



Chembio Diagnostics Reports Second Quarter 2020 Financial Results

August 6, 2020

HAUPPAUGE, N.Y., Aug. 06, 2020 (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 June 30, 2020.

Recent Accomplishments & Highlights

- Announced plans to seek U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) approval for a revised DPP COVID-19 IgM/IgG System in the third quarter and subsequently for the DPP COVID-19 Antigen System
- Awarded BARDA contract for \$628,071 to assist in the development of, and an EUA application for, a DPP COVID-19 Antigen System
- Received FDA 510(k) clearance for DPP Zika IgM System, including the first FDA approval for the company's Micro Reader
- Received \$1.5 million order from UNICEF for additional multiplex DPP Zika, Chikungunya and Dengue Systems
- Strengthened the balance sheet with \$28.4 million of net proceeds raised in a public offering of common stock

"Despite challenging circumstances in the quarter, we are optimistic that our scientific expertise and platform flexibility will allow us to develop additional high quality, easy to use point-of-care COVID-19 tests that will contribute to the decentralization of testing. Central laboratories are currently facing extreme testing volumes that are creating delays in returning results to patients and our technology can contribute to improving the current situation," said Richard Eberly, Chembio's President and Chief Executive Officer. "I am proud of the resiliency and dedication of our team over the past months. We are excited about the opportunities ahead of us."

The DPP COVID-19 Antigen System has been funded in part with 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 (BARDA), under Contract No. 75A50120C00138.

Second Quarter 2020 Financial Results

Total revenue for the second quarter of 2020 was \$5.1 million, a decrease of 48.3% compared to the prior year period. Financial results for the second quarter of 2020 reflected the impact of the product recall in the United States and the potential response by other regulators following the FDA's revocation of the EUA for Chembio's initial DPP COVID-19 IgM/IgG System. Net product sales for the second quarter of 2020 were \$3.8 million, a decrease of 56.8% compared to the prior year period. License and royalty revenue and R&D and grant revenue for the second quarter of 2020 totaled \$1.3 million, an increase of 19.7% compared to the prior year period.

Gross product margin for the second quarter of 2020 was negative \$1.9 million, compared to \$1.8 million for the prior year period. Gross product margin percentage for the second quarter of 2020 was negative 49.6%, compared to 20.4% for the prior year period. Gross product margin in the second quarter of 2020 was impacted by the cost of COVID-19 product returned by US customers and the cost of COVID-19 product shipments outside the US for which revenue was not recognized.

Research and development expenses decreased by \$0.2 million, or 8.5%, in the second quarter of 2020 compared to the prior year period. Selling, general and administrative expenses increased by \$0.3 million, or 7.3%, in the second quarter of 2020 compared to the prior year period, primarily related to one-time period costs and equity compensation costs.

Net loss for the second quarter of 2020 was \$7.8 million, or \$0.42 per diluted share, compared to a net loss of \$3.2 million, or \$0.19 per diluted share, for the prior year period.

Cash and cash equivalents as of June 30, 2020 totaled \$36.4 million, including net proceeds of \$28.4 million from the public offering of common stock.

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 844-369-8770 from the United States or 862-298-0840 from outside the United States. 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 for 90 days. A telephone replay will be available until 4:30 pm ET on August 20, 2020 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using the conference ID: 35830.

About Chembio Diagnostics

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases, including COVID-19, sexually transmitted disease, and fever and tropical disease. The company's proprietary DPP technology platform, which uses a small drop of blood from the fingertip or alternative sample types, provides high-quality, cost-effective results in approximately 15 minutes. 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

Statements contained in the first sentence following the bulleted items under "Recent Accomplishments & 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 further development of COVID-19 tests. 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 DPP COVID-19 diagnostic tests; 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 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, 2019 and its subsequent Quarterly Reports on Form 10-Q, particularly under the heading "Risk Factors."

DPP is Chembio's registered trademark. For convenience, this trademark appears in this release without ® symbols, but that practice does not mean that Chembio will not assert, to the fullest extent under applicable law, its rights to the trademark.

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

	For The Three Months Ended		For The Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
REVENUES:				
Net product sales	\$ 3,791,574	\$ 8,785,041	\$ 9,508,166	\$ 15,409,336
R&D and grant revenue	1,193,973	854,264	2,101,660	2,556,053
License and royalty revenue	125,625	248,831	360,929	465,022
TOTAL REVENUES	5,111,172	9,888,136	11,970,755	18,430,411
COSTS AND EXPENSES:				
Cost of product sales	5,670,737	6,989,975	10,045,179	12,001,611
Research and development expenses	1,922,306	2,101,020	3,881,159	4,318,652
Selling, general and administrative expenses	4,397,593	4,096,942	8,554,234	8,110,013
Severance, restructuring and other related costs	387,540	-	1,110,658	-
Acquisition Costs	-	-	63,497	395,612
	12,378,176	12,891,187	23,654,727	24,825,888
LOSS FROM OPERATIONS	(7,267,004)	(3,299,801)	(11,683,972)	(6,395,487)
OTHER INCOME:				
Interest (expense) income	(712,052)	5,918	(1,374,192)	12,602
LOSS BEFORE INCOME TAXES	(7,979,056)	(3,293,883)	(13,058,164)	(6,382,885)
Income tax benefit	(135,259)	(107,203)	(214,818)	(379,672)
NET LOSS	\$ (7,843,797)	\$ (3,186,680)	\$ (12,843,346)	\$ (6,003,213)
Basic and diluted loss per share	\$ (0.42)	\$ (0.19)	\$ (0.71)	\$ (0.36)
Weighted average number of shares outstanding, basic and diluted	18,868,144	16,914,171	18,032,723	16,906,936

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

(Unaudited)

	June 30, 2020	December 31, 2019
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 36,427,468	\$ 18,271,352
Accounts receivable, net of allowance for doubtful accounts of \$156,000 and \$62,000 as of June 30, 2020 and December 31, 2019, respectively	2,610,587	3,661,325
Inventories, net	14,131,540	9,598,030
Prepaid expenses and other current assets	742,908	693,013
TOTAL CURRENT ASSETS	53,912,503	32,223,720
FIXED ASSETS:		
Property, Plant and Equipment, net	7,705,890	5,933,569
Finance lease right-of-use asset, net	258,884	210,350
TOTAL FIXED ASSETS, net	7,964,774	6,143,919
OTHER ASSETS:		
Operating lease right-of-use assets, net	6,515,282	7,030,744
Intangible assets, net	3,605,194	3,914,352
Goodwill	5,534,624	5,872,690
Deposits and other assets	429,884	543,539
TOTAL ASSETS	\$ 77,962,261	\$ 55,728,964
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 9,290,887	\$ 5,526,243
Deferred revenue	4,097,155	125,000
Finance lease liabilities	55,712	41,894
Operating lease liabilities	776,691	568,294
Note payable	75,708	180,249
TOTAL CURRENT LIABILITIES	14,296,153	6,441,680
OTHER LIABILITIES:		
Long-term operating lease liabilities	6,565,019	6,969,603
Long-term finance lease liabilities	210,408	171,953
Long-term debt, less current portion, net	17,903,401	17,644,149
Deferred tax liability	250,326	466,326
TOTAL LIABILITIES	39,225,307	25,252,031
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$0.01 par value; 100,000,000 shares authorized; 20,194,832 shares and 17,733,617 shares issued at June 30, 2020 and December 31, 2019, respectively	201,948	177,335
Additional paid-in capital	124,143,171	95,433,077
Accumulated deficit	(84,428,349)	(71,585,003)
Treasury stock 33,290 and 0 shares at cost as of June 30, 2020 and December 31, 2019, respectively	(150,919)	-
Accumulated other comprehensive (loss) income	(1,028,897)	9,844
TOTAL STOCKHOLDERS' EQUITY	38,736,954	24,035,253
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 77,962,261	\$ 55,728,964

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

For The Six Months Ended
June 30, 2020 **June 30, 2019**

Net cash used in operating activities	\$ (7,330,984)	\$ (7,086,415)
Net cash used in investing activities	(2,449,346)	(1,003,738)
Net cash provided (used in) by financing activities	27,965,541	(92,158)
Effect of exchange rate changes on cash	(29,095)	161,835
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	18,156,116	(8,020,476)
Cash and cash equivalents - beginning of the period	18,271,352	12,524,551
Cash and cash equivalents - end of the period	\$ 36,427,468	\$ 4,504,075



Source: Chembio Diagnostics, Inc.