



Chembio Diagnostics Reports Fourth Quarter and Full Year 2021 Financial Results

March 3, 2022

HAUPPAUGE, N.Y., March 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 and year ended December 31, 2021.

Recent Highlights

- Achieved record quarterly total revenue of \$20.6 million and product revenue of \$17.4 million in the fourth quarter of 2021, representing growth of 101% and 154%, respectively, compared to the prior year period, including:
 - U.S. product revenue of \$3.2 million, representing growth of 268% compared to the prior year period
 - Latin America product revenue of \$12.0 million, representing growth of 415% compared to the prior year period
- Achieved record annual total revenue of \$47.8 million and product revenue of \$34.7 million for the full year 2021, representing growth of 47% and 40%, respectively, compared to the full year 2020, including:
 - U.S. product revenue of \$6.0 million, representing growth of 53% compared to 2020
 - Latin America product revenue of \$18.4 million, representing growth of 87% compared to 2020
- Initiated a Global Competitiveness Program intended to improve profitability by focusing on higher margin business, lowering manufacturing costs, reducing infrastructure costs and reviewing non-core businesses and assets
- Received ANVISA approval and CE mark for the DPP Respiratory Antigen Panel
- Submitted an EUA application for new DPP SARS-CoV-2 Antigen Test and a De Novo/510(k) request for the DPP Antigen Test System to the U.S. Food and Drug Administration, completing milestones under the BARDA product development award
- Strengthened its executive leadership team with the addition of Larry Steenvoorden as Chief Financial Officer

"In the fourth quarter, record quarterly revenue was driven by execution of the largest purchase order in company history, received from Bio-Manguinhos for DPP SARS-CoV-2 Antigen Tests in Brazil, while navigating the tight labor market and global supply chain issues for certain test components to ramp production. Chembio also finished the year with record annual revenue," said Richard Eberly, Chembio's President and Chief Executive Officer. "We are confident our investments in developing products in high value growing markets and registering existing products in additional geographies can drive sustained growth over the long-term. We are optimistic about our ability to improve profitability through continued product revenue growth and reduction of our cost infrastructure beginning in 2022."

Fourth Quarter 2021 Financial Results

Total revenue for the fourth quarter of 2021 was \$20.6 million, an increase of 101% compared to the prior year period. Net product sales for the fourth quarter of 2021 were \$17.4 million, an increase of 154% compared to the prior year period. Government grant, license and royalty, and R&D revenue for the fourth quarter of 2021 totaled \$3.2 million, a decrease of 6% compared to the prior year period.

Gross product margin for the fourth quarter of 2021 was (\$1.6) million, compared to \$0.5 million for the prior year period. Gross product margin percentage for the fourth quarter of 2021 was negative 9%, compared to 7% for the prior year period. Gross product margin in the fourth quarter of 2021 was impacted by an unfavorable mix of average selling prices, increased labor costs, and an inventory write down of \$2.5 million.

Research and development expenses increased by \$0.1 million, or 2%, in the fourth quarter of 2021 compared to the prior year period. Selling, general and administrative expenses decreased by \$0.3 million, or 10%, in the fourth quarter of 2021 compared to the prior year period.

Impairment, restructuring, severance and related costs for the fourth quarter of 2021 totaled \$4.6 million, including an impairment of goodwill and intangible assets from prior acquisitions.

Net loss for the fourth quarter of 2021 was \$14.0 million, or \$0.47 per diluted share, compared to a net loss of \$7.1 million, or \$0.35 per diluted share, for the prior year period. The net loss includes severance, restructuring, an impairment of goodwill and intangible assets from prior acquisitions and other related costs of \$4.6 million, or \$0.15 per share, for the fourth quarter of 2021, compared to a de minimis amount in the prior year period.

Full Year 2021 Financial Results

Total revenue for 2021 was \$47.8 million, an increase of 47% compared to 2020. Net product sales for 2021 were \$34.7 million, an increase of 40% compared to 2020. Government grant, license and royalty, and R&D revenue for 2021 totaled \$13.1 million, an increase of 70% compared to 2020.

Gross product margin for 2021 was \$0.2 million, compared to \$0.9 million in 2020. Gross product margin percentage for 2021 was 1%, compared to 4% for 2020. Gross product margin in 2021 was adversely impacted by an unfavorable mix of average selling prices, increased labor costs, and a fourth quarter inventory write down of \$2.5 million.

Research and development expenses increased by \$3.0 million, or 31%, in 2021 compared to 2020. The increase in research and development expenses was primarily associated with increased clinical trial costs related to the product development award from BARDA. Selling, general and administrative expenses increased by \$3.8 million, or 18%, in 2021 compared to 2020. The increase in selling, general and administrative expenses primarily reflected increased legal costs, recruiting fees and higher insurance costs.

Impairment, restructuring, severance and related costs including an impairment of goodwill and intangible assets from prior acquisitions totaled \$7.0 million in 2021 compared to \$1.1 million in 2020.

Net loss for 2021 was \$33.9 million, or \$1.40 per diluted share, compared to a net loss of \$25.5 million, or \$1.34 per diluted share, for 2020. The increase in loss per share was negatively impacted by Impairment, restructuring, severance and related costs including an impairment of goodwill and intangible assets from prior acquisitions.

Cash and cash equivalents as of December 31, 2021 totaled \$28.8 million.

Going Concern Considerations

Revenues during the twelve months ended December 31, 2021 did not meet the Company's expectations. The Company's increase in cash and cash equivalents over the year reflected our 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. For the year ending December 31, 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 our ability to continue as a going concern within one year after the date the audited consolidated financial statements will be issued (the "Issuance Date"). Because substantial doubt was determined to exist as the result of this initial assessment, management then assessed the mitigating effect of our 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 our ability to continue as a going concern.

During the twelve months ended December 31, 2021, the Company undertook measures to increase our total revenues and improve its liquidity position. These measures included:

- On July 19, 2021, the Company entered into an At the Market Offering Agreement ("ATM Agreement") with Craig Hallum Capital Group LLC ("Craig Hallum") pursuant to which we may sell from time to time, at our option, up to an aggregate of \$60,000,000 of shares of common stock. As of December 31, 2021, the Company has issued and sold pursuant to the ATM Agreement a total of 9,709,328 shares of common stock at a volume-weighted average price of \$4.20 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.
- The Company also 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 needs of Brazil's Ministry of Health in addressing the COVID-19 pandemic. As of December 31, 2021 \$16.8 million was recognized in connection with this order.
 - On July 22, 2021, the Company received a \$4.0 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. As of December 31, 2021 \$1.2 million was recognized in connection with this order.

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 has considered in particular how:

- 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 its 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 Credit Agreement and Guaranty (the "Credit Agreement"), that the Company and certain of its subsidiaries, as guarantors, entered into with Perceptive Credit Holdings II, LP, (the "Lender"). Those obligations include (a) covenants requiring i) minimum cash balance of \$3 million and ii) minimum total revenue amounts for the twelve months preceding each quarter end. For the next year, the minimum total revenue requirements range from \$42.0 million for the twelve months ending March 31, 2022 to \$47.4 million for the twelve months ending December 31, 2022 and (b) an obligation requiring the payment of principal installments, commencing with the payment of \$300,000 on 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 the Company's business, prospects, results of operations, liquidity and financial condition.

Accordingly, management determined the Company could not be certain that our plans and initiatives would be effectively implemented within one year after the Issuance Date. Without giving effect to the prospect of raising additional capital pursuant to the Company's 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 our required financial obligations, including the Company's 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.

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 516973. 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 March 17, 2022 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 44503.

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 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 the Chembio's R&D investments, development of certain products and registration of existing products in new geographies. 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 July Purchase Orders 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 recurrently 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 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 Commission on July 19, 2021, and its Quarterly Reports on Form 10-Q for the quarterly periods ended June 30, 2021 and September 30, 2021, particularly under the heading "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

	For the three months ended (Unaudited)		For the year ended	
	Dec. 31, 2021	Dec. 31, 2020	Dec. 31, 2021	Dec. 31, 2020
REVENUES:				
Net product sales	\$ 17,410,240	\$ 6,852,526	\$ 34,737,444	\$ 24,767,149
R&D	51,573	1,095,402	1,159,381	4,851,562
Government grant income	2,861,726	2,018,924	10,891,726	2,018,924
License and royalty revenue	250,000	260,112	1,029,901	832,562
TOTAL REVENUES	20,573,539	10,226,964	47,818,452	32,470,197
COSTS AND EXPENSES:				
Cost of product sales	19,004,846	6,361,480	34,495,802	23,874,487
Research and development expenses	3,385,061	3,275,455	12,487,424	9,508,494

Selling, general and administrative expenses	6,806,863	7,134,593	24,840,611	21,037,701
Impairment, restructuring, severance and related costs	4,606,796	-	7,047,779	1,122,310
Acquisition costs	-	-	-	63,497
	<u>33,803,566</u>	<u>16,771,528</u>	<u>78,871,616</u>	<u>55,606,489</u>
LOSS FROM OPERATIONS	(13,230,027)	(6,544,564)	(31,053,164)	(23,136,292)
OTHER INCOME:				
Interest expense, net	(737,227)	(731,818)	(2,912,415)	(2,841,830)
LOSS BEFORE INCOME TAXES	(13,967,254)	(7,276,382)	(33,965,579)	(25,978,122)
Income tax benefit (loss)	(5,878)	137,198	62,050	456,794
NET LOSS	\$ (13,973,132)	\$ (7,139,184)	\$ (33,903,529)	\$ (25,521,328)
Basic and diluted loss per share	\$ (0.47)	\$ (0.35)	\$ (1.40)	\$ (1.34)
Weighted average number of shares outstanding, basic and diluted	30,049,338	20,150,168	24,299,465	19,085,691

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

	<u>December 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 28,772,892	\$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of \$243,042 and \$296,793 as of December 31, 2021 and December 31, 2020, respectively	11,441,107	3,377,387
Inventories, net	12,920,451	12,516,402
Prepaid expenses and other current assets	1,710,194	778,683
TOTAL CURRENT ASSETS	<u>54,844,644</u>	<u>39,738,773</u>
FIXED ASSETS:		
Property, plant and equipment, net	8,556,773	8,688,403
Finance lease right-of-use asset, net	191,870	233,134
TOTAL FIXED ASSETS, net	<u>8,748,643</u>	<u>8,921,537</u>
OTHER ASSETS:		
Operating lease right-of-use assets, net	5,891,906	6,112,632
Intangible assets, net	-	3,645,986
Goodwill	3,022,787	5,963,744
Deposits and other assets	744,215	509,342
TOTAL ASSETS	\$ 73,252,195	\$ 64,892,014
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 13,127,993	\$ 10,042,790
Deferred revenue	-	1,606,997
Current portion of long term debt	1,200,000	-
Operating lease liabilities	886,294	642,460
Finance lease liabilities	68,176	58,877
TOTAL CURRENT LIABILITIES	<u>15,282,463</u>	<u>12,351,124</u>

OTHER LIABILITIES:

Long-term operating lease liabilities	5,976,151	6,327,143
Long-term finance lease liabilities	139,678	185,239
Long-term debt, less current portion, net	17,589,003	18,182,158
Deferred tax liability	-	69,941
TOTAL LIABILITIES	38,987,295	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; 30,101,393 shares and 20,223,498 shares issued at December 31, 2021 and December 31, 2020, respectively	301,050	202,235
Additional paid-in capital	165,772,636	124,961,514
Accumulated deficit	(131,009,860)	(97,106,331)
Treasury stock 48,057 and 41,141 shares at cost as of December 31, 2021 and December 31, 2020, respectively	(206,554)	(190,093)
Accumulated other comprehensive loss	(592,372)	(90,916)
TOTAL STOCKHOLDERS' EQUITY	34,264,900	27,776,409

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 73,252,195	\$ 64,892,014
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CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED

	<u>December 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	\$ 38,093,984	\$ 34,736,133
Cash paid to suppliers and employees	(65,273,967)	(50,238,409)
Cash paid for operating leases	(1,404,532)	(1,139,944)
Cash paid for finance leases	(20,077)	(19,987)
Interest and taxes, net	(2,281,124)	(2,225,031)
Net cash used in operating activities	(30,885,716)	(18,887,238)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of and deposits on fixed assets	(1,824,285)	(3,961,369)
Patent application costs	(33,398)	(205,493)
Net cash used in investing activities	(1,857,683)	(4,166,862)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net	38,811,958	28,436,740
Proceeds from option exercises	85,555	-
Principal payments for finance leases	(61,867)	(51,166)
Payments on note payable	-	(180,249)
Stimulus package loan	-	2,978,315
Payment of stimulus package loan	-	(2,978,315)
Payments of tax withholdings on stock award	(145,225)	(441,723)
Net cash provided by financing activities	38,690,421	27,763,602
Effect of exchange rate changes on cash	(240,431)	85,447
INCREASE IN CASH AND CASH EQUIVALENTS	5,706,591	4,794,949
Cash and cash equivalents - beginning of the period	23,066,301	18,271,352
Cash and cash equivalents - end of the period	\$ 28,772,892	\$ 23,066,301
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	\$ (33,903,529)	\$ (25,521,328)
Adjustments:		

Depreciation and amortization	2,930,976	2,697,126
Share based compensation	2,431,982	1,223,171
Benefit from deferred tax liability	(69,941)	(396,385)
Provision for doubtful accounts	(53,751)	270,193
Non-cash inventory changes	4,054,701	3,543,515
Impairment charges	5,880,741	-
Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	(8,009,969)	283,939
Inventories	(4,458,750)	(6,461,887)
Prepaid expenses and other current assets	(931,510)	(85,670)
Deposits and other assets	(234,874)	34,195
Accounts payable and accrued liabilities	3,085,205	4,043,896
Deferred revenue	(1,606,997)	1,481,997
Net cash used in operating activities	\$ (30,885,716)	\$ (18,887,238)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	\$ -	\$ 472,651
Contingent liability earnout	-	1,011,261



Source: Chembio Diagnostics, Inc.