

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): May 4, 2020



**CHEMBIO DIAGNOSTICS, INC.**

*(Exact name of registrant as specified in its charter)*

**Nevada**  
*(State or Other Jurisdiction of Incorporation or Organization)*

**0-30379**  
*(Commission File Number)*

**88-0425691**  
*(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 May 4, 2020, we issued a press release announcing financial results for the quarter ended March 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	Description
<a href="#">99.1</a>	Press release of Chembio Diagnostics, Inc. dated May 4, 2020

## 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: May 4, 2020

By: /s/ NEIL A. GOLDMAN

Neil A. Goldman

Executive Vice President and Chief Financial Officer

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## Chembio Diagnostics Reports First Quarter 2020 Financial Results

HAUPPAUGE, NY, May 4, 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 March 31, 2020.

### Recent Accomplishments & Highlights

- Attained FDA Emergency Use Authorization for the DPP COVID-19 IgM/IgG System serological test
  - o Announced the U.S. launch and shipments to customers of the DPP COVID-19 System
  - o Selected by Stony Brook Medicine as the testing solution to identify COVID-19 survivors for study on COVID-19 convalescent plasma therapy
  - o Received a \$4.0 million purchase order from Bio-Manguinhos for our DPP COVID-19 System
- Completed the reproducibility study and submitted data to the FDA for our DPP HIV-Syphilis test
- Appointed Richard Eberly as President and Chief Executive Officer and director and appointed Gail Page as Executive Chair of the Board
- Achieved total revenue of \$6.9 million and product revenue of \$5.7 million

“During the first quarter, we refocused our business strategy to address the escalating need for COVID-19 diagnostic tests. In a short period of time, we developed a COVID-19 serological testing system, received FDA Emergency Use Authorization and began shipping tests to customers in the United States and Brazil in April. Our differentiated testing system offers numerical discrete detection of both IgM and IgG antibodies in approximately 15 minutes from a fingerstick. Then, in approximately 15 seconds, the DPP COVID-19 System reads the test to provide numerical results using the portable Micro Reader analyzers that are engineered and produced by our wholly owned subsidiary in Germany. Numerical results reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests,” said Gail Page, Chembio’s Executive Chair of the Board. “We are proud to be serving the needs of clinicians and the broader healthcare community in this time of crisis.”

“It has been an extremely productive first few weeks in my new role as CEO. Amid these challenging circumstances, the skill and hard work of this team has enabled a successful strategic pivot as we prioritize manufacturing and commercialization of our DPP COVID-19 System,” said Richard Eberly, Chembio’s Chief Executive Officer. “Through efficient use of our resources and technical ability, we are scaling production of these tests due to the strong demand we are experiencing. We believe the features and benefits offered by our DPP COVID-19 System will make it a preferred solution.”

### First Quarter 2020 Financial Results

Total revenue for the first quarter of 2020 was \$6.9 million, a decrease of 20% compared to the prior year period. Net product sales for the first quarter of 2020 were \$5.7 million, a decrease of 14% compared to the prior year period. License and royalty revenue together with R&D and grant revenue for the first quarter of 2020 was \$1.1 million, a decrease of 40% compared to the prior year period.

Gross product margin for the first quarter of 2020 was \$1.3 million, compared to \$1.6 million for the prior year period. Gross product margin percentage for the first quarter of 2020 was 23.5%, compared to 24.3% for the prior year period, a decrease resulting primarily from unfavorable average selling prices due to geographic mix.

Research and development expenses decreased by \$0.3 million, or 12%, for the first quarter of 2020 compared to the prior year period. Selling, general and administrative expenses increased by \$0.5 million, or 12%, for the first quarter of 2020 compared to the prior year period, with \$0.4 million of the increase representing severance and related costs and acquisition costs, for a net increase of \$0.1 million, or 4%.

Net loss for the first quarter of 2020 was \$5.0 million, or \$(0.29) per diluted share, compared to a net loss of \$2.8 million, or \$(0.16) per diluted share, for the prior year period.

Cash and cash equivalents as of March 31, 2020 totaled \$11.2 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](http://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 May 18, 2020 by dialing 877-481-4010 from the United States or 919-882-2331 from outside the United States and using the conference ID: 34409.

### **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. Chembio's patented DPP technology platform, which uses a small drop of blood from the fingertip, 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](http://www.chembio.com).

### **Forward-Looking Statements**

*Statements contained in this release that are not historical facts may be forward-looking statements within the meaning of the Securities Act of 1933, as amended. Forward-looking statements include statements regarding the intent, belief or current expectations of Chembio and its management. Such statements 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 impact to our business, our suppliers and our customers of the COVID-19 pandemic and the actions taken to combat the COVID-19 pandemic; the ability of Chembio to maintain existing, and timely obtain additional, regulatory approvals, particularly for our DPP COVID-19 System; 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." You should interpret many of the risks identified in these reports as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic.*

*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.*

### **Investor Relations Contact**

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

	<u>For the three months ended</u>	
	<u>March 31, 2020</u>	<u>March 31, 2019</u>
<b>REVENUES:</b>		
Net product revenue	\$ 5,716,593	\$ 6,624,285
R&D and grant revenue	907,687	1,701,789
License and royalty revenue	235,304	216,191
<b>TOTAL REVENUES</b>	<b>6,859,584</b>	<b>8,542,265</b>
<b>COSTS AND EXPENSES:</b>		
Cost of product revenue	4,374,442	5,011,636
Research and development expenses	1,958,853	2,217,632
Selling, general and administrative expenses	4,156,641	4,013,071
Severance and related costs	723,118	-
Acquisition costs	63,497	395,612
	<b>11,276,551</b>	<b>11,637,951</b>
<b>LOSS FROM OPERATIONS</b>	<b>(4,416,967)</b>	<b>(3,095,686)</b>
<b>OTHER INCOME:</b>		
Interest (expense) income, net	(662,141)	6,684
<b>LOSS BEFORE INCOME TAXES</b>	<b>(5,079,108)</b>	<b>(3,089,002)</b>
Income tax (benefit)	(79,559)	(272,469)
<b>NET LOSS</b>	<b>\$ (4,999,549)</b>	<b>\$ (2,816,533)</b>
<b>Basic and Diluted loss per share</b>	<b>\$ (0.29)</b>	<b>\$ (0.16)</b>
<b>Weighted-average number of shares outstanding, basic</b>	<b>17,197,301</b>	<b>17,166,459</b>
<b>Weighted-average number of shares outstanding, diluted</b>	<b>17,197,301</b>	<b>17,166,459</b>

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

	(Unaudited) March 31, 2020	December 31, 2019
- ASSETS -		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 11,238,017	\$ 18,271,352
Accounts receivable, net	4,877,842	3,661,325
Inventories, net	10,930,159	9,598,030
Prepaid expenses and other current assets	798,228	693,013
<b>TOTAL CURRENT ASSETS</b>	<b>27,844,246</b>	<b>32,223,720</b>
<b>FIXED ASSETS:</b>		
Property, plant and equipment, net	6,659,279	5,933,569
Finance lease right-of-use asset	226,305	210,350
<b>TOTAL FIXED ASSETS, net</b>	<b>6,885,584</b>	<b>6,143,919</b>
<b>OTHER ASSETS:</b>		
Operating lease right-of-use asset, net	6,785,668	7,030,744
Intangible assets, net	3,655,858	3,914,352
Goodwill	5,493,045	5,872,690
Deposits and other assets	528,261	543,539
<b>TOTAL ASSETS</b>	<b>\$ 51,192,662</b>	<b>\$ 55,728,964</b>
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued liabilities	\$ 6,536,134	\$ 5,526,243
Deferred revenue	543,345	125,000
Note payable	112,928	180,249
Finance lease liabilities	47,192	41,894
Operating lease liabilities	766,896	568,294
<b>TOTAL CURRENT LIABILITIES</b>	<b>8,006,495</b>	<b>6,441,680</b>
<b>OTHER LIABILITIES:</b>		
Long-term operating lease liabilities	6,770,005	6,969,603
Long-term finance lease liabilities	184,095	171,953
Long-Term debt, less current portion, and debt discount and issuance costs	17,771,268	17,644,149
Deferred tax liability	327,542	466,326
<b>TOTAL LIABILITIES</b>	<b>33,059,405</b>	<b>31,693,711</b>
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock – 10,000,000 shares authorized, none outstanding	-	-
Common stock - \$0.01 par value; 100,000,000 shares authorized, 17,327,235 shares and 17,733,617 shares issued at March 31, 2020 and December 31, 2019, respectively	173,272	177,335
Additional paid-in capital	95,543,043	95,433,077
Accumulated deficit	(76,584,552)	(71,585,003)
Treasury Stock, 31,486 shares at cost	(145,056)	-
Accumulated other comprehensive (loss) income	(853,450)	9,844
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>18,133,257</b>	<b>24,035,253</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 51,192,662</b>	<b>\$ 55,728,964</b>

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

	<b><u>For the three months ended</u></b>	
	<b><u>March 31, 2020</u></b>	<b><u>March 31, 2019</u></b>
<b>Net cash used in operating activities</b>	<b>\$ (5,651,960)</b>	<b>\$ (4,754,878)</b>
<b>Net cash used in investing activities</b>	<b>(1,078,271)</b>	<b>(577,472)</b>
<b>Net cash provided by financing activities</b>	<b>(223,290)</b>	<b>(29,930)</b>
<b>Effect of exchange rate changes on cash</b>	<b>(79,814)</b>	<b>208,407</b>
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(7,033,335)</b>	<b>(5,153,873)</b>
Cash and cash equivalents - beginning of the period	<b>18,271,352</b>	<b>12,524,551</b>
<b>Cash and cash equivalents - end of the period</b>	<b><u>\$ 11,238,017</u></b>	<b><u>\$ 7,370,678</u></b>