

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 12, 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.)

3661 Horseblock Road, Medford, New York 11763
(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))

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 12, 2020, we issued a press release announcing financial results for the quarter and fiscal year ended December 31, 2019. 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
99.1	Press release of Chembio Diagnostics, Inc. dated March 12, 2020 with respect to financial results for the quarter and fiscal year ended December 31, 2019

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.

Dated: March 13, 2020

Chembio Diagnostics, Inc.

By: /s/ NEIL A. GOLDMAN

Neil A. Goldman

Executive Vice President and Chief Financial Officer



Chembio Diagnostics Reports Fourth Quarter and Full Year 2019 Financial Results

HAUPPAUGE, N.Y., March 12, 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 and year ended December 31, 2019.

Recent Accomplishments & Highlights

- Achieved full year 2019 product revenue of \$28.8 million and total revenue of \$34.5 million, an increase of 3.3% and decrease of 0.3%, respectively compared to 2018
- Achieved fourth quarter 2019 product revenue of \$5.5 million and total revenue of \$6.9 million representing a decrease of 5.9% and 11.8%, respectively, compared to the prior year period
- Announced a worldwide strategic partnership with LumiraDx to develop and commercialize COVID-19 tests on the DPP and LumiraDX platforms
- Appointed Richard Eberly as Chief Executive Officer
- Received \$1.5 million dollar UNICEF order for Multiplex Zika Systems
- Completed acquisition of Orangelife to diversify and expand our market penetration in Brazil and support Bio-Manguinhos, one of our major customers
- Received WHO Prequalification approval for both the HIV Self-Test and the Malaysia production facility
- Initiated production on our fully automated DPP manufacturing line and took delivery of our second and third automated lines for our other product platforms
- Continued collaborative work with the FDA on reproducibility study requirements for the HIV-Syphilis System PMA following acceptance of the syphilis and pregnant women data

“Though we were disappointed with the reduced rate of growth in our product revenues vs. prior years, our U.S. and European businesses were up, but they were mitigated by the shortfalls in Africa and Asia. We believe this is in large part due to the timing of annual tenders. As we examined our total revenue shortfall, it became apparent that it was principally driven by the decrease in R&D and grant revenue, which relates to the cadence of our collaboration work with customers such as AstraZeneca and Takeda.” said Gail Page, Chembio’s Interim Chief Executive Officer.

Ms. Page continued, “Reflecting on 2019, we accomplished several milestones that position the company favorably for future growth. These include multiple global product approvals and registrations, the acquisition of Orangelife that will enhance our commercial efforts in the largest infectious disease testing market, advancing development agreements with world-class partners, scaling production capacity through automation and an additional WHO prequalified facility, and strengthening the balance sheet.”

“As we look to 2020, we are very excited to partner up with LumiraDx and combine our collective scientific expertise to develop point-of-care tests for COVID-19. We are confident our combined solutions will be the preferred approach for healthcare providers to detect and monitor this pandemic. In addition, we are pleased to have appointed Richard Eberly as CEO to lead the next phase of Chembio’s growth. He is a diagnostics industry veteran who brings to the company years of experience commercializing and growing many product platforms. We are confident we have the right team and technology to extend our leadership in point-of-care diagnostics, grow revenues, and create long-term shareholder value.”

Fourth Quarter 2019 Financial Results

Total revenue for the three months ended December 31, 2019 was \$6.9 million, a decrease of 0.3% compared to the prior year period. Net product sales for the three months ended December 31, 2019 were \$5.5 million, an increase of 3.3% compared to the prior year period. License, royalty, R&D, and grant revenue combined in the three months ended December 31, 2019 were \$1.4 million, a decrease of 29.4% compared to the prior year period.

Gross product margin for the fourth quarter of 2019 was \$1.2 million compared to \$1.0 million in the prior year period. Gross product margin percent for the fourth quarter of 2019 was 21.6% compared to 17.7% for the prior year period. The increased gross product margin percent resulted primarily from a combination of geographic mix on average selling prices, benefits from our first automated assembly line, reduced contract labor costs, and favorable product revenues.

Research and development expenses for the fourth quarter of 2019 were \$2.0 million, compared to \$2.8 million the prior year, corresponding with the reduction in R&D and grant revenue. Selling, general and administrative expenses for the fourth quarter 2019 increased by \$0.5 million, or 14.8%, compared to the prior year period. The increase in selling, general and administrative expenses resulted primarily from the acquisition of Chembio Diagnostics Germany, higher non-cash equity compensation costs, and rent and other costs related to leasing our new facility in Hauppauge, NY.

Net loss for fourth quarter 2019 was \$3.9 million, or \$0.23 per diluted share, compared with a net loss of \$3.2 million, or \$0.20 per diluted share, for the prior year period.

Full Year 2019 Financial Results

Total revenue for 2019 was \$34.5 million, a decrease of 0.3% compared to the prior year. Net product sales for 2019 were \$28.8 million, an increase of 3.3% compared to the prior year. License, royalty, R&D, and grant revenue combined for 2019 were \$5.6 million, a decrease of 15.7% compared to the prior year.

Gross product margin for 2019 was \$6.5 million compared to \$5.3 million in the prior year period. Gross product margin percent for 2019 was 22.4% compared to 19.0% for the prior year. The increased gross product margin percent for 2019 reflected a combination of geographic mix on average selling prices, initial benefits from our first automated assembly line, reduced contract labor costs, and favorable product revenues.

Research and development expenses for 2019 were \$8.5 million, essentially flat compared to the prior year. Selling, general and administrative expenses increased by \$5.0 million, or 45%, for 2019 compared to the prior year. The increase in selling, general and administrative expenses resulted primarily from the acquisition of Chembio Diagnostics Germany, higher non-cash equity compensation costs, and rent and other costs related to leasing our new facility in Hauppauge, NY.

Net loss for 2019 was \$13.7 million, or \$0.81 per diluted share, compared with a net loss of \$7.9 million, or \$0.54 per diluted share, for the prior year.

Cash and cash equivalents as of December 31, 2019 totaled \$18.3 million.

Conference Call

Chembio will host a conference call today beginning at 4:30pm ET to discuss financial results and recent business highlights. Investors interested in listening to the call may do so by dialing 877-407-0778 from the U.S. or 201-689-8565 from outside the U.S. To listen to a live webcast, 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 the company's website for 90 days. A telephone replay will be available by dialing 877-481- 4010 from the U.S. or 919-882-2331 from outside the U.S. using the conference ID: 33460 until 4:30pm ET on March 26, 2020.

About Chembio Diagnostics

Chembio is a leading point-of-care diagnostics company focused on detecting and diagnosing infectious diseases. The company's patented DPP technology platform, which uses a small drop of blood from the fingertip, provides high-quality, cost-effective results in 15-20 minutes. Coupled with Chembio's extensive scientific expertise, its novel DPP technology offers broad market applications beyond infectious disease, a number of which are under active development with collaboration partners. 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 last paragraph under "Recent Accomplishments & Highlights" 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 the company and its management. Such statements, which are estimates 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 the above 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 ability of Chembio to timely close the Orangelife acquisition; the ability of Chembio to maintain existing, and timely obtain additional, regulatory approvals; and the risks of doing business with a foreign country, 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 these forward-looking statements to reflect events or circumstances that occur after the date hereof or to reflect any change in Chembio's expectations with regard to these forward-looking statements or the occurrence of unanticipated events. Factors that may impact Chembio's success are more fully disclosed in Chembio's most recent 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, 2018, particularly under the heading "Risk Factors."

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

Investor Relations Contact

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

	For the twelve months ended	
	December 31, 2019	December 31, 2018
REVENUES:		
Net product sales	\$ 28,844,997	\$ 27,913,209
R&D and grant revenue	4,680,282	5,719,458
License and royalty revenue	938,753	948,773
TOTAL REVENUES	34,464,032	34,581,440
COSTS AND EXPENSES:		
Cost of product sales	22,394,317	22,599,432
Research and development expenses	8,538,416	8,526,256
Selling, general and administrative expenses	16,138,424	11,100,775
Acquisition costs	721,465	337,645
	47,792,622	42,564,108
LOSS FROM OPERATIONS	(13,328,590)	(7,982,668)
OTHER INCOME:		
Interest (expense) income, net	(846,831)	49,498
LOSS BEFORE INCOME TAXES	(14,175,421)	(7,933,170)
Income tax benefit	500,292	67,521
NET LOSS	\$ (13,675,129)	\$ (7,865,649)
Basic and Diluted loss per share	\$ (0.81)	\$ (0.54)
Weighted average number of shares outstanding, basic	16,954,142	14,432,505
Weighted average number of shares outstanding, diluted	16,954,142	14,432,505

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

- ASSETS -	December 31, 2019	December 31, 2018
CURRENT ASSETS:		
Cash and cash equivalents	\$ 18,271,352	\$ 12,524,551
Accounts receivable, net	3,661,325	7,373,971
Inventories, net	9,598,030	7,851,222
Prepaid expenses and other current assets	693,013	702,010
TOTAL CURRENT ASSETS	32,223,720	28,451,754
FIXED ASSETS:		
Property, plant and equipment, net	5,933,569	2,873,920
Finance lease right-of-use asset	210,350	-
TOTAL FIXED ASSETS, net	6,143,919	2,873,920
OTHER ASSETS:		
Operating lease right-of-use asset	7,030,744	-
Intangible assets, net	3,914,352	3,884,831
Goodwill	5,872,690	4,983,127
Deposits and other assets	543,539	717,551
TOTAL ASSETS	\$ 55,728,964	\$ 40,911,183
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 5,526,243	\$ 5,888,681
Deferred revenue	125,000	422,905
Note payable	180,249	207,694
Finance lease liability	41,894	-
Operating lease liability	568,294	-
TOTAL CURRENT LIABILITIES	6,441,680	6,519,280
OTHER LIABILITIES:		
Long-term operating lease liabilities	6,969,603	-
Long-term finance lease liabilities	171,953	-
Long-Term debt net of debt discount and issuance costs	17,644,149	171,821
Deferred tax liability	466,326	892,308
TOTAL LIABILITIES	31,693,711	7,583,409
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding Common stock - \$.01 par value; 100,000,000 shares authorized, 17,733,617 and 17,166,459 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	-
Additional paid-in capital	177,335	171,664
Accumulated deficit	95,433,077	90,953,788
Accumulated other comprehensive income	(71,585,003)	(57,909,874)
	9,844	112,196
TOTAL STOCKHOLDERS' EQUITY	24,035,253	33,327,774
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 55,728,964	\$ 40,911,183

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

	For the twelve months ended	
	December 31, 2019	December 31, 2018
Net cash used in operating activities	\$ (9,055,506)	\$ (11,781,441)
Net cash used in investing activities	(3,753,786)	(6,958,396)
Net cash provided by financing activities	18,494,476	27,483,693
Effect of exchange rate changes on cash	61,617	(9,607)
INCREASE IN CASH AND CASH EQUIVALENTS	5,746,801	8,734,249
Cash and cash equivalents - beginning of the period	12,524,551	3,790,302
Cash and cash equivalents - end of the period	\$ 18,271,352	\$ 12,524,551