



## Chembio Diagnostics Reports Second Quarter 2021 Financial Results

August 5, 2021

HAUPPAUGE, N.Y., Aug. 05, 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 June 30, 2021.

### Recent Highlights

- Achieved second quarter 2021 total revenue of \$6.5 million and product revenue of \$3.9 million, representing growth of 26% and 4%, respectively, compared to the prior year period
- Initiated shipments under a \$28.3 million purchase order for DPP SARS-CoV-2 Antigen Tests received from Bio-Manguinhos to support the urgent needs of Brazil's Ministry of Health for delivery during 2021
- Received a \$4.0 Million HIV Test purchase order supported by The Global Fund for shipment to Ethiopia into early 2022
- Continued clinical trials for the DPP SARS-CoV-2 Antigen Test System, intended for use in applications for a new EUA and a 510(k)
- Launched an at the market ("ATM") offering of common stock and raised \$36.9 million of gross proceeds in July

"In the second quarter, we focused on international commercial opportunities where our DPP COVID test has been approved. These efforts were successful, resulting in the largest order in company history for DPP SARS-CoV-2 Antigen tests from our longstanding customer Bio-Manguinhos. We also made progress on our clinical activity to support U.S. regulatory submissions for our DPP COVID-19 tests," said Richard Eberly, Chembio's President and Chief Executive Officer. "Looking forward, we believe the investments we have made in product development, expanding our commercial infrastructure and our automated manufacturing operations position us for future success. The recently raised capital has strengthened the balance sheet and will support execution of our strategic initiatives."

### Second Quarter 2021 Financial Results

Total revenue for the second quarter of 2021 was \$6.5 million, an increase of 26% compared to the prior year period. Net product sales for the second quarter of 2021 were \$3.9 million, an increase of 4% compared to the prior year period. Government grant, license and royalty, and R&D revenue for the second quarter of 2021 totaled \$2.5 million, an increase of 92% compared to the prior year period.

Gross product margin for the second quarter of 2021 was negative \$0.1 million, compared to negative \$1.9 million for the prior year period. Gross product margin percentage for the second quarter of 2021 was negative 3%, compared to negative 50% for the prior year period. Gross product margin in the second quarter of 2021 was negatively impacted by a write-down of inventory. Gross product margins in the prior year period was impacted by several factors, including the cost of returned product and the recognition of cost of sales for product produced and shipped outside the U.S., but for which revenue was not recognized in that quarter.

Research and development expenses increased by \$0.9 million, or 46%, in the second quarter of 2021 compared to the prior year period. The increase in research and development expense was primarily associated with clinical and regulatory work related to pursuing an EUA and 510(k) from the U.S. Food and Drug Administration for the DPP SARS-CoV-2 Antigen test system and an EUA for the DPP Respiratory Panel. The DPP Respiratory Panel is a multiplex test being designed to provide simultaneous, discrete, and differential detection of Influenza A, Influenza B, and SARS-CoV-2 antigens from a single patient respiratory specimen, such as a nasal or nasopharyngeal swab, in approximately 20 minutes. Selling, general and administrative expenses increased by \$1.6 million, or 36%, in the second quarter of 2021 compared to the prior year period, primarily due to increased costs associated with professional fees and the expanded headcount of Chembio's U.S. commercial team.

During the second quarter of 2021, Chembio recognized \$1.3 million of non-cash impairment loss from the write-off of the intangible assets, net, leasehold improvements, net and right-of-use assets for leases, net associated with Malaysian operations. Chembio also recognized \$0.7 million of restructuring costs related to professional fees.

Net loss for the second quarter of 2021 was \$9.1 million, or \$0.45 per diluted share, compared to a net loss of \$7.8 million, or \$0.42 per diluted share, for the prior year period. The net losses reflected asset impairment, restructuring, severance, and related costs of \$2.0 million, or \$0.10 per share, for the second quarter of 2021, compared to \$0.3 million, or \$0.02 per diluted share, for the prior year period.

Cash and cash equivalents as of June 30, 2021 totaled \$5.6 million. Subsequent to the quarter-end, \$36.9 million of gross proceeds were raised through the ATM offering.

### Going Concern Considerations

Revenues during the three months ended June 30, 2021 did not meet the Company's expectations, and the shortfall in revenues was a principal cause of the Company's limited cash and cash-equivalents position as of June 30, 2021. The decrease in cash and cash-equivalents over the first two quarters of 2021 reflected market, clinical trial and regulatory complications the Company faced in seeking to develop and commercialize a portfolio of COVID-19 test systems during the continuing, but evolving, uncertainty of the COVID-19 pandemic. The decrease in cash and cash-equivalents also resulted in part from significant continuing expenses incurred in connection with pending legal matters and delayed achievement of milestones associated with government grant income, investments in inventory and the continuing automation of U.S. 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 the accompanying unaudited condensed consolidated

financial statements are 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 entity's ability to continue as a going concern.

Following June 30, 2021, the Company undertook and achieved measures to increase its total revenues and improve its liquidity position:

- The Company received significant purchase orders (the "Significant POs") from two customers. The Company had pursued the Significant POs for an extended period of time, but did not receive them until July 2021 as follows:
  - 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. Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation, is responsible for the development and production of vaccines, diagnostics and biopharmaceuticals, primarily to meet demands of Brazil's national public health system.
  - 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.
- The Company raised gross proceeds of approximately \$36.9 million from the issuance of 8,323,242 shares of common stock pursuant to an At the Market Offering Agreement (the "ATM Agreement") with Craig Hallum Capital Group LLC, pursuant to which Chembio may sell from time to time, at its option, up to an aggregate of \$60,000,000 of shares of common stock through Craig Hallum Capital Group LLC, as sales agent. Net of the placement fee and other transaction costs, the Company realized estimated net proceeds of approximately \$34.7 million.

These measures and other plans and initiatives of the Company were designed to provide the Company with adequate liquidity to meet its obligations for at least the twelve-month period following the date the Company's second quarter are to be issued. Such plans and initiatives are dependent, however, on factors that are beyond the Company's control or that may not be available on terms acceptable to the Company, or at all. The Company considered how the uncertainties around the delivery of the full number of tests covered by the Significant POs and other customer orders may be affected by limitations of the Company's supply chain, staffing and liquidity, uncertainties regarding the achievement of milestones and related recognition of revenue under government grants, and other matters outside the Company's control. The Company further considered how such uncertainties could impact its ability to meet the obligations specified in the Company's credit agreement over the next twelve months, which include attaining minimum total revenue ranging from approximately \$37.4 million to approximately \$43.8 million for the rolling twelve months as of the end of each quarter from September 30, 2021 through June 30, 2022. In the event of 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, Chembio 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. Chembio'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 by the Company 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 its plans and initiatives would be effectively implemented within one year after the date the accompanying unaudited condensed consolidated financial statements are issued.

Without giving effect to the prospect of raising additional capital pursuant to the ATM Agreement, 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 date the second quarter financial statements are to be issued.

The Company's second 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 date the financial statements are issued.

#### **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 629053. To listen to a live webcast of the call, please visit the Investor Relations section of Chembio's website at [www.chembio.com](http://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 19, 2021 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 41881.

#### **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](http://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 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 Significant POs. 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 Significant POs 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 and its Current Report on Form 8-K filed with the Securities and Exchange Commission on July 19, 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.*

#### Investor Relations Contact

Philip Taylor  
Gilmartin Group  
(415) 937-5406  
[investor@chembio.com](mailto:investor@chembio.com)

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

	For the three months ended		For the six months ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
<b>REVENUES:</b>				
Product revenue	\$ 3,931,383	\$ 3,791,574	\$ 7,956,045	\$ 9,508,166
R&D revenue	727	1,193,973	1,107,366	2,101,660
Government grant income	2,280,000	-	5,630,000	-
License and royalty revenue	250,000	125,625	493,058	360,929
<b>TOTAL REVENUES</b>	<b>6,462,110</b>	<b>5,111,172</b>	<b>15,186,469</b>	<b>11,970,755</b>
<b>COSTS AND EXPENSES:</b>				
Cost of product revenue	4,039,696	5,670,737	7,588,137	10,045,179
Research and development expenses	2,796,981	1,922,306	5,660,319	3,881,159
Selling, general and administrative expenses	6,001,353	4,397,593	12,086,422	8,554,234
Asset impairment, severance, restructuring and related costs	1,961,156	387,540	2,044,243	1,110,658
Acquisition costs	-	-	-	63,497
	<b>14,799,186</b>	<b>12,378,176</b>	<b>27,379,121</b>	<b>23,654,727</b>
<b>LOSS FROM OPERATIONS</b>	<b>(8,337,076)</b>	<b>(7,267,004)</b>	<b>(12,192,652)</b>	<b>(11,683,972)</b>
<b>OTHER EXPENSE:</b>				
Interest expense, net	(727,374)	(712,052)	(1,439,851)	(1,374,192)
<b>LOSS BEFORE INCOME TAXES</b>	<b>(9,064,450)</b>	<b>(7,979,056)</b>	<b>(13,632,503)</b>	<b>(13,058,164)</b>
Income tax benefit	65	135,259	67,955	214,818
<b>NET LOSS</b>	<b>\$ (9,064,385)</b>	<b>\$ (7,843,797)</b>	<b>\$ (13,564,548)</b>	<b>\$ (12,843,346)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.45)</b>	<b>\$ (0.42)</b>	<b>\$ (0.67)</b>	<b>\$ (0.71)</b>
<b>Weighted average number of shares outstanding, basic and diluted</b>	<b>20,219,617</b>	<b>18,868,144</b>	<b>20,191,657</b>	<b>18,032,723</b>

### CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

## AS OF

	(Unaudited)	December 31,
	June 30, 2021	2020
<b>- ASSETS -</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 5,564,349	\$ 23,066,301
Accounts receivable, net of allowance for doubtful accounts of \$193,535 and \$296,793 as of June 30, 2021 and December 31, 2020, respectively	2,977,082	3,377,387
Inventories, net	15,720,292	12,516,402
Prepaid expenses and other current assets	1,064,508	778,683
<b>TOTAL CURRENT ASSETS</b>	<b>25,326,231</b>	<b>39,738,773</b>
<b>FIXED ASSETS:</b>		
Property, Plant and Equipment, net	9,149,460	8,688,403
Finance lease right-of-use asset, net	225,947	233,134
<b>TOTAL FIXED ASSETS, net</b>	<b>9,375,407</b>	<b>8,921,537</b>
<b>OTHER ASSETS:</b>		
Operating lease right-of-use assets, net	6,274,945	6,112,632
Intangible assets, net	2,329,859	3,645,986
Goodwill	5,899,531	5,963,744
Deposits and other assets	370,644	509,342
<b>TOTAL ASSETS</b>	<b>\$ 49,576,617</b>	<b>\$ 64,892,014</b>
<b>- LIABILITIES AND STOCKHOLDERS' EQUITY -</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 8,091,368	\$ 10,042,790
Deferred revenue	404,486	1,606,997
Operating lease liabilities	867,154	642,460
Finance lease liabilities	65,435	58,877
<b>TOTAL CURRENT LIABILITIES</b>	<b>9,428,443</b>	<b>12,351,124</b>
<b>OTHER LIABILITIES:</b>		
Long-term operating lease liabilities	6,392,531	6,327,143
Long-term finance lease liabilities	174,466	185,239
Long-term debt, net	18,477,924	18,182,158
Deferred tax liability	-	69,941
<b>TOTAL LIABILITIES</b>	<b>34,473,364</b>	<b>37,115,605</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock – 10,000,000 shares authorized, none issued or 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	203,374	202,235
Additional paid-in capital	126,006,387	124,961,514
Accumulated deficit	(110,670,879)	(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	(245,536)	(90,916)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>15,103,253</b>	<b>27,776,409</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 49,576,617</b>	<b>\$ 64,892,014</b>

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

June 30,

June 30,

	2021	2020
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Cash received from customers and grants	\$ 14,493,073	\$ 16,993,648
Cash paid to suppliers and employees	(28,559,938)	(22,751,210)
Cash paid for operating leases	(696,188)	(457,277)
Cash paid for finance leases	(10,312)	(9,367)
Interest and taxes, net	(1,135,295)	(1,106,778)
<b>Net cash used in operating activities</b>	<b>(15,908,660)</b>	<b>(7,330,984)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of and deposits on fixed assets	(1,270,989)	(2,351,160)
Patent Application Costs	(28,023)	(98,186)
<b>Net cash used in investing activities</b>	<b>(1,299,012)</b>	<b>(2,449,346)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Issuance of stock, net	-	28,463,741
Stimulus package loan	-	2,978,315
Payment of stimulus package loan	-	(2,978,315)
Payments on note payable	-	(104,542)
Payments of tax withholdings on stock award	(119,513)	(343,080)
Payments on finance lease	(29,820)	(23,578)
<b>Net cash provided by financing activities</b>	<b>(149,333)</b>	<b>27,992,541</b>
Effect of exchange rate changes on cash	(144,947)	(29,095)
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(17,501,952)</b>	<b>18,183,116</b>
Cash and cash equivalents - beginning of the period	23,066,301	18,271,352
<b>Cash and cash equivalents - end of the period</b>	<b>\$ 5,564,349</b>	<b>\$ 36,454,468</b>
<b>RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:</b>		
<b>Net Loss</b>	<b>\$ (13,564,548)</b>	<b>\$ (12,843,346)</b>
Adjustments:		
Depreciation and amortization	1,390,897	1,441,823
Share based compensation	1,165,632	347,141
Non-cash inventory changes	863,612	-
Benefit from deferred tax liability	(69,941)	(216,000)
Impairment of long-lived assets	1,273,945	-
Provision (recovery) for doubtful accounts	(103,258)	94,262
Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	503,563	1,050,738
Inventories	(4,067,502)	(4,533,511)
Prepaid expenses and other current assets	(285,825)	(49,894)
Deposits and other assets	138,698	113,655
Accounts payable and accrued liabilities	(1,951,422)	3,291,993
Deferred revenue	(1,202,511)	3,972,155
<b>Net cash used in operating activities</b>	<b>\$ (15,908,660)</b>	<b>\$ (7,330,984)</b>
<b>Supplemental disclosures for non-cash investing and financing activities:</b>		
Deposits on manufacturing equipment transferred to fixed assets	\$ -	\$ 472,651



Source: Chembio Diagnostics, Inc.