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): **June 30, 2020**

CHEMBIO DIAGNOSTICS, INC.

(Exact name of registrant as specified in its charter)

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 1.01 Entry into a Material Definitive Agreement.

On June 30, 2020, we entered into an amendment, or the Amendment, to the letter agreement we entered into with Gail S. Page on June 15, 2020 with respect to her serving as Executive Chair. Pursuant to the Amendment, the term of Ms. Page's services as Executive Chair was terminated as of June 30, 2020.

Also on June 30, 2020, Ms. Page advised us of her decision to withdraw as a nominee for election as a director at the 2020 Annual Meeting of Stockholders. Ms. Page is expected to continue to serve as a member of the board of directors until her current term expires at the 2020 Annual Meeting.

Item 2.02 Results of Operation and Financial Condition.

On July 6, 2020, we issued a press release, which we refer to as the Release, announcing preliminary estimates of certain financial information for the quarter ended June 30, 2020. The full text of the Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

In addition, we held an investor conference call on July 7, 2020 to discuss, among other things, the information described in the Release and complementary matters. That discussion is included in the script for such call that is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02, in the Release furnished as Exhibit 99.1 to this report and the portion of the conference call script filed as Exhibit 99.2 to this report shall not be (a) 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 or (b) 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 7.01 Regulation FD Disclosure.

On July 6, 2020, we issued press releases titled "Chembio Announces Plans to Seek EUA Approval from FDA for Revised DPP COVID-19 IgM/IgG System and New DPP COVID-19 Antigen System" and "Chembio Diagnostics Awarded BARDA Grant for Development of DPP COVID-19 Point-of-Care Antigen System." Copies of those press releases are furnished as Exhibits 99.3 and 99.4, respectively, to this report.

We held an investor conference call on July 7, 2020. The script for such call is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information contained in this Item 7.01, in the script furnished as Exhibit 99.2 to this report, and in the press releases furnished as Exhibit 99.3 and Exhibit 99.4 to this report shall not be (a) deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section or Section 11 or 12(a)(2) of the Securities Act of 1933 or (b) 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 8.01 Other Events

Credit Agreement Waiver

We have received from Perceptive Credit Holdings II, LP, or Perceptive, a waiver of the minimum total revenue covenant contained in our Credit Agreement and Guaranty dated as of September 3, 2019, with Perceptive and the Guarantors named therein.

Certain Proceedings

As of July 7, 2020, four purported class action lawsuits had been filed by alleged stockholders of ours in the United States District Court for the Eastern District of New York, including: (1) *Sergey Chernysh v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page*, 20-cv-2706, filed on June 18, 2020, or *Chernysh*; (2) *James Gowen v. Chembio Diagnostics, Inc., Richard L. Eberly, and Gail S. Page*, 2:20-cv-02758, filed on June 22, 2020, or *Gowen*; and (3) *Anthony Bailey v. Chembio Diagnostics, Inc. Richard J. Eberly, Gail S. Page, and Neil A. Goldman*, 2:20-cv-02961, filed on July 3, 2020, or *Bailey*.

The *Chernysh, Gowen and Bailey* complaints are brought by purported individual stockholders of ours on behalf of all persons and entities who purchased our publicly traded stock during the alleged "class period" and purport to state claims for violations of Section 10(b) and 20(a) of the Securities and Exchange Act of 1934 and Rule 10b-5 promulgated thereunder by the Securities and Exchange Commission. The *Chernysh* and *Bailey* complaints define the "class period" as April 1, 2020 through June 16, 2020, inclusive, whereas the *Gowen* complaint defines the "class period" as March 12, 2020, through June 16, 2020, inclusive. The plaintiffs in these actions generally purport to allege that the defendants named therein misrepresented and failed to disclose that our DPP COVID-19 IgM/IgG System did not provide high-quality results and there were material performance concerns with the DPP COVID-19 IgM/IgG System's accuracy, including that it generates false results at a rate higher than expected and higher than reflected in its authorized labeling and was not effective in detecting antibodies against COVID-19. The *Chernysh*, *Gowen*, and *Bailey* complaints seek an award of damages ostensibly sustained as a result of our alleged wrongdoing in an amount to be

proven at trial as well as an award of reasonable attorneys' fees and expenses, including expert fees and pre- and post-judgment interest.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit No.	Description
99.1	Press release of Chembio Diagnostics, Inc., dated July 6, 2020, titled “Chembio Diagnostics Announces Preliminary Estimates of Second Quarter 2020 Revenues”
99.2	Script of conference call of Chembio Diagnostics, Inc. held on July 7, 2020
99.3	Press release of Chembio Diagnostics, Inc., dated July 6, 2020, titled “Chembio Announces Plans to Seek EUA Approval from FDA for Revised DPP COVID-19 IgM/IgG System and New DPP COVID-19 Antigen System”
99.4	Press release of Chembio Diagnostics, Inc., dated July 6, 2020, titled “Chembio Diagnostics Awarded BARDA Grant for Development of DPP COVID-19 Point-of-Care Antigen System”

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: July 7, 2020

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

Exhibit 99.1

Chembio Diagnostics Announces Preliminary Estimates of Second Quarter 2020 Revenues

Company to Host Conference Call Tuesday, July 7

HAUPPAUGE, N.Y., July 6, 2020 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading global point-of-care diagnostic company focused on infectious diseases, today announced its preliminary estimates of revenue results for the quarter ended June 30, 2020.

Total revenues for the three months ended June 30, 2020 are expected to be in the range of $4.5 million to $4.7 million, subject to increase by up to an additional $2.5 million of revenue with respect to products that were shipped outside the United States during the quarter. While Chembio continues to both ship DPP COVID-19 IgM/IgG systems and pursue additional opportunities outside the United States, it also continues to monitor any potential response by other regulators of the FDA's recent revocation of the EUA for the system. Chembio expects total revenues to be finalized prior to issuance of its financial statements for the quarter and six months ended June 30, 2020. Revenues from Chembio's COVID-19-related sales for the quarter are estimated to range from $0.8 million to $3.3 million, and inclusive in the high end of the range is the additional $2.5 million of product shipped outside the United States.

Total revenues for the three months ended June 30, 2019 were $9.9 million. The decrease in sales is related to a combination of the impact of the COVID-19 pandemic on historical products and markets, as well as the Company's shift to address the pandemic with its newly developed product during the three months ended June 30, 2020, combined with seasonally stronger sales of HIV tests to Latin America during the prior year period.

Cash and cash equivalents at June 30, 2020 are estimated to total approximately $36.6 million, including approximately $3.3 of restricted cash and cash equivalents, compared with $11.2 million at March 31, 2020. The increase in cash and cash equivalents compared to the prior quarter reflect the approximate net proceeds from the Company's secondary equity raise of $28.4 million, offset by capital expenditures, operating costs, and other items.

The estimated range and amounts for revenue results for the second quarter of 2020 and the estimated amount of cash and cash equivalents at June 30, 2020 are preliminary estimates because Chembio's financial closing procedures for the quarter remain to be performed and other developments may arise by the time the financial results for the quarter are completed. Until Chembio releases its second quarter operating results during the first week of August 2020, the preliminary results described in this press release are estimates only and are subject to revisions that could cause the final results to differ materially. Chembio undertakes no responsibility to update its preliminary estimates in the interim.

Conference Call Information
Chembio will host a conference call on Tuesday, July 7, 2020, at 8:00 am (Eastern time) to discuss the information described in those press releases and related business and financial matters. Interested parties can participate in the conference call by dialing 877-407-0778 (U.S. toll-free) or 201-689-8565 (international) or joining a live audio webcast available at www.chembio.com/investors/calendar-of-events/. Following the call, a replay of the call is expected to be available through July 10, 2020, by dialing 877-481-4010 (U.S. toll-free) or 919-882-2331 (international), conference ID code 35572, or by accessing www.chembio.com/investors/calendar-of-events/.

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.

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.

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

Exhibit 99.2

CHEMBIO SCRIPT – 7/7/2020

PHILIP TAYLOR, INVESTOR RELATIONS

Thank you. Before we begin today, let me remind you that Chembio's remarks during this conference call today, July 7, 2020, will include forward-looking statements within the meaning of the Securities Act of 1933 concerning the current beliefs of the company. Forward-looking statements are subject to numerous assumptions, risks and uncertainties, many of which are beyond Chembio's control, including risks and uncertainties described from time to time in Chembio's SEC filings with the Securities and Exchange Commission, including those under “Risk Factors” and elsewhere in Chembio’s Annual Report on Form 10-K for 2019 and its Quarterly Report on Form 10-Q for the first quarter of 2020. Chembio's results may differ materially from those projected. Chembio undertakes no obligation to publicly revise or update any forward-looking statement made today. I encourage you to review all of Chembio’s filings with the SEC concerning these and other matters.

With that, I would like to turn the call over to Rick Eberly, President and Chief Executive Officer.

RICK EBERLY, PRESIDENT & CEO

Thank you Trip, and thank you all for joining us this morning.

I would like to start by acknowledging the hard work and dedication that has been demonstrated by the employees across our organization as we continue with our efforts to develop and commercialize COVID-19 products for our customers who remain engaged in the global fight against this pandemic.

I also would like to acknowledge the patience and perseverance of our stockholders since the FDA’s revocation of the Emergency Use Authorization, or EUA, for our DPP COVID-19 IgM/IgG System. The EUA revocation was disappointing for all of us, and I know many stockholders have been looking for a business strategy update. I therefore would like to explain the timing of yesterday’s press releases describing our development plans and other news.

We began updating our product development plans on the day after the EUA revocation. We very much wanted to provide investors with an update on our plans. Given the circumstances, including multiple regulatory and governmental agencies, litigation matters, and a blackout period with our quarter coming to a close, our hands were tied with what we could say publicly. In addition, I felt strongly about providing a thoughtful and complete update, with as much transparency as permitted and appropriate.

We were unwilling to publicly announce what we considered good news – that is our development plans and the now finalized BARDA award -- while we also were aware generally that our second quarter revenues were likely to be negatively affected, to a then-unknown extent, by the revocation. So again, thank you for your patience.

With that understanding, I would like to review our product development plans. We plan to submit two, separate EUA applications to the FDA:

- first, an application for an EUA for a revised version of the DPP COVID-19 IgM/IgG System,
- to be followed by an application for an EUA for a new point-of-care DPP COVID-19 Antigen System.

Our principal goal this morning is to provide you with additional color about:

1. the FDA process that led to the EUA revocation;
2. our product development plans -- including how the Chembio team is working to limit the effects of the FDA's revocation of the original EUA; and,
3. our preliminary estimated revenue results for the second quarter, including commentary on the sales and related cadence during the second quarter.

In the current circumstances, given how quickly things are evolving and the other considerations I've described, Neil and I will not be in a position to take questions today. We acknowledge that may be frustrating, which is why we have worked hard to prepare today's update. Please rest assured that we will, as usual, respond to questions following our conference call in early August surrounding second quarter results. We appreciate your understanding of the present situation.

To begin our discussion of our DPP COVID-19 IgM/IgG System, I would like to briefly address the FDA process that led to the EUA revocation. We do not think it is appropriate or productive to get into details and specifics of the earlier regulatory process that led to the revocation. We do, however, believe that providing you with a high-level description of our understanding of the timing of the FDA's establishment of a key element of that process -- namely, specific performance criteria utilizing National Institutes of Health/National Cancer Institute, or NCI, testing -- may help you better understand our plans for moving forward.

When the EUA was granted for our system on April 14th, it was one of the first EUAs granted by the FDA for a COVID-19 serology test and the only EUA that included a claim for fingerstick blood. As you may recall, the FDA was moving quickly to help address the rapidly developing effects of the pandemic in the U.S. At the time our EUA was granted, the FDA had not publicly identified any performance criteria to be used in evaluating COVID-19 serology tests. The flexibility of our proprietary DPP platform enabled us to develop a COVID-19 serology test on an expedited timetable.

On June 16th, the FDA stated it was revoking our EUA based in part on the performance of our system in the NCI's methodology for the evaluation of COVID-19 serology tests. The FDA's original letter of authorization for the EUA required our participation in the NCI study. However, the letter stated that the NCI submission and evaluation would only be used to revise our product labeling. After we learned of the results of the NCI study -- but before the FDA took action with respect to the EUA -- we engaged in a number of communications with the FDA about the results of the NCI study and other topics.

The regulatory process with respect to performance criteria, including the use of the NCI evaluation, was only a part of our interactions with the FDA. I would like to focus on this aspect of the process, because it provides two key takeaways that convey why our team continues to be excited about our opportunities in the market for COVID-19 serology test kits.

- first, we stand behind the real-world clinical data, including that which we submitted to the FDA, in connection with the DPP COVID-19 IgM/IgG System EUA, and
- second, the FDA's recent identification of the performance criteria for COVID-19 serology tests has clarified our path forward in working to revise the DPP COVID-19 IgM/IgG System to meet or exceed current FDA requirements.

I'd like to give you some more insight into each of these.

As I said, first, we stand behind our real-world clinical data for our original DPP COVID-19 System, including the data we submitted to the FDA in connection with our system's EUA.

- While we are disappointed by the FDA's decision to revoke our EUA, we acknowledge the policy change that led the FDA to create performance criteria and rely on the NCI study for those purposes.
- On April 15, 2020, the DPP COVID-19 IgM/IgG System was granted an EUA. Subsequently, the FDA announced the adoption of a performance review process based in part on a NCI methodology for the evaluation of COVID 19 serology tests. The NCI report acknowledges that this process, which evaluates COVID-19 serology test sensitivity and specificity using a panel of pre-selected samples, may not be indicative of either performance in the real-world or performance of finger stick blood as used in the Chembio system.
- In addition, the NCI study does not invalidate the real-world clinical data that we submitted to the FDA, including that compiled by Chembio as well as independent evaluators at two university medical centers.
- The importance of our system's real-world performance has been highlighted by a number of customers. One customer, for example, left us an unsolicited voice message last Thursday asking how they might help make our system available again in the U.S. in light of [quote] "customers believing in your technology based on real data on the front line and comparing it to other test kits at the same time." [unquote]

As a second takeaway, the FDA's identification of its performance criteria for COVID-19 serology tests has clarified our path forward in working to revise the DPP COVID-19 IgM/IgG System to meet or exceed current FDA requirements.

- When our EUA was revoked, we began working literally the next day to modify the design of our COVID-19 serology test to achieve performance targets consistent with the NCI study that, as mentioned above, were issued subsequent to the granting of our original EUA.
- As I've said, our intention is to submit an application for a new EUA. The versatility of our DPP platform was critical to our ability to develop the initial DPP COVID-19 IgM/IgG System quickly, and we expect that same flexibility will facilitate our objective of revising the system to meet the FDA performance criteria.
- Based on the progress we have made to date, we expect to submit an EUA application for a revised DPP COVID-19 IgM/IgG System during the third quarter of 2020.
- Please be aware that these plans, as with plans for product development generally, are subject to change due to unexpected developments. Among other things, the FDA continues to gain new information and experience, that they may choose to incorporate in new or updated EUA requirements or changes to regulatory processes or review timelines. Indeed, in modifying our serology system, we are seeking to respond to the FDA's new performance criteria, as well as the rapidly evolving scientific and clinical understanding of the virus that led to the adoption of those criteria.

As I've said, the EUA revocation has been a setback for Chembio, but we are working hard towards the goal of making that a short-term setback. We have confidence in the flexibility of our platform and the expertise of our scientists, and we are optimistic that we can meet the challenge and move forward with a revised rapid DPP COVID-19 serology system. This is currently our top priority, and we are addressing the situation with urgency, as we and our customers know the benefits our test can provide to clinicians and patients in facing the pandemic.

I would now like to transition to the expansion of our COVID testing portfolio. We know that our DPP technology offers the flexibility to produce different types of tests where there are unmet needs for patient management. I'm pleased to share that we conducted feasibility work for an antigen detection system and, following positive preliminary results, we decided to pursue development of a point-of-care DPP COVID-19 Antigen System, which currently is expected to consist of a DPP COVID-19 Antigen Assay and a DPP Micro Reader, and use a respiratory specimen such as a nasal or nasopharyngeal swab, to detect COVID-19 antigens.

We intend to bring an antigen system to market to help with the rapid and direct detection of the COVID-19 virus. As with other DPP-based systems, we expect it to run in approximately 15 minutes without requiring the significant up-front investment and infrastructure needed for molecular detection systems. We believe our simpler, point-of-care design, based on our DPP technology will be able to help identify infection rates closer to real time, where and when needed.

As announced yesterday, we were honored to be awarded a contract from the Biomedical Advanced Research and Development Authority, known as BARDA, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The contract is intended to assist in our development and pursuit of an EUA for our a COVID-19 point-of-care antigen system based on our DPP platform. The award totals approximately $628,000 and is to be distributed in periodic funding over the next several months. We will use the grant funds to develop the DPP COVID-19 Antigen System and submit it for an EUA.

In addition, building upon our announced product development efforts, we are focused on commercializing our current COVID-19 System outside the United States. We also continue to sell our legacy products and advance regulatory processes, including the PMA for DPP HIV-Syphilis, and our recently awarded FDA 510(k) for the DPP Zika IgM System, which notably marked the FDA's approval of the Micro Reader, which as you have seen is the same analyzer being used in our COVID-19 programs.

In that context, I'm pleased to announce that UNICEF has exercised a portion of their option under our previously announced Long Term Agreement for our DPP Zika/Chikungunya/Dengue IgM/IgG Systems, which includes the DPP Micro Reader from $1.5 to $2.5 million. An initial partial shipment was completed during the second quarter and the balance continues periodically through the third quarter of 2021. This DPP System provides six separate results from a single fingerstick drop of blood, and it is the same platform we use for our COVID-19 serology and antigen systems.

This has been a challenging period for the company, but our commitment to producing high quality point-of-care tests is unwavering. We are confident in our scientific team and appreciate all of our employees' continued dedication and sense of urgency as we work through these challenges. At the same time, we remain excited about the opportunities ahead of us and the contributions we can make in combating this pandemic around the world.

I would now like to turn the microphone over to Neil, who will discuss preliminary estimates of revenues for the second quarter.

NEIL GOLDMAN, EXECUTIVE VP & CHIEF FINANCIAL OFFICER

Thanks, Rick, and good morning, everyone. We are supplementing our discussion of our product development plans with the limited financial information for the second quarter that is known to us one week into July. That information consists of preliminary estimates of certain revenue amounts, as well as an estimate of our cash and cash equivalents position at the end of the second quarter. We have begun working on closing the books for the second quarter, but for obvious reasons our procedures are not far enough along to provide additional financial information for the quarter. We expect to issue our earnings release for the second quarter during the first full week of August. Until that time, please understand that our preliminary estimates, particularly as to revenue, remain subject to change and that no inferences should be made regarding other second quarter financial information, whether as compared to prior periods or otherwise.

Total revenues for the three months ended June 30, 2020 are expected to be in the range of $4.5 million to $4.7 million, subject to increase by up to an additional $2.5 million of revenue for products that were shipped outside the United States during the quarter. While Chembio continues to both ship DPP COVID-19 IgM/IgG systems and pursue additional opportunities outside the United States, there is of course, always the possibility that regulators in foreign jurisdictions may act based upon the FDA's recent revocation of the EUA for the system. Chembio expects total revenues to be finalized prior to issuance of our financial statements for the quarter and six months ended June 30, 2020. Revenues from Chembio's COVID-19-related sales for the quarter are estimated to range from $0.8 million to $3.3 million, and inclusive in the high end of that range is the additional $2.5 million of product shipped outside the United States.

The other portion of our estimated revenues include R&D Services and Royalty revenues, together with product revenues from HIV and other infectious disease tests. As you might expect, within the U.S., many HIV clinics have been closed due to the COVID-19 pandemic, and internationally, both governments and global NGOs have shifted their focus to addressing the pandemic. Our non-COVID-related business appears to have been relatively balanced across the U.S., EMEA, Latin America, and Africa.

Cash and cash equivalents at June 30, 2020 are estimated to total approximately $36.6 million, including approximately $3.3 of restricted cash and cash equivalents, compared with $11.2 million at March 31, 2020. The increase in cash and cash equivalents compared to the prior quarter reflect customer collections, the approximate net proceeds from the Company's secondary equity raise of $28.4 million, offset by capital expenditures, operating costs, and other items.

With that as a backdrop, I will now provide some information on the cadence of the second quarter leading up to the FDA's decision.

- During the weeks between Chembio receiving the FDA authorization and shortly after receiving EUA approval, we received approximately two thousand leads, or expressions of interest in purchasing the DPP COVID-19 IgM/IgG System. Our U.S. sales and marketing team immediately began qualifying those leads, including confirming, in accordance with our EUA, that potential U.S. customers had at least a moderately complex laboratory designation under CLIA.
- As we have described in the past, our business strategy includes a razor-razorblade model of placing Micro Reader analyzers in the hands of customers, who then will place ongoing re-orders of the DPP Assays themselves. Therefore, rather than focusing on individual, one-time "large" customer orders, our sales team sought to begin building a customer base intended to eventually generate recurring, predictable revenue… initially using COVID-19 tests and with the longer term goal of providing a broader menu of product solutions.
- We encountered little resistance in the U.S. market to direct-sales price points for the tests at the higher end of the $20-$30 range that we had previously observed in the market. We attributed this to the value of Chembio's DPP COVID-19 System, which provides two separate results -- both IgM and IgG – from a single fingerstick drop of blood. In addition, feedback from both customers and our CMS consultants confirmed that private and public payors were providing reimbursement generally ranging from $35 to $45 for each of these results, for a combined amount of $70 to $90 per patient.
- Similarly, customer feedback for our sub-$1,500 price points for both Micro Reader analyzers was positive.

As we had anticipated, it became imperative for us to significantly increase our distribution channels to take advantage of the numerous opportunities.

- On May 18, 2020, we announced an agreement for Thermo Fisher Scientific's healthcare channel to distribute our DPP COVID-19 System in the United States. Over the next few weeks, we worked with Fisher to train their sales team and provide field sales support, and we received modest initial orders. Unfortunately, the EUA revocation was issued just as Fisher was beginning to gain sales traction.
- On June 2, 2020, Chuck Caso joined Chembio as Vice President of North American Sales and Marketing, and he immediately began working with our sales team and Fisher, plus evaluating expanded distribution.
- Since beginning shipments of our DPP COVID-19 System, we were balancing our allocation of product between the U.S. and Brazil. Considering our direct sales run-rate, shipment schedule to Brazil, demand indications from Fisher, and other opportunities at the time of the EUA revocation, our sales team was projecting, for internal planning purposes, total revenues for the second quarter of 2020 ranging from $11 to $13 million.

On the manufacturing front, we were prepared to fulfill that demand. As Rick stated during our Q1'2020 earnings call, we ramped our production according to market demand. We were also pleased with the responsiveness of our team at Chembio Diagnostics Germany that manufactures the analyzers, including their success at adapting to challenges in the international electronic component supply chain related to the COVID-19 pandemic.

Now, I'll turn the call back to Rick for concluding remarks.

RICK EBERLY

Thanks, Neil.

The COVID-19 testing market has experienced exponential growth and continues to unfold in many new markets, including customers from outside historical healthcare verticals such as companies with back-to-work programs. We are very optimistic about this opportunity and confident in our ability to both take significant share in this market and sustain a leadership position for the long-term.

There are many points of view as to how the COVID-19 testing market will unfold and how long the period will be sustained. We believe that, both in the U.S. and around the world, the answers to those questions will depend on both governmental policies and personal decisions. What is clear to us is that the pandemic is ongoing and persistent, driving the need for decentralized testing solutions.

Based on our product development timeline as discussed today, we plan to continue expanding our marketing, customer service, distribution channels, and commercial infrastructure to capitalize on the continued market demand and be part of the solution to the pandemic.

In conclusion, I want to reiterate my long-term strategy to leverage the opportunity with COVID-19 products and build Chembio into a high value diagnostics company.

- As discussed today, we are planning to submit an application to the FDA for two Emergency Use Authorizations: first, a revised version of the DPP COVID-19 IgM/IgG System during the third quarter of 2020 – that's a COVID-19 point-of-care serological test system, and second, the DPP COVID-19 Antigen System, a new point-of-care antigen test system that is supported by a BARDA grant of approximately $628,000
- Longer term, our product strategy is focused on diversifying from historically low margin, tender-driven products to higher value, higher margin products.
- And finally, we will build off the leadership we have established in our base business. Our future product portfolio will utilize the platform, technology, and scientific expertise developed in Chembio's global infectious disease markets.

Thank you for joining us. For reasons I explained at the start of the call, we will not be responding to questions today. We will, as usual, look forward to responding to questions following our conference call in early August regarding second quarter results. We sincerely appreciate your understanding that we are trying to be as transparent as we can be in the current environment. Thank you, and I wish everyone good health and safety.

Exhibit 99.3

Chembio Announces Plans to Seek EUA Approval from FDA for Revised DPP COVID-19 IgM/IgG System and New DPP COVID-19 Antigen System

HAUPPAUGE, N.Y., July 6, 2020 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading global point-of-care diagnostic company focused on infectious diseases, today announced its plans to submit applications to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) for a revised version of the DPP COVID-19 IgM/IgG System, a COVID-19 point-of-care serology system, and the DPP COVID-19 Antigen System, a new COVID-19 point-of-care antigen system.

Revised DPP COVID-19 IgM/IgG System

The DPP COVID-19 IgM/IgG System consists of Chembio's serology test for COVID-19 and a DPP Micro Reader analyzer. On April 15, 2020, the DPP COVID-19 IgM/IgG System was granted an EUA. Subsequently, the FDA announced performance review based in part on a National Institutes of Health/National Cancer Institute (NCI) process for the evaluation of COVID-19 serology tests. The NCI report acknowledges that this process, which evaluates COVID-19 serology test sensitivity and specificity using a panel of pre-selected samples, may not be indicative of either performance in the real-world or performance of finger stick blood as used in the Chembio system.

On June 16, 2020, the FDA revoked the EUA for the DPP COVID-19 IgM/IgG System. As a result, Chembio is revising its system with the objective of meeting the FDA's new criteria, including the use of the NCI process. The versatility of Chembio's proprietary DPP platform was critical to Chembio's ability to initially develop the DPP COVID-19 IgM/IgG System expeditiously, which enabled the system to become one of the first COVID-19 antibody tests to receive an EUA. The flexibility of the DPP platform will facilitate Chembio's objective of revising the system to meet the new FDA performance criteria, and Chembio expects, based on its development efforts to date, to apply for an EUA for the revised system during the third quarter of 2020.

"We believe recent positive feedback from a number of customers confirms that our rapid DPP COVID-19 IgM/IgG System can add tremendous value in quickly evaluating patient COVID-19 IgM and IgG antibody values in a variety of settings. We remain confident that the unique features and benefits of our test platform will make it one of the preferred solutions for antibody testing worldwide," stated Rick Eberly, Chembio's President and Chief Executive Officer. "In modifying our serology system, we are seeking to respond to the FDA's new performance criteria, as well as the rapidly evolving scientific and clinical understanding of the virus that led to the adoption of those criteria."

Chembio continues to offer the DPP COVID-19 IgM/IgG System outside the United States.

DPP COVID-19 Antigen System

After having recently obtained positive results from feasibility work, Chembio is pursuing development of a point-of-care DPP COVID-19 Antigen System. The DPP COVID-19 Antigen System is expected to consist of a DPP COVID-19 Antigen Assay and a DPP Micro Reader analyzer and to use a respiratory specimen, such as a nasal or nasopharyngeal swab, to detect COVID-19 antigens. The new system will be developed using the DPP platform, with the objective of offering COVID-19 detection for diagnosis at the point of care, to improve clinical outcomes.

“We intend to bring an antigen system to market to help with the rapid and direct detection of the COVID-19 virus,” stated Mr. Eberly. “As with other DPP-based systems, we expect it to run in approximately 15 minutes without requiring the significant up-front investment and infrastructure needed for molecular detection systems. We believe a simpler, point-of-care design based on our DPP technology will be able to help identify infection rates closer to real time, where and when needed.”

In a separate press release issued today entitled “Chembio Diagnostics Awarded BARDA Grant for Development of DPP COVID-19 Point-of-Care Antigen System,” Chembio announced it had been awarded a contract from the Biomedical Advanced Research and Development Authority, known as BARDA, intended to assist Chembio in developing its COVID-19 point-of-care antigen system and in submitting an EUA for the system.

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 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 with respect to the development of, and obtaining an EUA for, a revised COVID-19 serology system and a COVID-19 point-of-care antigen system. 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: Chembio’s research, development and commercialization efforts may not result in its successfully and timely developing and commercializing either or both of the proposed COVID-19 systems; Chembio may be unable to anticipate or respond to FDA regulatory requirements, or changes in those requirements, with respect to one or both of the proposed COVID-19 systems, or otherwise may be unable to obtain or maintain an EUA, or other necessary regulatory approvals, for either or both of such COVID-19 systems, including approvals for use of the COVID-19 antigen system as a point-of-care solution; potential customers may not adopt antibody or point-of-care antigen systems to the extent expected by Chembio; and Chembio may not be able to compete successfully with other companies that have developed, or develop in the future, COVID-19 antibody or antigen detection systems, some of which companies have substantially greater resources than Chembio. 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.” Readers 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.

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Exhibit 99.4

Chembio Diagnostics Awarded BARDA Contract for Development of DPP COVID-19 Point-of-Care Antigen System

HAUPPAUGE, NY, July 6, 2020 -- Chembio Diagnostics, Inc. (Nasdaq: CEMI), a leading point-of-care diagnostic company focused on infectious diseases, today announced it has been awarded a contract from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. The contract is intended to assist Chembio in developing a COVID-19 point-of-care antigen system using Chembio's proprietary DPP technology and requesting a U.S. Food and Drug Administration Emergency Use Authorization (EUA) for the system. The award totals $628,071 and is to be distributed in periodic funding over the next several months.

Chembio will use the funds under contract number 75A50120C00138 to accelerate development of its DPP COVID-19 Antigen System, which is expected to consist of a DPP COVID-19 Antigen Assay and DPP Micro Reader and to use a respiratory specimen, such as a nasal or nasopharyngeal swab, to detect SARS-CoV-2 antigens.

"We are honored to again partner with BARDA and appreciate their support on a shared mission to expand and decentralize COVID-19 testing," stated Rick Eberly, Chembio's President and Chief Executive Officer. "We believe offering virus detection for diagnosis at the point of care can improve clinical outcomes and play a major role in combating the ongoing pandemic."

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