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): **March 11, 2021**

CHEMBIO DIAGNOSTICS, INC.

Nevada	**0-30379**	**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 March 11, 2021, we issued a press release announcing financial results for the quarter and fiscal year ended December 31, 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 March 11, 2021
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: March 11, 2021

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

Exhibit 99.1

Chembio Diagnostics Reports Fourth Quarter and Full Year 2020 Financial Results

HAUPPAUGE, NY, March 11, 2021 -- Chembio Diagnostics, Inc. (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, 2020.

Recent Accomplishments & Highlights

- Achieved fourth quarter 2020 total revenue of $10.2 million and product revenue of $6.9 million, representing growth of 62% and 39%, respectively, compared to the prior year period
- Received FDA Premarket Application (PMA) approval for the DPP HIV-Syphilis test
- Expanded manufacturing capabilities by validating and implementing automated lines

COVID-19 Testing Portfolio Update

- Received notice in January 2021 that the FDA was declining to review the DPP SARS-CoV-2 Antigen test system based on its updated prioritization guidance, under which review of the system was not a priority. The FDA supplementally advised on the type and nature of information it would need to receive in a subsequent EUA application in order for the DPP SARS-CoV-2 Antigen test system to be prioritized for review.
- Signed an in-licensing agreement to distribute a, point-of-care, EUA approved, respiratory panel for the detection of SARS-CoV-2 Antigens, Flu A and Flu B in the U.S., which is scheduled to launch in March.
- Obtained CE mark for the DPP SARS-CoV-2 Antigen test system and the DPP SARS-CoV-2 IgM/IgG antibody test system.
- Received ANVISA approval for the DPP SARS-CoV-2 Antigen test system through our subsidiary in Brazil.
- Awarded $12.7 million by Biomedical Advanced Research and Development Authority (BARDA) for the development and issuance of an Emergency Use Authorization (EUA) application for the DPP Respiratory Antigen Panel and the preparation and receipt of 510(k) clearance for the rapid DPP SARS-CoV-2 Antigen System.

“We appreciate the FDA’s updated guidance regarding our COVID-19 antigen sytem. As part of our commitment to the COVID-19 testing market and ongoing work with BARDA, we are engaged in testing and development to submit a new EUA application and 510(k) application for the DPP SARS-CoV-2 Antigen System,” said Richard Eberly, Chembio’s President and Chief Executive Officer. “To immediately enhance our product portfolio, we signed an in-licensing agreement that will provide an additional COVID-19 testing solution for our expanded US commercial team to offer along with our DPP HIV-Syphilis system and broader HIV portfolio.”

“In 2020 we implemented a strategic business model shift at Chembio, Mr. Eberly stated. “We have realigned our organization to address higher value U.S. opportunities and capitalize on the launch of products like the DPP HIV-Syphilis System and the portfolio of COVID-19 tests being developed. We built a more comprehensive commercial team including management, sales and customer service professionals who have established deeper relationships and distribution channels. These changes have established a foundation for the business to achieve more profitable growth.”

Mr. Eberly continued, “While we have faced challenges on the regulatory front regarding our portfolio of COVID-19 tests, we remain committed to obtaining FDA approval for these tests. We plan to build upon our the regulatory approvals received in other regions by driving international commercialization of our tests in their approved geographies. Looking ahead to 2021, our top priorities include improving product margins through expanded manufacturing automation, focusing on controlling costs through operational excellence and building long-term customer relationships. We are confident we now have the team and strategy in place to work towards driving sustained, profitable growth.”

Fourth Quarter 2020 Financial Results
Total revenue for the fourth quarter of 2020 was $10.2 million, an increase of 62% compared to the prior year period. Net product sales for the fourth quarter of 2020 were $6.9 million, an increase of 39% compared to the prior year period. Government grant, license and royalty, and R&D revenue for the fourth quarter of 2020 totaled $3.4 million, an increase of 143% compared to the prior year period.

Gross product margin for the fourth quarter of 2020 was $492,000, compared to $1.2 million for the prior year period. Gross product margin percentage for the fourth quarter of 2020 was 7.2%, compared to 24% for the prior year period. Gross product margin in the fourth quarter of 2020 was impacted by unfavorable geographic product mix and operational inefficiencies.

Research and development expenses increased by $1.2 million, or 64%, in the fourth quarter of 2020 compared to the prior year period. The increase in research and development expense was primarily due to clinical trial expenses related to development of the DPP SARS-CoV-2 Antigen and DPP Respiratory Panel test systems. Selling, general and administrative expenses increased by $3.5 million, or 100%, in the fourth quarter of 2020 compared to the prior year period. The increase in selling, general and administrative expenses was primarily due to the expansion of Chembio's U.S. commercial organization, together with legal expenses and facility costs related to the COVID-19 pandemic.

Net loss for the fourth quarter of 2020 was $7.1 million, or $0.35 per diluted share, compared to a net loss of $3.9 million, or $0.23 per diluted share, for the prior year period.

Full Year 2020 Financial Results
Total revenue for 2020 was $32.5 million, a decrease of 6% compared to the prior year period. Net product sales for the full year 2020 were $24.8 million, a decrease of 14% compared to the prior year period. Government grant, license and royalty, and R&D revenue for 2020 totaled $7.7 million, an increase of 37% compared to the prior year period.

Gross product margin for 2020 was $0.9 million, compared to $6.5 million for the prior year period. Gross product margin percentage for 2020 was 4%, compared to 22% for the prior year period. Gross product margin in 2020 was impacted by product returns in the U.S., unfavorable geographic mix, and other operational inefficiencies, offset in part by savings from the retrenchment of Chembio's Malaysian facility.

Research and development expenses increased by $0.9 million, or 11%, in 2020 compared to the prior year period primarily due to costs related to the development of and clinical trials related to the DPP SARS-CoV-2 systems. Selling, general and administrative expenses increased by $4.9 million, or 30%, in 2020 compared to the prior year period. The increase in selling, general and administrative expenses was primarily due to Chembio's expanded U.S. commercial organization, legal expenses, and a full year of operations for Chembio's facility in Brazil following its acquisition in the fourth quarter of 2019, offset somewhat by the retrenchment of its Malaysia facility in May 2020.

Net loss for 2020 was $25.5 million, or $1.34 per diluted share, compared to a net loss of $13.7 million, or $0.81 per diluted share, for the prior year period.

Cash and cash equivalents as of December 31, 2020 totaled $23.1 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 888-506-0062 from the United States or 973-528-0011 from outside the United States and providing entry code 663365. 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 25, 2021 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using passcode 40186.

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.

About the 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 three 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 availability, timing, functionality and regulatory approval of Chembio's COVID-19 diagnostic tests as well as 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, 2019 and subsequent Quarterly Reports on Form 10-Q, particularly under the heading "Risk Factors."

Investor Relations Contact
Philip Taylor
Gilmartin Group
(415) 937-5406
investor@chembio.com

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

	For the three months ended (Unaudited)		For the year ended	
	Dec. 31, 2020	Dec. 31, 2019	**Dec. 31, 2020**	Dec. 31, 2019
REVENUES:				
Net product sales	**$ 6,852,526**	$ 4,925,043	**$ 24,767,149**	$ 28,844,997
R&D	**1,095,402**	1,152,249	**4,851,562**	4,025,538
Government Grants	**2,018,924**	-	**2,018,924**	654,744
License and royalty revenue	**260,112**	235,401	**832,562**	938,753
TOTAL REVENUES	**10,226,964**	6,312,693	**32,470,197**	34,464,032
COSTS AND EXPENSES:				
Cost of product sales	**6,361,480**	3,743,592	**23,874,487**	22,394,317
Research and development expenses	**3,275,455**	1,995,826	**9,508,494**	8,538,416
Selling, general and administrative expenses	**7,134,593**	3,572,823	**21,037,701**	16,138,424
Severance, restructuring and other related costs	-	-	**1,122,310**	-
Acquisition Costs	-	325,852	**63,497**	721,465
	16,771,528	9,638,093	**55,606,489**	47,792,622
LOSS FROM OPERATIONS	**(6,544,564)**	(3,325,400)	**(23,136,292)**	(13,328,590)
OTHER INCOME:				
Interest Expense, net	(731,818)	(663,463)	(2,841,830)	(846,831)
LOSS BEFORE INCOME TAXES	**(7,276,382)**	(3,988,863)	**(25,978,122)**	(14,175,421)
Income tax benefit	**137,198**	99,953	**456,794**	500,292
NET LOSS	**$ (7,139,184)**	$ (3,888,910)	**$ (25,521,328)**	$ (13,675,129)
Basic and diluted loss per share	**$ (0.35)**	$ (0.23)	**$ (1.34)**	$ (0.81)
Weighted average number of shares outstanding, basic and diluted	**20,150,168**	17,079,151	**19,085,691**	16,954,142

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

	December 31, 2020	December 31, 2019
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 23,066,301**	$ 18,271,352
Accounts receivable, net of allowance for doubtful accounts of $254,232 and $62,000 as of December 31, 2020 and December 31, 2019, respectively	**3,377,387**	3,661,325
Inventories, net	**12,516,402**	9,598,030
Prepaid expenses and other current assets	**778,683**	693,013
TOTAL CURRENT ASSETS	**39,738,773**	32,223,720
FIXED ASSETS:		
Property, Plant and Equipment, net	**8,688,403**	5,933,569
Finance lease right-of-use asset, net	**233,134**	210,350
TOTAL FIXED ASSETS, net	**8,921,537**	6,143,919
OTHER ASSETS:		
Operating lease right-of-use assets, net	**6,112,632**	7,030,744
Intangible assets, net	**3,645,986**	3,914,352
Goodwill	**5,963,744**	5,872,690
Deposits and other assets	**509,342**	543,539
TOTAL ASSETS	**$ 64,892,014**	$ 55,728,964
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 10,042,790**	$ 5,526,243
Deferred revenue	**1,606,997**	125,000
Operating lease liabilities	**642,460**	41,894
Finance lease liabilities	**58,877**	568,294
Note payable	**-**	180,249
TOTAL CURRENT LIABILITIES	**12,351,124**	6,441,680
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,327,143**	6,969,603
Long-term finance lease liabilities	**185,239**	171,953
Long-term debt, less current portion, net	**18,182,158**	17,644,149
Deferred tax liability	**69,941**	466,326
TOTAL LIABILITIES	**37,115,605**	25,252,031
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**-**	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 20,223,498 shares and 17,733,617 shares issued at December 31, 2020 and December 31, 2019, respectively	**202,235**	177,335
Additional paid-in capital	**124,961,514**	95,433,077
Accumulated deficit	**(97,106,331)**	(71,585,003)
Treasury stock 41,141 and 0 shares at cost as of December 31, 2020 and December 31, 2019, respectively	**(190,093)**	-
Accumulated other comprehensive (loss) income	**(90,916)**	9,844
TOTAL STOCKHOLDERS' EQUITY	**27,776,409**	24,035,253
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 64,892,014**	$ 55,728,964

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

FOR THE YEARS ENDED

	December 31, 2020	December 31, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 34,736,133**	$ 37,930,172
Cash paid to suppliers and employees	**(50,238,409)**	(45,655,562)
Cash paid for operating leases	**(1,139,944)**	(632,952)
Cash paid for finance leases	**(19,987)**	(7,892)
Interest and taxes, net	**(2,225,031)**	(689,272)
Net cash used in operating activities	**(18,887,238**	(9,055,506)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of businesses, net of cash acquired	**-**	(100,000)
Acquisition of and deposits on fixed assets	**(3,961,369)**	(3,502,540)
Patent Application Costs	**(205,493)**	(297,006)
Working capital adjustment related to business combination	**-**	145,760
Net cash used in investing activities	**(4,166,862)**	(3,753,786)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock, net	**28,436,740**	-
Proceeds from option exercises	**-**	32,486
Principal payments for finance leases	**(51,166)**	(19,875)
Payments on debt issuance costs	**-**	(186,313)
Payments on note payable	**(180,249)**	(181,822)
Proceeds from issuance of long-term debt, net	**-**	18,850,000
Stimulus package loan	**2,978,315**	-
Payment of stimulus package loan	**(2,978,315)**	-
Payments of tax withholdings on stock award	**(441,723)**	-
Net cash provided by financing activities	**27,763,602**	18,494,476
Effect of exchange rate changes on cash	**85,447**	61,617
INCREASE IN CASH AND CASH EQUIVALENTS	**4,794,949**	5,746,801
Cash and cash equivalents - beginning of the period	**18,271,352**	12,524,551
Cash and cash equivalents - end of the period	**$ 23,066,301**	$ 18,271,352
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	**$ (25,521,328)**	$ (13,675,129)
Adjustments:		
Depreciation and amortization	**2,697,126**	1,916,194
Share based compensation	**1,223,171**	1,655,900
Benefit from deferred tax liability	**(396,385)**	(513,715)
Provision for doubtful accounts	**270,193**	20,000
Non-cash inventory changes	**3,543,515**	-
Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	**283,939**	3,764,045
Inventories	**(6,461,887)**	(1,457,612)
Prepaid expenses and other current assets	**(85,670)**	64,355
Deposits and other assets	**34,195**	(90,624)
Accounts payable and accrued liabilities	**4,043,896**	(441,015)
Deferred revenue	**1,481,997**	(297,905)
Net cash used in operating activities	**$ (18,887,238)**	$ (9,055,506)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 472,651**	$ 430,000
Issuance of common stock for net assets of business acquired	**–**	443,291
Contingent liability earnout	**1,011,261**	1,225,000