UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 5, 2020**

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

Nevada	**000-30379**	**88-0425691**
(State or Other Jurisdiction of Incorporation or Organization)	*(Commission File Number)*	*(I.R.S. Employer Identification No.)*

555 Wireless Blvd. Hauppauge, NY 11788
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: **(631) 924-1135**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.01 par value	CEMI	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2020, we issued a press release announcing financial results for the quarter ended September 30, 2020. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of Section 11 or Section 12(a)(2) of the Securities Act of 1933. The information contained in this Item 2.02 and in the press release furnished as Exhibit 99.1 to this report shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by us whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Chembio Diagnostics, Inc., dated November 5, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

CHEMBIO DIAGNOSTICS, INC.

Dated: November 5, 2020

By:/s/ RICHARD L. EBERLY
Chief Executive Officer and President

Exhibit 99.1

Chembio Diagnostics Reports Third Quarter 2020 Financial Results

HAUPPAUGE, NY, November 5, 2020 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostics company focused on infectious diseases, today reported financial results for the quarter ended September 30, 2020.

Recent Accomplishments & Highlights

- Achieved total revenue of $10.3 million and product revenue of $8.4 million for the third quarter of 2020, representing growth of 6% and a decrease of 1% respectively, compared to the prior year period
- Submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for the DPP SARS-CoV-2 Antigen test system, which was funded with the support of the U.S. 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
- Submitted an EUA application to the FDA for the DPP SARS-CoV-2 IgM/IgG test system
- Received FDA Pre-Market Approval (PMA) for the DPP HIV-Syphilis System, the first rapid test approved in the U.S. to aid in diagnosis of both HIV and Syphilis from single patient sample

“Over the past months we have executed our COVID-19 product development and regulatory strategy ahead of our expectations. The potential launch of antigen and antibody test systems that leverage the DPP platform will provide much needed and expanded access to decentralized COVID-19 testing amid the resurgance of cases across the U.S. Running both types of tests on the same Micro Reader analyzer will enable clinicians to address the needs of a broader patient population throughout all phases of the pandemic,” said Richard Eberly, Chembio’s President and Chief Executive Officer. “Our third quarter results demonstrate improvement in total revenues, which include revenue from DPP COVID-19 IgM/IgG systems shipped outside the U.S. in the second quarter.”

“We have significantly expanded our U.S commercial team with experienced industry professionals and are continuing to do so. We are also actively launching the DPP HIV-Syphilis System,” Mr. Eberly continued. “Looking forward, we are excited about Chembio’s future, serving multiple end markets that combined represent the most significant opportunity in the company’s history.”

Third Quarter 2020 Financial Results

Total revenue for the third quarter of 2020 was $10.3 million, an increase of 6% compared to the prior year period. Net product sales for the third quarter of 2020 were $8.4 million, a decrease of 1% compared to the prior year period. License and royalty revenue and R&D and grant revenue for the third quarter of 2020 totaled $1.9 million, an increase of 54% compared to the prior year period.

Gross product margin for the third quarter of 2020 was $0.9 million, compared to $1.9 million for the prior year period. Gross product margin percentage for the third quarter of 2020 was 11.2%, compared to 21.9% for the prior year period. Gross product margin in the third quarter of 2020 was impacted by a high concentration of sales outside the U.S. where average selling prices are lower, and operational inefficiencies, including those triggered by the recall of products starting at the end of the second quarter of 2020 together with activities related to qualifying automated manufacturing lines.

Research and development expenses increased by $0.1 million, or 6%, in the third quarter of 2020 compared to the prior year period. Selling, general and administrative expenses increased by $0.9 million, or 20%, in the third quarter of 2020 compared to the prior year period.

Net loss for the third quarter of 2020 was $5.5 million, or $0.28 per diluted share, compared to a net loss of $3.8 million, or $0.22 per diluted share, for the prior year period.

Cash and cash equivalents as of September 30, 2020 totaled $28.7 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 844-602-0380 from the United States or 862-298-0970 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 November 19, 2020 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using the conference ID: 38202.

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, Agência Nacional de Vigilância Sanitária (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 disease, and fever and tropical disease. 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 first paragraph 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 availability and functionality 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 nine months ended	
	September 30, 2020	September 30 2019	**September 30, 2020**	September 30, 2019
REVENUES:				
Net product sales	**$ 8,406,457**	$ 8,510,629	**$ 17,914,623**	$ 23,381,906
R&D and grant revenue	**1,654,500**	971,980	**3,756,161**	3,528,033
License and royalty revenue	**211,521**	238,330	**572,450**	703,352
TOTAL REVENUES	**10,272,478**	9,720,939	**22,243,234**	27,613,291
COSTS AND EXPENSES:				
Cost of product sales	**7,467,746**	6,649,114	**17,512,925**	18,112,676
Research and development expenses	**2,351,880**	2,223,939	**6,233,040**	6,542,591
Selling, general and administrative expenses	**5,348,958**	4,455,588	**13,903,192**	12,565,601
Severance, restructuring and other related costs	**11,651**	-	**1,122,310**	-
Acquisition Costs	**-**	-	**63,497**	395,612
	15,180,235	13,328,641	**38,834,964**	37,616,480
LOSS FROM OPERATIONS	**(4,907,757)**	(3,607,702)	**(16,591,730)**	(10,003,189)
OTHER INCOME:				
Interest Expense, net	(735,819)	(195,970)	(2,110,011)	(183,368)
LOSS BEFORE INCOME TAXES	**(5,643,576)**	(3,803,672)	**(18,701,741)**	(10,186,557)
Income tax benefit	**104,778**	20,667	**319,597**	400,339
NET LOSS	**$ (5,538,798)**	$ (3,783,005)	**$ (18,382,144)**	$ (9,786,218)
Basic and diluted loss per share	**$ (0.28)**	$ (0.22)	**$ (0.98)**	$ (0.58)
Weighted average number of shares outstanding, basic and diluted	**20,104,547**	16,923,695	**18,728,372**	16,912,583

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

	(Unaudited) September 30, 2020	December 31, 2019
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 28,687,453**	$ 18,271,352
Accounts receivable, net of allowance for doubtful accounts of $276,210 and $62,000 as of September 30, 2020 and December 31, 2019, respectively	**3,522,498**	3,661,325
Inventories, net	**12,363,486**	9,598,030
Prepaid expenses and other current assets	**1,007,473**	693,013
TOTAL CURRENT ASSETS	**45,580,910**	32,223,720
FIXED ASSETS:		
Property, Plant and Equipment, net	**8,033,112**	5,933,569
Finance lease right-of-use asset, net	**248,892**	210,350
TOTAL FIXED ASSETS, net	**8,282,004**	6,143,919
OTHER ASSETS:		
Operating lease right-of-use assets, net	**6,316,221**	7,030,744
Intangible assets, net	**3,648,495**	3,914,352
Goodwill	**5,696,679**	5,872,690
Deposits and other assets	**462,664**	543,539
TOTAL ASSETS	**$ 69,986,973**	$ 55,728,964
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 6,558,782**	$ 5,526,243
Deferred revenue	**3,865,754**	125,000
Finance lease liabilities	**57,715**	41,894
Operating lease liabilities	**710,535**	568,294
Note payable	**-**	180,249
TOTAL CURRENT LIABILITIES	**11,192,786**	6,441,680
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,448,515**	6,969,603
Long-term finance lease liabilities	**200,397**	171,953
Long-term debt, less current portion, net	**18,040,427**	17,644,149
Deferred tax liability	**165,326**	466,326
TOTAL LIABILITIES	**36,047,451**	25,252,031
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 20,213,956 shares and 17,733,617 shares issued at September 30, 2020 and December 31, 2019, respectively	**202,139**	177,335
Additional paid-in capital	**124,622,252**	95,433,077
Accumulated deficit	**(89,967,147)**	(71,585,003)
Treasury stock 33,290 and 0 shares at cost as of September 30, 2020 and December 31, 2019, respectively	**(150,919)**	-
Accumulated other comprehensive (loss) income	**(766,803)**	9,844
TOTAL STOCKHOLDERS' EQUITY	**33,939,522**	24,035,253
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 69,986,973**	$ 55,728,964

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

	For the nine months ended	
	September 30, 2020	September 30, 2019
Net cash used in operating activities	**$ (14,146,887)**	$ (6,398,207)
Net cash used in investing activities	**(3,182,180)**	(2,769,147)
Net cash provided by financing activities	**27,870,382**	18,517,604
Effect of exchange rate changes on cash	**(125,214)**	(6,909)
INCREASE IN CASH AND CASH EQUIVALENTS	**10,416,101**	9,343,341
Cash and cash equivalents - beginning of the period	**18,271,352**	12,524,551
Cash and cash equivalents - end of the period	**$ 28,687,453**	$ 21,867,892