from the Partnership for Supply Chain Management, supported by The Global Fund, for the purchase of HIV 1/2 STAT-PAK Assays for shipment to Ethiopia into early 2022.

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 Issuance Date. The Company's execution of those measures and its other plans and initiatives continue to depend, however, on factors 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:

- Limitations of the Company's staffing, supply chain and liquidity have impaired, and are expected to continue to impair, the Company's ability to fulfill at least $11.5 million of the July Purchase Order from Bio-Manguinhos by December 31, 2021, the end of the existing shipment schedule under the order.
- Earlier delays in clinical trials, which reflected the impact of the COVID-19 vaccination rollout and the related decline in positivity rates at clinical trials on the Company's clinical plan enrollment levels, and continuing requirements of achievement of regulatory approvals may limit the Company's ability to achieve a portion of the revenue- and cash-generating milestones under a $12.7 million award granted pursuant to the Company's contract dated December 2, 2020 with the BARDA, which contract will, unless extended by BARDA, expire on December 2, 2021.
- The ongoing healthcare and economic impacts of the COVID-19 pandemic 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 the Company's existing credit agreement. Those obligations include a covenant requiring minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from $40.3 million for the twelve months ending December 31, 2021 to $ 45.6 million for the twelve months ending September 30, 2022. 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 its plans and initiatives would be effectively implemented within one year after the Issuance Date. Without giving effect to the prospect of raising additional capital in at-the-market offerings, 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 rent, 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 Issuance Date.

The Company's third quarter financial statements are being 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 Issuance Date.

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 938540. 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 18, 2021 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 43155.

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 two paragraphs 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 distribution and sale of Chembio's diagnostic tests, the availability, timing, functionality and regulatory approval of Chembio's COVID-19 diagnostic tests, and Chembio's ability to maintain sufficient liquidity to fund its operation, including its sales of tests pursuant to the July Purchase Orders. 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 generate revenue from the July Purchase Orders or other product orders, and the margins it can realize from that revenue, 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, particularly for its proposed COVID-19 diagnostic tests, which approvals are subject to processes that can change recurringly without notice; Chembio's dependence upon, and limited experience with, COVID-19 diagnostic tests; the highly competitive and rapidly developing market for testing solutions for COVID-19, 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, its Current Report on Form 8-K filed with the Securities and Exchange Commisson on July 19, 2021, and its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, particularly under the heading "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 nine months ended (Unaudited)	
	September 30, 2021	September 30, 2020	**September 30, 2021**	September 30, 2020
REVENUES:				
Product revenue	**$ 9,371,160**	$ 8,406,457	**$ 17,327,204**	$ 17,914,623
R&D revenue	**441**	1,444,724	**1,107,808**	3,546,385
Government grant income	**2,400,000**	209,776	**8,030,000**	209,776
License and royalty revenue	**286,843**	211,521	**779,901**	572,450
TOTAL REVENUES	**12,058,444**	10,272,478	**27,244,913**	22,243,234
COSTS AND EXPENSES:				
Cost of product revenue	**7,902,819**	7,467,746	**15,490,956**	17,512,925
Research and development expenses	**3,442,044**	2,351,880	**9,102,363**	6,233,040
Selling, general and administrative expenses	**5,947,327**	5,348,958	**18,033,748**	13,903,192
Asset impairment, severance, restructuring and related costs	**396,740**	11,651	**2,440,983**	1,122,310
Acquisition costs	**-**	-	**-**	63,497
	17,688,930	15,180,235	**45,068,050**	38,834,964

LOSS FROM OPERATIONS	**(5,630,486)**	(4,907,757)	**(17,823,137)**	(16,591,730)
OTHER EXPENSE:				
Interest expense, net	(735,336)	(735,819)	(2,175,188)	(2,110,011)
LOSS BEFORE INCOME TAXES	**(6,365,822)**	(5,643,576)	**(19,998,325)**	(18,701,741)
Income tax (provision) benefit	**(28)**	104,778	**67,928**	319,597
NET LOSS	**$ (6,365,850)**	$ (5,538,798)	**$ (19,930,397)**	$ (18,382,144)
Basic and diluted loss per share	**$ (0.24)**	$ (0.28)	**$ (0.89)**	$ (0.98)
Weighted average number of shares outstanding, basic and diluted	**26,701,546**	20,104,547	**22,361,899**	18,728,372

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

	(Unaudited) September 30, 2021	December 31, 2020
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 36,004,000**	$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of $193,535 and $296,793 as of September 30, 2021 and December 31, 2020, respectively	**6,782,798**	3,377,387
Inventories, net	**16,805,669**	12,516,402
Prepaid expenses and other current assets	**1,191,678**	778,683
TOTAL CURRENT ASSETS	**60,784,145**	39,738,773
FIXED ASSETS:		
Property, Plant and Equipment, net	**8,744,713**	8,688,403
Finance lease right-of-use asset, net	**208,908**	233,134
TOTAL FIXED ASSETS, net	**8,953,621**	8,921,537
OTHER ASSETS:		
Operating lease right-of-use assets, net	**6,085,655**	6,112,632
Intangible assets, net	**2,178,186**	3,645,986
Goodwill	**5,674,132**	5,963,744
Deposits and other assets	**367,396**	509,342
TOTAL ASSETS	**$ 84,043,135**	$ 64,892,014
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 10,182,488**	$ 10,042,790
Deferred revenue	**20,195**	1,606,997
Operating lease liabilities	**856,917**	642,460
Finance lease liabilities	**66,790**	58,877
Current portion of long-term debt	**300,000**	-
TOTAL CURRENT LIABILITIES	**11,426,390**	12,351,124
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,207,698**	6,327,143
Long-term finance lease liabilities	**157,251**	185,239
Long-term debt, net	**18,333,267**	18,182,158
Deferred tax liability	**-**	69,941
TOTAL LIABILITIES	**36,124,606**	37,115,605

STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none issued or outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 30,086,283 shares and 20,223,498 shares issued at September 30, 2021 and December 31, 2020, respectively	**300,863**	202,235
Additional paid-in capital	**165,442,942**	124,961,514
Accumulated deficit	**(117,036,729)**	(97,106,331)
Treasury stock 41,141 shares at cost as of September 30, 2021 and December 31, 2020, respectively	**(190,093)**	(190,093)
Accumulated other comprehensive loss	**(598,454)**	(90,916)
TOTAL STOCKHOLDERS' EQUITY	**47,918,529**	27,776,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 84,043,135**	$ 64,892,014

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

	September 30, 2021	September 30, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 22,355,958**	$ 26,122,815
Cash paid to suppliers and employees	**(43,732,182)**	(37,776,303)
Cash paid for operating leases	**(1,049,198)**	(797,482)
Cash paid for finance leases	**(15,358)**	(14,762)
Interest and taxes, net	**(1,709,704)**	(1,681,155)
Net cash used in operating activities	**(24,150,484)**	(14,146,887)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	**(1,387,601)**	(3,000,763)
Patent Application Costs	**(32,648)**	(181,417)
Net cash used in investing activities	**(1,420,249)**	(3,182,180)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of stock, net	**38,811,960**	28,463,741
Stimulus package loan	**-**	2,978,315
Payment of stimulus package loan	**-**	(2,978,315)
Payments on note payable	**-**	(180,249)
Payments of tax withholdings on stock award	**(119,513)**	(348,944)
Payments on finance lease	**(45,680)**	(37,166)
Net cash provided by financing activities	**38,646,767**	27,897,382
Effect of exchange rate changes on cash	**(138,335)**	(125,214)
DECREASE IN CASH AND CASH EQUIVALENTS	**12,937,699**	10,443,101
Cash and cash equivalents - beginning of the period	**23,066,301**	18,271,352
Cash and cash equivalents - end of the period	**$ 36,004,000**	$ 28,714,453
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	**$ (19,930,397)**	$ (18,382,144)
Adjustments:		
Depreciation and amortization	**2,186,684**	2,057,275
Share based compensation	**1,802,056**	824,345
Non-cash inventory changes	**926,499**	2,530,444
Benefit from deferred tax liability	**(69,941)**	(301,000)
Impairment of long-lived assets	**1,273,945**	-
Provision (recovery) for doubtful accounts	**(103,258)**	214,210

Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	**(3,302,153)**	138,827
Inventories	**(5,215,766)**	(5,295,899)
Prepaid expenses and other current assets	**(412,995)**	(314,460)
Deposits and other assets	**141,946**	80,873
Accounts payable and accrued liabilities	**139,698**	559,888
Deferred revenue	**(1,586,802)**	3,740,754
Net cash used in operating activities	**$ (24,150,484)**	$ (14,146,887)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ -**	$ 472,651

Source: Chembio Diagnostics, Inc.