

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): September 7, 2022



CHEMBIO DIAGNOSTICS, INC.

Nevada
(State or Other Jurisdiction of Incorporation or
Organization)

001-35569
(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. ☐

On September 7, 2022, we filed with the Securities and Exchange Commission a registration statement on Form S-1, or the Registration Statement, relating to a proposed public offering of our common stock, par value \$0.01 per share, and pre-funded warrants to purchase shares of common stock, in each case together with warrants to purchase shares of common stock. We included the following information in the Registration Statement:

Recent Developments*Strategic Matters*

The Company recently completed its future strategic planning process (the “Strategic Planning Process”), which has been approved by our board of directors. The plan is premised on a transformation of the Company that along with other pillars, bases our commercial focus on differentiated point-of-care and over-the-counter target markets with higher average-selling prices in the United States, Europe Middle East, and Africa (the “EMEA”), and Brazil. Aligned with our Global Competitiveness Program, we are planning our sales focus opportunities to be on our core product portfolio with higher margins in growth markets and recurring revenues. We have begun implementing cost reduction programs to right-size the business, and we plan to leverage our manufacturing automation investments in recent years to scale with future higher volumes.

In addition, our board of directors has previously initiated a review of strategic alternatives, including a potential sale or merger transaction, and a review of our financing strategy. We have retained Craig-Hallum Capital Group LLC as our financial advisor to assist with this strategic review. This strategic review process is substantially complete, and we are not currently in active discussions regarding any such strategic transaction. Even if a sale, merger or financing transaction were to be consummated, it may not return any value to holders of our common stock. Regardless of whether we execute a sale, merger or financing transaction, the adverse pressures negatively impacting our business that we have experienced may continue or intensify, and we will likely continue to face all of the risks we currently face, including the risk that we may not be able to continue as a going concern.

Sale of Common Stock under the ATM Agreement

As of September 6, 2022, we have sold 14,372,538 shares of common stock, for gross proceeds of \$44.7 million and net proceeds, after giving effect to commissions and other transaction costs, of \$42.6 million under the At the Market Offering Agreement, entered into July 19, 2021, pursuant to which we may sell from time to time, at our option, up to an aggregate of \$60.0 million of shares of common stock through Craig-Hallum Capital Group LLC, as sales agent (the “ATM Agreement”). These sales include sales of common stock for gross proceeds of \$3.9 million and net proceeds of \$3.8 million since June 30, 2022. We are currently subject to General Instruction I.B.6 to Form S-3 (the “baby shelf rule”) and are generally limited to sales pursuant to our existing shelf registration statement during any twelve-month period of an amount equal to one-third of the aggregate market value of our common equity held by non-affiliates.

Contract from the CDC for Development and Clinical Validation of Dual-Path Platform Syphilis Screen & Confirm Assay

On September 6, 2022, the Company announced a \$3.2 million contract award from the Centers for Disease Control and Prevention (CDC) for the development and clinical validation of a rapid point-of-care (POC) diagnostic test for syphilis. We will undertake to develop a syphilis test and confirm assay based on our Dual Path Platform (DPP) technology and proprietary DPP Micro Reader II.

Litigation*Putative Stockholder Securities Class-Action Litigation*

We and the other parties in the consolidated putative class action litigation captioned *In re Chembio Diagnostics, Inc. Securities Litigation* convened an in-person mediation before a mediator on July 14, 2022. Although the parties did not resolve the matter during that session, they continued their discussions through the mediator. On August 26, 2022, we and the other parties reached an agreement in principle on the financial terms of a proposed settlement of all claims that were asserted, or could have been asserted, on an individual and class-wide basis against all defendants in the case, including under both the Securities Act and the Securities Exchange Act of 1934 (the “Exchange Act”). The agreement in principle to settle contemplates an \$8.1 million payment on behalf of the defendants, approximately \$209,000 of which is to be paid by us with the remainder being funded by certain of our insurers. After the date of this prospectus, the parties will undertake to negotiate and prepare a formal stipulation of settlement setting forth the full terms of the proposed settlement, as well as the related documents which will be submitted to the court for approval together with the parties’ stipulation.

Accordingly, on August 29, 2022, we and certain other defendants filed a letter motion requesting that the court stay all proceedings to allow the parties to focus their efforts on negotiating and preparing the stipulation or settlement and related papers. The court granted the motion on August 31, 2022 and ordered the parties to file their stipulation on or before October 17, 2022. There can be no assurance that the parties will be able to reach agreement on the terms of a stipulation or settlement, or that if the parties reach agreement, the stipulation will be granted preliminary and final approval by the court.

Putative Stockholder Derivative Litigation

The parties in the actions captioned *Karen Wong, derivatively on behalf of Chembio Diagnostics, Inc., Plaintiff v. Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan and John G. Potthoff, Defendants, and Chembio Diagnostics, Inc., Nominal Defendant* and *Michelle Chen, derivatively on behalf of Chembio Diagnostics, Inc., Plaintiff v. Richard L. Eberly, Gail S. Page, Neil A. Goldman, Javan Esfandiari, Katherine L. Davis, Mary Lake Polan and John G. Potthoff, Defendants, and Chembio Diagnostics, Inc., Nominal Defendant* have reached an agreement in principle on the terms of a proposed settlement of both actions, other than with respect to the maximum amount of attorneys’ fees which plaintiffs may request that the court approve, and have executed a memorandum of understanding to that effect. The proposed settlement contemplates the adoption of certain corporate governance measures and does not entail any monetary compensation or payment by us other than attorneys’ fees not exceeding an amount to be negotiated.

There can be no assurance that we and the other parties to the putative stockholder derivative action will reach agreement on the maximum amount of plaintiffs’ attorneys’ fees that plaintiffs may request court approval on or on the terms of a formal stipulation of settlement, or that the court will approve the terms of a stipulation of settlement.

Liquidity Issues

We may experience significant liquidity issues in the future, and, as of August 31, 2022, we had approximately \$22.3 million in cash and cash equivalents. On September 30, 2022, we are required to begin making \$300,000 monthly principal payments on our \$20 million Credit Agreement (as defined below) with the remaining balance due on September 4, 2023. In the event the offering to which the Registration Statement relates does not generate sufficient liquidity or we are not able to refinance the debt owed under our Credit Agreement (whether at maturity or earlier in the event of a covenant breach and acceleration), we may be forced to pursue a reorganization under the U.S. Bankruptcy Code.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy any of our securities, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act, nor shall there be any sale of our securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

This Current Report on Form 8-K contains statements reflecting our views about our future performance that constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are generally identified through the inclusion of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “objective,” “outlook,” “plan,” “potential,” “project,” “seek,” “should,” “strategy,” “target,” “will,” “would” or variations of such words or similar expressions. All statements addressing our future operating performance, and statements addressing events and developments that we expect or anticipate will occur in the future, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based upon currently available information, operating plans, and projections about future events and trends.

This Current Report on Form 8-K contain estimates, projections and other data concerning our industry, our business and the markets for our products. Where expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by the World Health Organization (the “WHO”). We also include data that we have compiled, obtained, identified or otherwise derived from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. Other than the WHO, we do not expressly refer to the sources from which this data is derived.

Forward-looking statements and statistical estimates inherently involve risks and uncertainties that could cause actual results to differ materially from those predicted or expressed in this report. These risks and uncertainties include those described in the “Risk Factors” section in the Prospectus and in Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and in Part II, Item 1A, “Risk Factors,” of subsequently filed Quarterly Reports on Forms 10-Q. 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 COVID-19. Investors are cautioned not to place undue reliance on any forward-looking statements or statistical estimates, which speak only as of the date they are made. We undertake no obligation to update any forward-looking statement or statistical estimate, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
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: September 7, 2022

By: /s/ Richard L. Eberly

Chief Executive Officer and President
