Chembio Diagnostics Reports First Quarter 2021 Financial Results

May 6, 2021

HAUPPAUGE, N.Y., May 06, 2021 (GLOBE NEWSWIRE) -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today reported financial results for the quarter ended March 31, 2021. Chembio achieved first quarter 2021 total revenue of $8.7 million and product revenue of $4.0 million, representing growth of 27% and a decline of 30%, respectively, compared to the prior year period.

Commercial and Product Accomplishments

- Launched marketing programs with national distribution partners in the U.S to promote and supply the rapid DPP HIV-Syphilis test system across decentralized healthcare markets
- Completed registrations in and received initial purchase orders for shipment to multiple countries in Africa and Southeast Asia for the World Health Organization prequalified SURE CHECK HIV Self-Test

COVID-19 Testing Portfolio Update

- Completed milestones resulting in the recognition of $3.4 million of revenue in the first quarter as part of the $12.7 million BARDA award for the development and issuance of an Emergency Use Authorization (EUA) application for the DPP Respiratory Panel and the development and receipt of 510(k) clearance for the rapid, point-of-care DPP SARS-CoV-2 Antigen test system
- Continued the close collaboration with BARDA under the $628,000 award in pursuit of an EUA for the DPP SARS-CoV-2 Antigen test system
- Received regulatory approval for the DPP SARS-CoV-2 Antigen test system from Agência Nacional de Vigilância Sanitária (ANVISA), Brazil's health regulatory agency, in collaboration with Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation that is responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet demands of Brazil's national public health system
- Initiated U.S. distribution of the in-licensed rapid, point-of-care, EUA approved Status COVID-19/Flu A&B test that is sourced from a third party

"In recent months we have advanced several strategic initiatives focused on leveraging the capabilities of our network of distributors and fully scaled U.S. salesforce across our diversified product portfolio," said Richard Eberly, Chembio's President and Chief Executive Officer. "Commercially, we are seeing good momentum with our SURE CHECK HIV Self-Test via our international channels and our DPP HIV-Syphilis system in the United States."

Mr. Eberly continued, "In addition, we are seeing positive reaction from customers regarding the Status COVID-19/Flu A&B test. These include both customer commitments and planned product evaluations in anticipation of the return of flu season in the late summer and early fall. Together with BARDA, we remain actively engaged in pursuit of an EUA for the rapid, point-of-care DPP SARS-CoV-2 Antigen System and DPP Respiratory Panel, and are continuing our work towards 510(k) clearance for the DPP SARS-CoV-2 Antigen System. As we look ahead, we remain committed to delivering profitable growth by leveraging our growing customer base and expanded commercial team while also focusing on gross margin expansion through manufacturing automation and operational excellence."

First Quarter 2021 Financial Results

Total revenue for the first quarter of 2021 was $8.7 million, an increase of 27% compared to the prior year period. Net product sales for the first quarter of 2021 were $4.0 million, a decrease of 30% compared to the prior year period. Government grant, license and royalty, and R&D revenue for the first quarter of 2021 totaled $4.7 million, an increase of 311% compared to the prior year period.

Gross product margin for the first quarter of 2021 was $0.5 million, compared to $1.3 million for the prior year period. Gross product margin percentage for the first quarter of 2021 was 12%, compared to 24% for the prior year period. Gross product margin in the first quarter of 2021 was impacted by unfavorable geographic product mix and fixed manufacturing overhead.

Research and development expenses increased by $0.9 million, or 46%, in the first quarter of 2021 compared to the prior year period. The increase in research and development expense was primarily associate with work 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. Selling, general and administrative expenses increased by $1.9 million, or 46%, in the first quarter of 2021 compared to the prior year period. The increase in selling, general and administrative expenses was primarily due to increased costs associated with professional fees.

Net loss for the first quarter of 2021 was $4.5 million, or $0.22 per diluted share, compared to a net loss of $5.0 million, or $0.29 per diluted share, for the prior year period.

Cash and cash equivalents as of March 31, 2021 totaled $14.4 million.

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 877-545-0320 from the United States or 973-528-0016 from outside the United States and providing entry code 562459. To listen to a live webcast of the call, please visit the Investor Relations section of Chembio's website at www.chembio.com. Following the call, a replay will be available on the Investor Relations section of Chembio's website. A telephone replay will be available until 4:30 pm ET on May 19, 2021 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 40896.

Highlighted Product Features and Clinical Applications

The SURE CHECK HIV Self-Test uses the world's smallest blood sample required by any rapid HIV test and provides results in 15 minutes. The unique design of the SURE CHECK HIV Self-Test integrates the capillary device and buffer solution, eliminating the need for separate collection devices and buffer solution bottles required by other HIV self-tests. In 2016, the WHO recommended HIV self-testing (HIVST) as a safe, accurate, convenient, and confidential option for HIV testing, and that it is a way to reach people who may not test otherwise, including people from key populations, men and young people. Lay users can perform HIVST reliably and accurately and achieve performance comparable to that of trained health-care workers. In 2019, the WHO reported that "thirty-two randomized controlled trials showed that, compared with standard facility-based HIV testing, HIVST increases the uptake of HIV testing."

Chembio's DPP HIV-Syphilis System is a multiplex, single-use, 15-minute test, which is designed, in combination with the Micro Reader analyzer, to simultaneously detect antibodies to HIV types 1 and 2 and *Treponema pallidum*, the bacteria that causes syphilis. The U.S. Centers for Disease Control recently reported that from 2015 to 2019, primary and secondary syphilis infections have risen 178% , and congenital syphilis infections have risen 291%. Untreated syphilis in pregnant women results in still birth or infant death in 40% of cases, and patients with active infections are 2 to 5 times more likely to contract HIV when exposed.

About the DPP Rapid Test Platform

Chembio's proprietary DPP technology platform provides high-quality, rapid diagnostic results in 15 to 20 minutes using a small drop of blood from the fingertip or alternative samples. Through advanced multiplexing, the DPP platform can detect up to eight, distinct test results from a single patient sample, delivering greater clinical value than other rapid tests. For certain applications, Chembio's easy-to-use, highly portable, battery-operated DPP Micro Reader optical analyzer then reports accurate results in approximately 15 seconds, making it well-suited for decentralized testing where real-time results enable patients to be clinically assessed while they are still on-site. Objective results produced by the DPP Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many rapid tests.

Chembio's portfolio of DPP-based point-of-care tests with FDA regulatory approvals include the DPP HIV-Syphilis System (PMA approved), DPP HIV 1/2 Assay (PMA approved and CLIA waived), DPP Zika IgM System (510(k)), and DPP Ebola Antigen System (EUA). Additionally, DPP-based tests have received regulatory approvals from the World Health Organization, CE-Mark, ANVISA, and other global organizations, where they aid in the detection and diagnosis of several other critical diseases and conditions.

All DPP tests are developed and manufactured in the United States and are the subject of a range of domestic and global patents and patents pending.

About Chembio Diagnostics

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases, including COVID-19, sexually transmitted, respiratory and insect vector diseases. 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.

About the BARDA Projects

Chembio will use the federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50121P00012 and Contract No. 75A50120C00138.

Forward-Looking Statements

Certain statements contained in the two paragraphs following the bulleted items under "COVID-19 Testing Portfolio Update" 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 achieve profitability or 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 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020, 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	
	March 31, 2021	March 31, 2020
REVENUES:		
Product revenue	**$ 4,024,662**	$ 5,716,593
R&D revenue	**1,106,639**	907,687
Government grant income	**3,350,000**	-
License and royalty revenue	**243,058**	235,304
TOTAL REVENUES	**8,724,359**	6,859,584
COSTS AND EXPENSES:		
Cost of product revenue	**3,548,441**	4,374,442
Research and development expenses	**2,863,338**	1,958,853
Selling, general and administrative expenses	**6,085,067**	4,156,641
Severance, restructuring and other related costs	**83,087**	723,118
Acquisition costs	**-**	63,497
	12,579,933	11,276,551
LOSS FROM OPERATIONS	**(3,855,574)**	(4,416,967)
OTHER EXPENSE:		
Interest expense, net	(712,477)	(662,141)
LOSS BEFORE INCOME TAXES	**(4,568,051)**	(5,079,108)
Income tax benefit	**67,888**	79,559
NET LOSS	**$ (4,500,163)**	$ (4,999,549)
Basic and diluted loss per share	**$ (0.22)**	$ (0.29)
Weighted average number of shares outstanding, basic and diluted	**20,163,386**	17,197,301

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

	(Unaudited)	
	March 31, 2021	December 31, 2020
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 14,350,953**	$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of $354,528 and $296,793 as of March 31, 2021 and December 31, 2020, respectively	**2,413,552**	3,377,387
Inventories, net	**14,690,627**	12,516,402
Prepaid expenses and other current assets	**812,638**	778,683
TOTAL CURRENT ASSETS	**32,267,770**	39,738,773
FIXED ASSETS:		
Property, plant and equipment, net	**9,582,872**	8,688,403
Finance lease right-of-use asset, net	**217,376**	233,134
TOTAL FIXED ASSETS, net	**9,800,248**	8,921,537

OTHER ASSETS:		
Operating lease right-of-use assets, net	**5,904,299**	6,112,632
Intangible assets, net	**3,377,003**	3,645,986
Goodwill	**5,689,315**	5,963,744
Deposits and other assets	**374,862**	509,342
TOTAL ASSETS	**$ 57,413,497**	$ 64,892,014
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 8,396,994**	$ 10,042,790
Deferred revenue	**404,486**	1,606,997
Operating lease liabilities	**572,478**	642,460
Finance lease liabilities	**60,064**	58,877
TOTAL CURRENT LIABILITIES	**9,434,022**	12,351,124
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,197,527**	6,327,143
Long-term finance lease liabilities	**169,765**	185,239
Long-term debt, net	**18,327,037**	18,182,158
Deferred tax liability	**-**	69,941
TOTAL LIABILITIES	**34,128,351**	37,115,605
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 20,285,695 shares and 20,223,498 shares issued at March 31, 2021 and December 31, 2020, respectively	**202,857**	202,235
Additional paid-in capital	**125,425,514**	124,961,514
Accumulated deficit	**(101,606,494)**	(97,106,331)
Treasury stock 41,141 shares at cost as of March 31, 2021 and December 31, 2020, respectively	**(190,093)**	(190,093)
Accumulated other comprehensive (loss) income	**(546,638)**	(90,916)
TOTAL STOCKHOLDERS' EQUITY	**23,285,146**	27,776,409
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 57,413,497**	$ 64,892,014

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

	March 31, 2021	March 31, 2020
Net cash used in operating activities	**$ (7,261,260)**	$ (5,651,960)
Net cash used in investing activities	**(1,239,168)**	(1,078,271)
Net cash used by financing activities	**(129,341)**	(223,290)
Effect of exchange rate changes on cash	**(85,579)**	(79,814)
INCREASE IN CASH AND CASH EQUIVALENTS	**(8,715,348)**	(7,033,335)
Cash and cash equivalents - beginning of the period	**23,066,301**	18,271,352
Cash and cash equivalents - end of the period	**$ 14,350,953**	$ 11,238,017

Source: Chembio Diagnostics, Inc.