UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended June 30, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from: _____ to _____

000-30379
(Commission File Number)

Chembio Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Nevada	**88-0425691**
(State or other jurisdiction of incorporation)	*(IRS Employer Identification Number)*

555 Wireless Blvd.
Hauppauge, NY 11788
(Address of principal executive offices including zip code)

(631) 924-1135
(*Registrant's telephone number, including area code)*

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☐
Emerging growth company ☐

Accelerated filer ☒
Smaller reporting 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.
Yes ☐ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

As of July 31, 2020, the registrant had 20,161,542 shares outstanding of its common stock, $.01 par value.

Quarterly Report on Form 10-Q
For The Quarterly Period Ended
June 30, 2020

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Unless the context requires otherwise, the words ‘‘we,’’ “us,” ‘‘our,’’ ‘‘our company,’’ ‘‘Chembio,’’ and similar terms refer to Chembio Diagnostics, Inc. and its consolidated subsidiaries.

DPP, STAT-PAK, STAT-VIEW and SURE CHECK are our registered trademarks, and CHEMBIO, MICRO READER and our logo design are our trademarks. For convenience, these trademarks appear in this report without ® and ™ symbols, but that practice does not mean that we will not assert, to the fullest extent under applicable law, our rights to the trademarks.

FORWARD-LOOKING STATEMENTS AND STATISTICAL ESTIMATES

This report 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 report contains 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, or 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 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 Part I, Item 1A “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 13, 2020, in Part II, Item 1A. “Risk Factors” in our Quarterly Reoprt on Form 10-Q for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on May 4, 2020, and in Part II, Item 1A, “Risk Factors,” of this report. 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. 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.

PART I

Item 1. FINANCIAL STATEMENTS

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

	(Unaudited) June 30, 2020	December 31, 2019
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 36,427,468**	$ 18,271,352
Accounts receivable, net of allowance for doubtful accounts of $156,000 and $62,000 as of June 30, 2020 and December 31, 2019, respectively	**2,610,587**	3,661,325
Inventories, net	**14,131,540**	9,598,030
Prepaid expenses and other current assets	**742,908**	693,013
TOTAL CURRENT ASSETS	**53,912,503**	32,223,720
FIXED ASSETS:		
Property, plant and equipment, net	**7,705,890**	5,933,569
Finance lease right-of-use asset, net	**258,884**	210,350
OTHER ASSETS:		
Operating lease right-of-use assets, net	**6,515,282**	7,030,744
Intangible assets, net	**3,605,194**	3,914,352
Goodwill	**5,534,624**	5,872,690
Deposits and other assets	**429,884**	543,539
TOTAL ASSETS	**$ 77,962,261**	$ 55,728,964
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 9,290,887**	$ 5,526,243
Deferred revenue	**4,097,155**	125,000
Finance lease liabilities	**55,712**	41,894
Operating lease liabilities	**776,691**	568,294
Note payable	**75,708**	180,249
TOTAL CURRENT LIABILITIES	**14,296,153**	6,441,680
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,565,019**	6,969,603
Long-term finance lease liabilities	**210,408**	171,953
Long-term debt, less current portion, net	**17,903,401**	17,644,149
Deferred tax liability	**250,326**	466,326
TOTAL LIABILITIES	**39,225,307**	31,693,711
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY:		
Preferred stock - 10,000,000 shares authorized; none outstanding	-	-
Common stock - $0.01 par value; 100,000,000 shares authorized; 20,194,832 shares and 17,733,617 shares issued at June 30, 2020 and December 31, 2019, respectively	**201,948**	177,335
Additional paid-in capital	**124,143,171**	95,433,077
Accumulated deficit	**(84,428,349)**	(71,585,003)
Treasury stock - 33,290 and 0 shares at cost, at June 30, 2020 and December 31, 2019, respectively	**(150,919)**	-
Accumulated other comprehensive (loss) income	**(1,028,897)**	9,844
TOTAL STOCKHOLDERS' EQUITY	**38,736,954**	24,035,253
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 77,962,261**	$ 55,728,964

See accompanying notes to condensed consolidated financial statements

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

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2020	June 30, 2019	**June 30, 2020**	June 30, 2019
REVENUES:				
Net product sales	**$ 3,791,574**	$ 8,785,041	**$ 9,508,166**	$ 15,409,326
R&D and grant revenue	**1,193,973**	854,264	**2,101,660**	2,556,053
License and royalty revenue	**125,625**	248,831	**360,929**	465,022
TOTAL REVENUES	**5,111,172**	9,888,136	**11,970,755**	18,430,401
COSTS AND EXPENSES:				
Cost of product sales	**5,670,737**	6,989,975	**10,045,179**	12,001,611
Research and development expenses	**1,922,306**	2,101,020	**3,881,159**	4,318,652
Selling, general and administrative expenses	**4,397,593**	4,096,942	**8,554,234**	8,110,013
Severance, restructuring and other related costs	**387,540**	-	**1,110,658**	-
Acquisition costs	-	-	**63,497**	395,612
	12,378,176	13,187,937	**23,654,727**	24,825,888
LOSS FROM OPERATIONS	**(7,267,004)**	(3,299,801)	**(11,683,972)**	(6,395,487)
OTHER INCOME:				
Interest (expense) income	**(712,052)**	5,918	**(1,374,192)**	12,602
LOSS BEFORE INCOME TAXES	**(7,979,056)**	(3,293,883)	**(13,058,164)**	(6,382,885)
Income tax benefit	**(135,259)**	(107,203)	**(214,818)**	(379,672)
NET LOSS	**$ (7,843,797)**	$ (3,186,680)	**$ (12,843,346)**	$ (6,003,213)
Basic loss per share	**$ (0.42)**	$ (0.19)	**$ (0.71)**	$ (0.36)
Diluted loss per share	**$ (0.42)**	$ (0.19)	**$ (0.71)**	$ (0.36)
Weighted average number of shares outstanding, basic	**18,868,144**	16,914,171	**18,032,723**	16,906,936
Weighted average number of shares outstanding, diluted	**18,868,144**	16,914,171	**18,032,723**	16,906,936

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2020	June 30, 2019	**June 30, 2020**	June 30, 2019
Net loss	**$ (7,843,797)**	$ (3,186,680)	**$ (12,843,346)**	$ (6,003,213)
Other comprehensive loss:				
Foreign currency translation adjustments	**(175,447)**	(313,225)	**(1,038,741)**	(111,039)
Comprehensive loss	**$ (8,019,244)**	$ (3,499,905)	**$ (13,882,087)**	$ (6,114,252)

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	For The Six Months Ended June 30, 2020							
	Common Stock		Additional	Treasury Stock		Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Paid-in-Capital	Shares	Amount	Deficit	Income	Total
Balance at December 31, 2019	**17,733,617**	**$ 177,335**	**$ 95,433,077**	**-**	**$ -**	**$ (71,585,003)**	**$ 9,844**	**$ 24,035,253**
Common Stock:								
Restricted stock issued	34,249	343	117,956	-	-	-	-	118,299
Restricted stock compensation, net	(440,631)	(4,406)	(292,495)	-	-	-	-	(296,901)
Shares tendered for withholding taxes	-	-	145,056	(31,486)	(145,056)	-	-	-
Options:								
Stock option compensation	-	-	139,449	-	-	-	-	139,449
Comprehensive loss	-	-	-	-	-	-	(863,294)	(863,294)
Net loss	-	-	-	-	-	(4,999,549)	-	(4,999,549)
Balance at March 31, 2020	**17,327,235**	**$ 173,272**	**$ 95,543,043**	**(31,486)**	**$ (145,056)**	**$ (76,584,552)**	**$ (853,450)**	**$ 18,133,257**
Common Stock:								
Issuance of stock, net	2,619,593	26,196	28,410,545	-	-	-	-	28,436,741
Restricted stock issued	18,858	189	(189)	-	-	-	-	-
Restricted stock compensation, net	(29,543)	(296)	262,405	-	-	-	-	262,109
Shares tendered for withholding taxes	-	-	(192,161)	(1,804)	(5,863)	-	-	(198,024)
Options:								
Exercised	5,528	55	(55)	-	-	-	-	-
Stock option compensation	-	-	122,115	-	-	-	-	122,115
Warrants exercised	253,161	2,532	(2,532)	-	-	-	-	-
Comprehensive loss	-	-	-	-	-	-	(175,447)	(175,447)
Net loss	-	-	-	-	-	(7,843,797)	-	(7,843,797)
Balance at June 30, 2020	**20,194,832**	**$ 201,948**	**$ 124,143,171**	**(33,290)**	**$ (150,919)**	**$ (84,428,349)**	**$ (1,028,897)**	**$ 38,736,954**

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	For The Six Months Ended June 30, 2019					
	Common Stock		Additional Paid-in-Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2018	**17,166,459**	**$ 171,664**	**$ 90,953,788**	**$ (57,909,874)**	**$ 112,196**	**$ 33,327,774**
Common Stock:						
Restricted stock compensation	-	-	281,248	-	-	281,248
Options:						
Stock option compensation	-	-	66,259	-	-	66,259
Comprehensive loss	-	-	-	-	202,186	202,186
Net loss	-	-	-	(2,816,533)	-	(2,816,533)
Balance at March 31, 2019	**17,166,459**	**$ 171,664**	**$ 91,301,295**	**$ (60,726,407)**	**$ 314,382**	**$ 31,060,934**
Common Stock:						
Restricted stock issued	375,000	3,750	(3,750)	-	-	-
Restricted stock compensation	-	-	307,774	-	-	307,774
Options:						
Exercised	24,075	241	(241)	-	-	-
Stock option compensation	-	-	69,097	-	-	69,097
Comprehensive loss	-	-	-	-	(313,225)	(313,225)
Net loss	-	-	-	(3,186,680)	-	(3,186,680)
Balance at June 30, 2019	**17,565,534**	**$ 175,655**	**$ 91,674,175**	**$ (63,913,087)**	**$ 1,157**	**$ 27,937,900**

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE SIX MONTHS ENDED
(Unaudited)

	June 30,2020	June 30, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 16,993,648**	**$ 17,627,823**
Cash paid to suppliers and employees	**(22,751,210)**	(24,421,683)
Cash paid for operating leases	**(457,277)**	(305,157)
Cash paid for finance leases	**(9,367)**	-
Interest and taxes, net	**(1,106,778)**	12,602
Net cash used in operating activities	**(7,330,984)**	(7,086,415)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Patent application costs	**(98,186)**	(72,295)
Acquisition of and deposits on fixed assets	**(2,351,160)**	(1,077,203)
Acquisitions	**-**	145,760
Net cash used in investing activities	**(2,449,346)**	(1,003,738)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance of stock, net	**28,436,741**	**-**
Stimulus package loan	**2,978,315**	-
Payment of stimulus package loan	**(2,978,315)**	**-**
Payments of tax withholding on stock award	**(343,080)**	-
Payments on note payable	**(104,542)**	(92,158)
Payments on finance leases	**(23,578)**	-
Net cash (used in) provided by financing activities	**27,965,541**	(92,158)
Effect of exchange rate changes on cash	**(29,095)**	161,835
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**18,156,116**	(8,020,476)
Cash and cash equivalents - beginning of the period	**18,271,352**	12,524,551
Cash and cash equivalents - end of the period	**$ 36,427,468**	**4,504,075**
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net loss	**$ (12,843,346)**	**$ (6,003,213)**
Adjustments:		
Depreciation and amortization	**1,441,823**	750,322
Benefit from deferred tax liability	**(216,000)**	(379,672)
Provision of doubtful accounts	**94,262**	**-**
Share based compensation	**347,141**	724,378
Changes in assets and liabilities:		
Accounts receivable	**1,050,738**	(360,037)
Inventories	**(4,533,511)**	(1,219,454)
Prepaid expenses and other current assets	**(49,894)**	131,752
Deposits and other assets	**113,655**	(255,124)
Accounts payable and accrued liabilities	**3,291,993**	(570,872)
Deferred revenue	**3,972,155**	95,505
Net cash used in operating activities	**$ (7,330,984)**	**$ (7,086,415)**
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 472,651**	**$ -**

See accompanying notes to condensed consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2020
(Unaudited)

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. ("Chembio") and its subsidiaries (collectively with Chembio, the "Company") develop and commercialize rapid tests used for the detection and diagnosis of infectious diseases.

The Company has been expanding its product portfolio based upon its proprietary DPP technology, a novel, rapid diagnostic platform that uses a drop of blood from the fingertip to provide high-quality, cost-effective diagnostic results in approximately 15 minutes.

The Company's product development and commercialization efforts are focused on infectious disease testing. During the six months ended June 30, 2020, the Company refocused its business strategy on the development and commercialization of the DPP COVID-19 System, which consists of a new serological test for COVID-19 and a Micro Reader analyzer. In the six months ended June 30, 2020, the Company developed, received regulatory approval in the US, Brazil and Europe for, and commercialized the DPP COVID-19 System, and began developing its strategy for a portfolio of products both related to and expanding beyond COVID-19. Near the end of that period, the U.S. FDA revoked the Company's Emergency Use Authorization for the DPP COVID-19 System, and the Company immediately began developing a revised version.

In addition to the DPP COVID-19 System, the Company has a broad portfolio of infectious disease products, which it expects to generate a diminished amount of revenue for the foreseeable future while it focuses on the development, manufacture, and commercialization of the DPP COVID-19 System and related products. Through Research & Development ("R&D") Services, the Company is developing tests for a rare disease in collaboration with Takeda Pharmaceutical Company Limited and a biomarker development project in collaboration with AstraZeneca plc.

Large and growing markets have been established for these types of tests, initially in high prevalence regions where they are indispensable for large-scale prevention and treatment programs. More generally, the Company believes there is and will continue to be a growing demand for diagnostic products that can provide accurate, actionable diagnostic information in a rapid, cost-effective manner at the point of care.

The Company's products are sold globally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments under the Company's DPP, STAT PAK, SURE CHECK and STAT-VIEW registered trademarks or under the private labels of the Company's marketing partners.

Through R&D Services, the Company develops tests for third parties using its DPP platform and, in limited cases, other platforms in projects that the Company believes have the potential to create value for the rest of its business. In addition, the Company routinely enters into arrangements with governmental and non-governmental organizations for the funding of certain R&D efforts.

NOTE 2 — SIGNIFICANT ACCOUNTING POLICIES:

(a) Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements include the accounts of Chembio and its subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X issued by the Securities and Exchange Commission (the "SEC"). Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto contained in Chembio's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the SEC.

The Company's future working capital needs will depend on many factors, including the rate of its business and revenue growth, the timing of its continuing automation of U.S. manufacturing, and the timing of its investment in research and development as well as sales and marketing. If the Company is unable to increase its revenues and manage its expenses in accordance with its operating plan, it may need to reduce the level or slow the timing of the growth plans contemplated by its operating plan, which would likely curtail or delay the growth in its business contemplated by its operating plan and could impair or defer its ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements.

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2020
(Unaudited)

All adjustments contained in the accompanying unaudited condensed consolidated financial statements are of a normal recurring nature and are necessary to present fairly the financial position of the Company as of June 30, 2020. Interim results are not necessarily indicative of results that may be expected for any other interim period or for an entire year.

(b) Use of Estimates:

The preparation of the consolidated financial statements in conformity with GAAP requires management to make assumptions and estimates that affect the amounts reported in the accompanying unaudited condensed consolidated financial statements and these notes. Judgments and estimates of uncertainties are required in applying the Company's accounting policies in certain areas. Generally, matters subject to estimation and judgment include accounts receivable realization, inventory obsolescence, asset impairments, recognition of revenue including variable consideration and pursuant to milestones, useful lives of intangible and fixed assets, stock-based compensation, business combinations, and deferred tax asset valuation allowances. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may be based upon amounts that differ from those estimates.

(c) Fair Value of Financial Instruments:

The carrying values for cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and other current liabilities approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents were $26.8 million and $16.0 million as of June 30, 2020 and December 31, 2019, respectively, of money market funds that are Level 1 fair value measurements under the hierarchy. The fair value of the Company's total debt of $20.0 million (carrying value of $17.9 million) and $20.0 million (carrying value of $17.6 million) as of June 30, 2020 and December 31, 2019, respectively, is a Level 2 fair value measurement under the hierarchy, and the carrying value approximates fair value.

Fair value measurements of all financial assets and liabilities that are measured and reported on a fair value basis are required to be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and,

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

(d) Cash and Cash Equivalents:

Cash and cash equivalents are defined as short-term, highly liquid investments with original maturities of three months or less, and include restricted cash of $3.3 million and $0 as of June 30, 2020 and December 31, 2019, respectively.

The Company is contractually obligated to maintain the restricted cash balance on deposit with a bank as security for the bank's issuance of a guarantee on behalf of the Company for its performance under purchase orders from and related advance payments by a customer. The Company expects that the restriction will be released within the next twelve months.

(e) Concentrations of Credit Risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of temporary cash investments and trade receivables. The Company places its temporary cash instruments with well-known financial institutions and, at times, may maintain balances in excess of the Federal Deposit Insurance Corporation insurance limit. The Company monitors the credit ratings of the financial institutions to mitigate this risk. Concentration of credit risk with respect to trade receivables is principally mitigated by the Company's ability to obtain letters of credit from certain foreign customers and its diverse customer base, both in number of customers and geographic locations.

(f) Fixed Assets:

Fixed assets are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets, which range from three to seven years. Leasehold improvements are amortized over the useful life of the asset or the lease term, whichever is shorter. Deposits paid for fixed assets are capitalized and not depreciated until the related asset is placed in service.

(g) License Agreements:

The Company records up-front payments related to license agreements as prepaids and amortizes them over their respective economic life. As of both June 30, 2020 and 2019, total prepaids related to license agreements were $100,000.

(h) Valuation of Long-Lived Assets and Intangible Assets:

Long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the related carrying amounts may not be recoverable. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment. If there are indications of impairment, the Company uses future undiscounted cash flows of the related asset or asset grouping over the remaining life in measuring whether the assets are recoverable. In the event such cash flows are not expected to be sufficient to recover the recorded asset values, the assets are written down to their estimated fair value. No impairment of long-lived tangible and intangible assets was recorded for the six months ended June 30, 2020 or 2019.

(i) Revenue Recognition:

The Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under Accounting Standards Update (“ASU”) 2014-09: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligation.

Product Revenue

Revenues from product sales are recognized and commissions are accrued when the customer obtains control of the Company’s product, which occurs at a point in time, typically upon tendering the product to the customer. The Company expenses incremental costs of obtaining a contract as and when incurred, because the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial. Freight and distribution activities on products are performed after the customer obtains control of the goods. The Company has made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in cost of product sales. The Company excludes certain taxes from the transaction price (e.g., sales, value added and some excise taxes).

The Company’s contracts with customers often include promises to transfer products or services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require judgment. Typical products sold are diagnostic tests and typical services performed are R&D studies. Revenues from product sales are recognized at a point-in-time and revenues from R&D studies are recognized ratably over the period of the agreement, unless the related performance obligations indicate otherwise.

Judgment is required to determine the stand-alone selling price (“SSP”) for each distinct performance obligation. SSP is directly observable and the Company can use a range of amounts to estimate SSP, as it sells products and services separately, and can determine whether there is a discount to be allocated based on the relative SSP of the various products and services, for the various geographies.

The Company's payment terms vary by the type and location of the Company's customer and products or services offered. Payment terms differ by jurisdiction and customer, but payment is generally required in a term ranging from 30 to 60 days from date of shipment or satisfaction of the performance obligation.

Reserves for Discounts and Allowances

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers. The Company's process for estimating reserves established for these variable consideration components does not differ materially from its historical practices.

Product revenue reserves, which are classified as a reduction in product revenues, are generally related to discounts. Estimates of variable consideration and the determination of whether to include estimated amounts in the transaction price are based on all information (historical, current, and forecasted) that is reasonably available to the Company, taking into consideration the type of customer, the type of transaction, market events and trends, and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts, allowances and returns may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative revenues recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on revenue and earnings in the period of adjustment.

License and Royalty Revenue

The Company receives royalty revenue on sales by its licensee of products covered under patents that the Company owns. The Company does not have future performance obligations under this license arrangement. The Company records revenue based on estimates of the sales that occurred during the relevant period as a component of license and royalty revenue. The relevant period estimates of sales are based on interim data provided by the licensee and analysis of historical royalties that have been paid to the Company, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenue are adjusted for in the period in which they become known, typically the following quarter. Historically, adjustments have not been material when compared to actual amounts paid by licensees.

R&D and Grant Revenue

All contracts with customers are evaluated under the five-step model described above. For certain contracts that represent grants where the funder does not meet the definition of a customer, the Company recognizes revenue when earned in accordance with Accounting Standards Codification ("ASC") Topic 958. Such contracts are further described under *Disaggregation of Revenue* below. Grants are invoiced and revenue is recognized ratably as that is the depiction of the timing of the transfer of services. The R&D study, which encompasses various phases of product development processes: design feasibility & planning, product development and design optimization, design verification, design validation and process validation, and pivotal studies, is also recognized ratably.

In June 2018, the Financial Accounting Standards Board (the "FASB") issued ASU 2018-08, Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made. This ASU clarifies the guidance presented in ASC Topic 958, "Not-for-Profit Entities," for evaluating whether a transaction is reciprocal (i.e., an exchange transaction) or nonreciprocal (i.e., a contribution) and for distinguishing between conditional and unconditional contributions. The ASU also clarified the guidance used by entities other than not-for-profits to identify and account for contributions made.

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Disaggregation of Revenue

The following table disaggregates total revenues:

	For the Three Months Ended					
	June 30, 2020			June 30, 2019		
	Exchange Transactions	Non-Exchange Transactions	Total	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 3,791,574**	**$ -**	**$ 3,791,574**	$ 8,785,041	$ -	$ 8,785,041
R&D and grant revenue	**1,193,973**	**-**	**1,193,973**	619,139	235,125	854,264
License and royalty revenue	**125,625**	**-**	**125,625**	248,831	-	248,831
	$ 5,111,172	**$ -**	**$ 5,111,172**	$ 9,653,011	$ 235,125	$ 9,888,136

	For the Six Months Ended					
	June 30, 2020			June 30, 2019		
	Exchange Transactions	Non-Exchange Transactions	Total	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	**$ 9,508,167**	**$ -**	**$ 9,508,166**	$ 15,409,326	$ -	$ 15,409,326
R&D and grant revenue	**2,101,660**	**-**	**2,101,660**	1,392,204	1,163,849	2,556,053
License and royalty revenue	**360,928**	**-**	**360,929**	465,022	-	465,022
	$ 11,970,755	**$ -**	**$ 11,970,755**	$ 17,266,552	$ 1,163,849	$ 18,430,401

Exchange transactions are recognized in accordance with ASC Topic 606, while non-exchange transactions are recognized in accordance with ASU 2018-08.

The following table disaggregates revenues by geographic location of the customer:

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Africa	**$ 552,570**	$ 2,342,740	**$ 1,436,085**	$ 4,759,040
Asia	**119,319**	119,548	**482,607**	240,646
Europe & Middle East	**1,635,016**	1,107,558	**3,811,172**	3,250,779
Latin America	**780,567**	4,897,297	**2,896,963**	6,177,770
United States	**2,023,699**	1,420,993	**3,343,928**	4,002,166
	$ 5,111,172	$ 9,888,136	**$ 11,970,755**	$ 18,430,401

Contract Liabilities

Deferred revenue relates to payments received in advance of performance under the contract. Deferred revenue is recognized as revenue as (or when) the Company performs under the contract. At June 30, 2020, the Company reported $4,097,155 in deferred revenue, of which $1.4 million is expected to be recognized during the three months ending September 30, 2020, and the remainder over the next 12 months.

(j) Inventories:

Inventories consisted of the following at:

	June 30, 2020	December 31, 2019
Raw materials	**$ 5,136,583**	$ 2,901,319
Work in process	**2,609,407**	793,343
Finished goods	**6,385,550**	5,903,368
	$ 14,131,540	$ 9,598,030

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(k) Loss Per Share:

Basic loss per share is computed by dividing net loss attributable to holders of Chembio's common stock ("common stock") by the weighted-average number of shares of common stock outstanding for the period excluding unvested restricted stock. Diluted loss per share for the six months ended June 30, 2020 and 2019 reflected the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 56,995 and 641,839 restricted shares awards outstanding as of June 30, 2020 and 2019, respectively, that were not included in the calculation of diluted income per share for the three and six months ended June 30, 2020 and 2019, because their effect would have been anti-dilutive. There were 1,034,124 and 688,122 weighted-average options outstanding as of June 30, 2020 and 2019, respectively, that were not included in the calculation of diluted income per share for the three and six months ended June 30, 2020 and 2019, respectively, because their effect would have been anti-dilutive.

(l) Research and Development:

R&D costs are expensed as incurred. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

(m) Equity Plans:

Effective June 3, 2008, Chembio's stockholders voted to approve the 2008 Stock Incentive Plan (the "SIP"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011, Chembio's stockholders voted to approve an increase to the shares of common stock issuable under the SIP by 125,000 to 750,000. Under the terms of the SIP, which expired during 2018, the Board of Directors of Chembio (the "Board") or its Compensation Committee had the discretion to select the persons to whom awards were to be granted. Awards could be stock options, restricted stock and/or restricted stock units (collectively, "Equity Award Units"). The awards became vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through June 30, 2020, there were 694,000 options expired, forfeited or exercised, and at June 30, 2020, 56,000 options were outstanding. No Equity Award Units are available to be issued under the SIP.

Effective June 19, 2014, Chembio's stockholders voted to approve the 2014 Stock Incentive Plan (the "SIP14"), with 800,000 shares of common stock available to be issued. Under the terms of the SIP14, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of Equity Award Units. The awards vest at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through June 30, 2020, there were 432,502 Equity Award Units expired, forfeited or exercised. At June 30, 2020, 346,437 Equity Award Units were outstanding, and 21,061 Equity Award Units remained available to be issued under the SIP14.

Effective June 18, 2019, Chembio's stockholders voted to approve the 2019 Omnibus Incentive Plan (the "2019 Plan"), with 2,400,000 shares of common stock available to be issued. In addition, shares of common stock underlying any outstanding award granted under the 2019 Plan that, following the effective date of the 2019 Plan, expire, or are terminated, surrendered or forfeited for any reason without issuance of such shares, shall be available for the grant of new awards under the 2019 Plan. Under the terms of the 2019 Plan, the Board or its Compensation Committee has the discretion to select the persons to whom awards are to be granted. Awards can be in the form of options, stock appreciation rights, restricted stock, restricted stock units, or other stock-based awards under the 2019 Plan (collectively, "2019 Equity Units"). The 2019 Equity Units become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through June 30, 2020, 436,728 2019 Equity Units has been exercised or forfeited. At June 30, 2020, 1,251,072 2019 Equity Units were outstanding, and 712,200 2019 Equity Units were available to be awarded under the 2019 Plan.

(n) Stock-Based Compensation:

The fair value of restricted stock and performance/restricted stock unit awards are determined on the date of grant. Stock-based compensation expense for stock options is calculated using the Black-Scholes valuation model. Stock based compensation is reduced for actual forfeitures in the period in which the forfeiture occurs and generally recognized on a straight-line basis over the service period of the grant. During the three and six months ended June 30, 2020, 29,543 and 470,174 shares of restricted stock were forfeited, respectively.

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Stock-based compensation expense (net of recovery) recognized in the condensed consolidated statements of operations was classified as follows:

	For The Three Months Ended June 30,		For The Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Cost of product sales	**$ -**	$ 2,300	**$ 6,300**	$ 5,800
Research and development expenses	**90,924**	56,300	**154,737**	116,100
Selling, general and administrative expenses	**293,301**	318,300	**610,089**	602,478
Severance and related costs	-	-	**(423,984)**	-
	$ 384,225	$ 376,900	**$ 347,142**	$ 724,378

The weighted-average assumptions made in calculating the fair values of options are as follows:

	For the Three and Six Months Ended June 30, 2020
Expected term (in years)	6.3
Expected volatility	45.37%
Expected dividend yield	0.00%
Risk-free interest rate	1.33%

The following table provides stock option activity for the six months ended June 30, 2020:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2019	**642,625**	**$ 5.79**	**3 years**	**$ 285,925**
Granted	702,499	2.50		
Exercised	(36,000)	6.30		95,976
Forfeited/expired/cancelled	(275,000)	3.59		
Outstanding at June 30, 2020	**1,034,124**	**$ 4.12**	**6 years**	**$ 598,628**
Exercisable at June 30, 2020	**224,333**	**$ 7.24**	**3 years**	**$ -**

As described in Note 5(f) – Litigation, the information in the above table and elsewhere in these notes does not reflect certain options that were received by Chembio's former chief executive officer and that had vested as of the time of his resignation on January 3, 2020 because the Board's Compensation Committee has determined that the former chief executive officer failed to exercise such options in a timely manner prior to their expiration.

The following table summarizes information about stock options outstanding at June 30, 2020:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Number of Shares	Average Remaining Contract Term (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1 to $2.79999	672,616	6.71	$ 2.36	$ 598,628	-	$ -	$ -
$2.8 to $4.59999	-	-	-	-	-	-	-
$4.6 to $6.39999	106,758	2.94	5.78	-	58,125	5.77	-
$6.4 to $8.19999	207,875	3.56	7.31	-	147,458	7.28	-
$8.2 to $12	46,875	3.10	11.45	-	18,750	11.45	-
Total	1,034,124	5.52	$ 4.12	$ 598,628	224,333	$ 7.24	$ -

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As of June 30, 2020, there was $932,799 of net unrecognized compensation cost related to stock options that had not vested, which is expected to be recognized over a weighted-average period of approximately 2.57 years. The total fair value of shares vested during the six months ended June 30, 2020 and 2019 was $112,311 and $235,578, respectively.

The following table summarizes information about restricted stock, restricted stock units and performance stock units outstanding as of June 30, 2020:

	Number of Shares & Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2019	545,986	$ 7.47
Granted	610,301	2.57
Vested	(66,728)	3.62
Forfeited/expired/cancelled	(470,174)	6.58
Outstanding at June 30, 2020	**619,385**	**$ 3.32**

As of June 30, 2020, there was $1,551,837 of net unrecognized compensation cost related to restricted stock and restricted stock units that had not vested, which is expected to be recognized over a weighted-average period of approximately 2.29 years.

(o) Geographic Information and Economic Dependency

The Company produces only one group of similar products known collectively as “rapid medical tests”, and it operates in a single operating segment. Net product revenue by geographic area were as follows:

	For The Three Months Ended June 30,		For The Six Months Ended June 30,	
	2020	2019	2020	2019
Africa	**$ 552,570**	$ 2,342,740	**$ 1,436,085**	$ 4,759,040
Asia	**119,319**	119,548	**482,607**	240,646
Europe & Middle East	**734,073**	741,641	**1,909,162**	1,919,666
Latin America	**780,567**	4,897,297	**2,896,963**	6,177,770
United States	**1,605,045**	683,815	**2,783,349**	2,312,204
	$ 3,791,574	$ 8,785,041	**$ 9,508,166**	$ 15,409,326

Property, plant and equipment by geographic area were as follows:

	June 30, 2020	December 31, 2019
Asia	**$ 357,921**	$ 393,299
Europe & Middle East	**171,767**	165,029
Latin America	**43,701**	60,527
United States	**7,132,501**	5,314,714
	$ 7,705,890	$ 5,933,569

(p) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consisted of:

	June 30, 2020	December 31, 2019
Accounts payable – suppliers	**$ 6,588,598**	$ 3,144,098
Accrued commissions and royalties	**486,998**	931,760
Accrued payroll	**188,858**	231,753
Accrued vacation	**547,307**	410,199
Accrued bonuses	**350,479**	215,000
Accrued severance	**260,481**	-
Accrued expenses – other	**868,166**	593,433
TOTAL	**$ 9,290,887**	$ 5,526,243

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(q) Goodwill, Long-Lived Assets and Intangible Assets:

The following table reflects changes in goodwill:

Beginning balance at December 31, 2019	$ 5,872,690
Change in foreign currency exchange rate	(338,066)
Balance at June 30, 2020	$ 5,534,624

Intangible assets consisted of the following:

		June 30, 2020			December 31, 2019		
	Weighted Average Remaining Useful Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	**6**	**$ 1,470,556**	**$ 366,353**	**$ 1,104,203**	$ 1,418,681	$ 299,232	$ 1,119,449
Developed technology	**6**	**1,924,990**	**400,304**	**1,524,686**	1,922,682	266,550	1,656,132
Customer contracts/relationships	**7**	**1,232,474**	**327,525**	**904,949**	1,325,521	270,902	1,054,619
Trade names	**8**	**107,796**	**36,440**	**71,356**	114,946	30,794	84,152
		$ 4,735,816	**$ 1,130,622**	**$ 3,605,194**	$ 4,781,830	$ 867,478	$ 3,914,352

Intellectual property, developed technology, customer contracts/relationships and trade names are amortized over 10, 7, 10, and 11 years, respectively. Amortization expense for the six months ended June 30, 2020 and 2019 was approximately $287,253 and $306,700, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to be $572,383 per year from 2020 through 2024, and total $1,031,987 for all remaining years combined.

(r) Taxes:

At the end of each interim reporting period, the Company estimates its effective tax rate expected to be applied for the full year. This estimate is used to determine the income tax provision or benefit on a year-to-date basis, and may change in subsequent interim periods. Accordingly, the Company's effective tax rate for the three and six months ended June 30, 2020 was 1.7% and 1.7%, compared to the effective tax rate of 3.3% and 6.0% for the three and six months ended June 30, 2019. The Company's effective tax rates for both periods were affected primarily by a full valuation allowance on domestic net deferred tax assets and a benefit from foreign net operating losses.

(s) Allowance for Doubtful Accounts:

The Company records allowances for doubtful accounts for the estimated probable losses on uncollectible accounts receivable. The allowance is based upon the credit worthiness of the Company's customers, the Company's historical experience, the age of the receivable and current market and economic conditions. Receivables are written off against these allowances in the period they are determined to be uncollectible.

(t) Foreign Currency Translation:

The functional currency of a foreign subsidiary is the local currency. Assets and liabilities of foreign subsidiaries that use a currency other than U.S. dollars as their functional currency are translated to U.S. dollars at end of period currency exchange rates. The consolidated statements of operations of foreign subsidiaries are translated to U.S. dollars at average period currency exchange rates. The effect of translation for foreign subsidiaries is generally reported in other comprehensive (loss) income. Foreign transaction gains and losses have been immaterial.

(u) Acquisition Costs:

Acquisition costs include period expenses, primarily professional services, related to acquisition activities. For the six months ended June 30, 2020 and 2019, the Company recognized $63,497 and $395,612 in acquisition costs related to its acquisition of Orangelife and opTricon GmbH, respectively.

(v) Recently Issued Accounting Standards:

Recently Adopted

ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13")

In June 2016, the FASB issued ASU 2016-13. ASU 2016-13 provides guidance on measurement of credit losses on financial instruments that changes the impairment model for most financial assets and certain other instruments, including trade and other receivables, held-to-maturity debt securities and loans, and that requires entities to use a new, forward-looking "expected loss" model that is expected to generally result in the earlier recognition of allowances for losses. The guidance became effective for annual periods beginning after December 15, 2019, including interim periods within those years. The Company has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2018-13, Fair Value Measurement - Disclosure Framework (Topic 820) ("ASU 2018-13")

In August 2018, the FASB issued ASU 2018-13. ASU 2018-13 improves the disclosure requirements on fair value measurements. The updated guidance became effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

ASU 2017-4, Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment ("ASU 2017-4")

In January 2017, the FASB issued ASU 2017-4. ASU 2017-4 simplifies the subsequent measurement of goodwill and eliminates Step 2 from the goodwill impairment test. ASU 2017-4 is effective for annual and interim goodwill tests beginning after December 15, 2019. The Company has evaluated the effects of this standard and determined that the adoption did not have a material impact on the Company's consolidated financial statements.

Not Yet Adopted

ASU 2020-04, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting

In March 2020, the FASB issued ASC Topic 848. ASC Topic 848 provides relief for impacted areas as it relates to impending reference rate reform. ASC Topic 848 contains optional expedients and exceptions for applying GAAP to debt arrangements, contracts, hedging relationships, and other areas or transactions that are impacted by reference rate reform. This guidance is effective for upon issuance for all entities and elections of certain optional expedients are required to apply the provisions of the guidance. The Company continues to assess all potential impacts of the standard and will disclose the nature and reason for any elections that the Company makes.

ASU 2019-12, Simplifications to Accounting for Income Taxes ("ASU 2019-12")

In December 2019, the FASB issued ASU 2019-12. ASU 2019-12 removes certain exceptions for recognizing deferred taxes for investments, performing intra-period allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including deferred taxes for goodwill and allocating taxes for members of a consolidated group. ASU 2019-12 is effective for all entities for fiscal years beginning after December 15, 2020, and earlier adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2019-12 on its consolidated financial statements.

(w) Severance, restructuring and other related costs:

During the six months ended June 30, 2020, the Company recognized $0.7 million in net severance expenses related to the departure of Chembio's former chief executive officer and the elimination of certain positions as part of its multi-faceted expense reduction program to reduce operating expenses. The Company undertook actions to adjust the size and composition of the organization, including by removing positions that were non-essential in light of its new business strategy, and to remove other expenses, all of which the Company expects expect will provide savings throughout, and after, 2020.

In light of market dynamics, the Company retrenched its Malaysian operations, including the termination of employment of its Malaysian workforce. The Company will maintain its Malaysian subsidiary and sustain the product registrations that were obtained throughout southeast Asia, with the benefit of having that entity and the WHO prequalification certified facility.

Based on these activities, the Company has taken restructuring actions totaling $0.4 million to realign and resize its production capacity and cost structure. All expenses have been paid as of June 30, 2020.

NOTE 3 – ACQUISITION:

Orangelife

On November 25, 2019, pursuant to a quota purchase agreement, the Company acquired all of the outstanding equity securities of Orangelife Comercio e Industria Ltda. ("Orangelife"), a privately held Brazilian company, that is an original equipment manufacturer of point-of-care tests approved by the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, or "ANVISA") for infectious diseases that include human immunodeficiency virus ("HIV"), Hepatitis C, Zika, Chikungunya and Dengue Fever. Orangelife tests are manufactured in its Rio de Janeiro facility, which is ISO-certified and approved by ANVISA to produce Class II/III/IV medical devices. The purchase price includes the following consideration:

- $150,000 in cash and 153,707 shares of common stock.
- Issuance of 316,456 shares of common stock to the founder and former chief executive officer of Orangelife, based on the transfer and approval of registration of certain of the Company's product in Brazil prior to November 25, 2022. All of the shares may be deliverable in the event of change in control of Chembio. The number of shares issued was subject to adjustments based upon Orangelife's working capital at closing. The fair value of the shares on the date of the acquisition was recorded in equity and was valued at $1.2 million.

The acquisition of Orangelife allowed the Company to expand its commercial presence by offering its products to the state, private and pharmacy markets in Brazil, in addition to providing local support to its long-time customer Bio-Manguinhos, a subsidiary of the Oswaldo Cruz Foundation (Fiocruz), which oversees development and production of vaccines, diagnostics, and biopharmaceuticals to meet the demands of Brazil's national public health system. The results of Orangelife's operations have been reflected in the consolidated financial statements since November 25, 2019.

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The acquisition was accounted for using the purchase method of accounting. The following table summarizes the allocation of the purchase price to the estimated fair values of the assets acquired and liabilities assumed on the closing date of November 25, 2019:

	Amount
Net current assets	$ 320,293
Property, plant and equipment and other assets	226,035
Inventory	289,205
Goodwill	986,058
Deferred tax liability	(50,000)
Other intangible assets (estimated useful life):	
Trade name (0.5 years)	5,000
Customer contracts / relationships (5 years)	195,000
Total consideration	$ 1,971,591

The Company calculated the estimated fair value of the fixed assets based on the net book value of Orangelife, which approximated fair value. The estimated fair value of the trade name, customer contracts/relationships and contingent earnouts were based on discounted cash flows using management estimates.

As a result of the consideration paid exceeding the fair value of the net assets acquired, goodwill in the amount of $986,058 was recorded in connection with this acquisition, none of which is deductible for tax purposes. In addition, the Company recorded $200,000 in intangible assets associated with the addition of Orangelife's trade name and customer base.

The following represents pro forma operating results for the year ended December 31, 2019 as if the operations of Orangelife had been included in the Company's consolidated statements of operations effective as of January 1, 2019. This pro forma financial information is unaudited and presented for illustrative purposes only and is not necessarily indicative of the operating results that would have occurred if the acquisition of Orangelife and the other transactions contemplated by this acquisition had been completed as of January 1, 2019, nor is it necessarily indicative of the future operating results of the Company and Orangelife on a combined and consolidated basis.

	Unaudited Pro Forma December 31, 2019
Total revenues	$ 35,157,248
Net loss	$ (13,654,001)
Net loss per common share	$ (0.80)
Diluted net loss per common share	$ (0.80)

NOTE 4 – STOCKHOLDERS' EQUITY:

(a) Common Stock

During the first six months of 2020 and 2019, there were 36,000 and 46,875 options exercised, and 2,619,593 and 0 new shares issued in an underwritten secondary public offering, respectively.

(b) Preferred Stock

Chembio has 10,000,000 shares of preferred stock authorized, none of which are outstanding. These shares can become issuable upon an approved resolution by the Board and the filing of a Certificate of Designation with the State of Nevada.

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(c) Treasury Stock

Chembio has 33,290 shares of treasury stock from restricted stock awards that were remitted to satisfy tax withholding requirements.

(d) Options, Restricted Stock and Restricted Stock Units

The Board or its Compensation Committee may grant options, restricted stock, and restricted stock units pursuant to equity incentive plans that have been approved by Chembio's stockholders.

NOTE 5 – COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

(a) Concentrations:

The following table discloses product sales the Company had to the only customer that purchased in excess of 10% of the Company's net product sales for the periods indicated:

	For The Three Months Ended				For The Six Months Ended				Accounts Receivable as of	
	June 30, 2020		June 30, 2019		June 30, 2020		June 30, 2019		June 30, 2020	Dec. 31, 2019
	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales	Sales	% of Sales		
Customer 1	**$ 657,304**	**17.0%**	$ 4,573,434	54%	**$ 2,297,376**	**24.0%**	$ 5,615,932	38%	**$ 806,196**	$ 941,962
Customer 2	**$ -**	**0.0%**	$ 1,627,075	19%	**$ -**	**0.0%**	$ 3,460,666	23%	**$ -**	$ -

Revenue includes product sales only, while accounts receivable reflects the total due from the customer, including freight.

For the three and six months ended June 30, 2020 and 2019, there were no vendors that sold to the Company in excess of 10% of the Company's total purchases.

The Company currently buys materials that are purchased under intellectual property rights agreements and are important components in its products. Management believes that other suppliers could provide similar materials on comparable terms. A change in suppliers, however, could cause a delay in manufacturing, either from the logistic and regulatory implications of changing suppliers or from product attributable changes to new components, any of which could result in a possible loss of sales and adversely affect operating results.

(b) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration, the U.S. Department of Agriculture, certain U.S., state and local agencies, and/or comparable regulatory bodies in other countries. Most aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and record keeping, are subject to regulatory review. After marketing approval has been granted, the Company must continue to comply with governmental regulations. Failure to comply with applicable requirements can lead to sanctions, including withdrawal of products from the market, recalls, refusal to authorize government contracts, product seizures, civil monetary penalties, injunctions, and criminal prosecution.

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(c) Employment Contracts:

As of June 30, 2020, the Company had multi-year contracts with two key employees that include salaries presently aggregating $765,000 per year. The contracts expire in December 2020 and December 2022. The following table is a schedule of future minimum salary commitments related to those contracts as of June 30, 2020:

2020	$ 382,500
2021	765,000
2022	400,000

(d) Pension Plan:

Chembio has a 401(k) plan established for the Company's employees whereby the Company matches 40% of the first 5% of salary (or up to 2% of salary) that an employee contributes to the plan. For the six months ending June 30, 2020 and 2019, matching contribution expenses totaled $49,407, and $49,000, respectively.

(e) Leases:

The Company leases facilities in New York, Germany, Malaysia, and Brazil, and certain equipment.

The Company's facility leases generally include optional renewal periods. Upon entering into a new facility lease, the Company evaluates the leasehold improvements and regulatory requirements related to its operations in that location. To the extent that the initial lease term of the related facility lease is less than the useful life of the leasehold improvements and potential regulatory costs associated with moving the facility, the Company concludes that it is reasonably certain that a renewal option will be exercised, and thus that renewal period is included in the lease term and the related payments are reflected in the right-of-use asset and lease liability.

The Company's facility leases generally include fixed rental payments with defined annual increases. While certain of the Company's facility leases are gross leases, the majority of the Company's facility leases are net leases in which the Company makes separate payments to the lessor based on the lessor's property and casualty insurance costs, the property taxes assessed on the property, and a portion of the common area maintenance where applicable. The Company has elected the practical expedient not to separate lease and non-lease components for all of the Company's facility leases. The Company has also elected the practical expedient for short term lease exception for all of its facility leases.

The components of lease expense were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating lease expense	**$ 388,951**	$ 400,658	**$ 852,808**	$ 682,261
Finance lease cost				
Amortization of right-of-use assets	**$ 14,687**	$ -	**$ 27,085**	$ -
Interest on lease liabilities	**5,156**	-	**9,367**	-
Total finance lease expense	**$ 19,843**	$ -	**$ 36,452**	$ -

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Supplemental cash flow information related to leases was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows for operating leases	**$ 292,058**	$ 147,107	**$ 457,277**	$ 305,157
Operating cash flows for finance leases	**5,156**	-	**9,367**	-
Financing cash flows for finance leases	**12,666**	-	**23,578**	-
Right-of-use assets obtained in exchange for lease obligations:				
Operating leases	-	-	-	6,949,611
Finance leases	**$ 47,499**	$ 233,722	**$ 75,852**	$ 233,722

Supplemental balance sheet information related to leases was as follows:

	June 30, 2020	**June 30, 2019**
Finance Leases		
Finance lease right of use asset	**$ 309,574**	$ 233,722
Accumulated depreciation	**(50,690)**	-
Finance lease right of use asset, net	**$ 258,884**	233,722
Weighted-Average Remaining Lease Term		
Operating leases	**9 years**	10 years
Finance leases	**4 years**	5 years
Weighted-Average Discount Rate		
Operating leases	**8.62%**	8.52%
Finance leases	**9.73%**	7.0%

During the three months ended March 31, 2019, the Company executed an operating sublease related to its former Holbrook, New York facility. The sublease ran conterminously with the base lease, for which the Company was primarily responsible until the end of the lease term in April 2020.

At the time of the initial assessment, the Company did not have an established incremental borrowing rate and the interest rates implicit in each of the leases were not readily determinable. Therefore, the Company used an interest rate based on the market place for the public debt. In September 2019, the Company entered into a credit agreement for a $20 million term loan as described on Note 6 - Long Term Debt.

Maturities of lease liabilities were as follows.

	June 30, 2020		June 30, 2019	
	Operating Leases	**Finance Leases**	**Operating Leases**	**Finance Leases**
2019 and 2020	**$ 682,667**	**$ 37,720**	$ 1,129,543	$ 27,768
2021	**1,209,787**	**75,440**	998,071	55,536
2022	**1,057,757**	**75,440**	1,026,044	55,536
2023	**1,026,272**	**75,440**	1,011,085	55,536
2024	**1,018,875**	**47,672**	-	55,536
Thereafter	**5,773,887**	**4,774**	6,792,767	27,767
Total lease payments	**$ 10,769,245**	**$ 316,486**	$ 10,957,510	$ 277,679
Less: imputed interest	**3,427,535**	**50,366**	3,986,013	43,957
Total	**$ 7,341,710**	**$ 266,120**	$ 6,971,497	$ 233,722

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(f) Litigation:

Employee Litigation

John J. Sperzel III, our former chief executive officer, has asserted a right to exercise certain options to purchase, for an aggregate exercise price of $943,126, a total of 266,666 shares of common stock that were vested when he resigned on January 3, 2020. Under their terms, those options were exercisable for a period of thirty days after his service to our company ended. The compensation committee of the board, acting in its discretion in accordance with the terms of the underlying equity incentive plans, has determined that Mr. Sperzel failed to exercise the options in a timely manner prior to their expiration. Chembio intends to vigorously defend against any claim by Mr. Sperzel that he continues to have a right to exercise any options.

Stockholder Litigation

As of July 31, 2020, four purported class action lawsuits had been filed by alleged stockholders of Chembio Diagnostics, Inc. ("Chembio") 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; and (4) Ken Hayes v. Chembio Diagnostics, Inc., Richard L. Eberly, Gail S. Page, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff, 1:20-cv-02918, filed on July 1, 2020, or Hayes.

The Chernysh, Gowen and Bailey complaints are brought by purported individual stockholders of Chembio on behalf of all persons and entities who purchased Chembio 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 Chembio's 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 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. Chembio and the plaintiffs in Chernysh, Gowen and Bailey have entered into a stipulation, approved by the Court on July 17, 2020, relieving the defendants from the obligation to respod to the complaints in the cases pending the designation of a lead plaintiff. Pursuant to the stipulation, within ten days following the entry of an order by the Court appointing a lead plaintiff and a lead plaintiff's counsel, counsel for the defendants and the lead plaintiff are to confer and submit to the Court a proposed schedule for the filing of a consolidated amended complaint and the defendants' response to that pleading.

The Hayes complaint purports to state claims for violations of Section 14(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder by the Securities and Exchange Commission, declaratory relief, and state law claims for breach of fiduciary duty, brought by plaintiff on behalf of himself and all of Chembio's other public stockholders against Chembio and members of our board of directors to remedy alleged misstatements of material information in the proxy statement disseminated by Chembio in advance of our Annual Meeting of Stockholders held on July 28, 2020 (the "Annual Meeting"). The Hayes plaintiff alleges that the Schedule 14A Proxy Statement filed by Chembio on June 16, 2020 with the Securities and Exchange Commission, or the Proxy Statement, in which Chembio is soliciting stockholder approval of, inter alia, a proposal to change Chembio's state of incorporation from the State of Nevada to the State of Delaware (the "Reincorporation Proposal"), contains misstatements of Nevada and Delaware law. The Hayes plaintiff seeks a declaration that the Proxy Statement is false and misleading and entry of an order enjoining the stockholder vote on the Reincorporation Proposal until such time as the Proxy Statement has been corrected as well as an order finding our directors liable for breaching their fiduciary duties and awarding plaintiff the costs and disbursements of the action, including attorneys' and expert fees. On July 8, 2020, Chembio filed an amended proxy statement correcting, among other things, the issues raised in the Hayes complaint. As a consequence of the supplementation, the plaintiff withdrew its motion for a preliminary injunction. On July 23, 2020, Chembio and the plaintiff entered into a stipulation to the dismissal of the action, with prejudice as to the claims of the named plaintiff. The stipulation was subject to plaintiff's reservation of the right to apply for an award of attorneys' fees and expenses from Chembio within 45 days after entry of an order approving the stipulation in the event the parties are unable to reach agreement on plaintiff's claim for entitlement to fees. Also, on July 23, 2020, the plaintiff filed a notice dismissing the named plaintiff's claims, with prejudice, as to the individual defendants. On July 27, 2020, the Court entered an order closing the case and providing that plaintiff shall have until September 28, 2020 to move to reopen the case if the attorneys' fee issue has not been resolved.

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NOTE 6 – LONG-TERM DEBT:

In September 2017, Chembio entered into an agreement with an equipment vendor to purchase automated assembly equipment for approximately $660,000. The terms call for payments of 30% down, 60% at time of factory acceptance testing and 10% after delivery. The vendor agreed to lend Chembio 15%, 40% and 10% of each originally scheduled payment, respectively. The Company paid interest at an annual rate of 12% until delivery. Beginning in September 2018, Chembio began making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a 24-month period. The remaining balance was classified short-term as of December 31, 2019.

On September 3, 2019, Chembio entered into a Credit Agreement and Guaranty (the “Credit Agreement”) with Perceptive Credit Holdings II, LP (the “Lender”). The Credit Agreement provides for a $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. Under the terms of the Credit Agreement, Chembio may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of Chembio’s existing indebtedness and (iii) to pay fees, costs and expenses incurred in connection with the Credit Agreement, including the Lender’s closing cost amount of $550,000, which was netted from the proceeds, and a financing fee of $600,000 (3.0% of gross proceeds) payable to Chembio’s financial advisor for the financing.

Principal outstanding under the Credit Agreement bears interest at a rate per annum equal to the sum of (a) the greater of the one-month London Interbank Offered Rate and 2.5%plus (b) 8.75%. At any time at which an event of default has occurred and is continuing, the interest rate will increase by 4.0%. Accrued interest is payable on a monthly basis. On June 30, 2020 the interest rate was 11.25%.

No principal repayments are due under the Credit Agreement prior to September 30, 2022, unless Chembio elects to prepay principal or principal is accelerated pursuant to an event of default identified in the Credit Agreement. Principal installments in the amount of $300,000 are payable on the last day of each of the 11 months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. Chembio may prepay outstanding principal from time to time, subject to payment of a premium on the prepaid principal amount equal to 10% through September 3, 2020, 8% from September 4, 2020 through September 3, 2021, and 4% from September 4, 2021 through September 3, 2022. No premium will be due with respect to any prepayment made on or after September 4, 2022.

Chembio’s obligations under the Credit Agreement are secured by a first priority, perfected lien on substantially all of its property and assets, including its equity interests in subsidiaries.

As of June 30, 2020, the loan balance, net of unamortized discounts and debt issuance costs, was $17.9 million, and Chembio was in compliance with its cash balance loan covenant, but not in compliance with its revenue loan covenant. Chembio obtained a written waiver from the Lender with respect to Chembio’s failure to meet the revenue loan covenant for the three months ended June 30, 2020. Chembio's obligations under the Credit Agreement are secured by a first priority, perfected lien on substantially all of its property and assets, including its equity interests in subsidiaries.

NOTE 7 – WARRANTS:

In connection with entering into the Credit Agreement, on September 3, 2019, Chembio issued to the Lender a seven-year warrant (the “Warrant”) to purchase up to 550,000 shares of common stock at a per-share exercise price of $5.22. The Warrant was exercisable for cash or on a net, or “cashless,” basis, and the exercise price of the Warrant was subject to price-based, weighted-average antidilution adjustments for one year after issuance.

The Warrant was evaluated by the Company and classified as stockholder’s equity. Its fair value was estimated using a Black-Scholes option-pricing model using the following assumptions:

Stock price on issuance date	$	5.40
Strike Price	$	5.22
Risk-free interest rate		1.45%
Volatility		43.65%
Expected life		7 years

On the date of grant, the fair value of the Warrant was determined to be approximately $1.4 million at $2.49 per share.

The balance recorded in the Company’s Stockholders’ Equity for the Warrant, net of allocated issuance costs, was $1.2 million.

During the three months ended June 30, 2020, the Warrant was exercised in full on a cashless basis and the Lender received a total of 253,161 shares of common stock from the net exercise.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our unaudited consolidated financial statements and related notes included elsewhere in this report. In addition to historical information, the following discussion contains forward-looking statements that involves risks, uncertainties and assumptions. See "Forward-Looking Statements and Statistical Estimates" on page 3 of this report. Please read Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as filed with the Securities and Exchange Commission on March 13, 2020, Part II, Item1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2020, as filed with the Securities and Exchange Commission on May 4, 2020, and Part II, Item1A. "Risk Factors" of this report for a discussion of factors that could cause our actual results to differ materially from our expectations.

Overview of Six Months Ended June 30, 2020

We develop, manufacture and commercialize diagnostic tests used for the detection and diagnosis of infectious diseases. We have been expanding our product portfolio based upon our proprietary DPP technology, a novel, rapid diagnostic platform that uses a drop of blood or alternative sample types from the fingertip to provide high-quality, cost-effective results in approximately 15 minutes. Our products are sold globally to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals, and retail establishments.

The global COVID-19 pandemic significantly affected our operating results for the six months ended June 30, 2020. We anticipated that, in addition to the business disruption and general economic effects caused by the pandemic, a substantial portion of the funding that would otherwise have been available for testing for infectious diseases addressed by our diagnostic tests, such as the human immunodeficiency virus or HIV, would be redirected to testing for the novel coronavirus that causes COVID-19. In February 2020 we began the process of shifting substantially all of our resources to leverage our DPP lateral flow technology to address the acute and escalating need for an accurate diagnostic test for COVID-19.

In the latter half of the first quarter of 2020, we developed, and began to manufacture for commercialization, the DPP COVID-19 System, which consists of our new serological test for COVID-19 and our Micro Reader analyzer. The DPP COVID-19 System can provide discrete, accurate readings for IgM and IgG antibody levels in approximately 15 minutes from a simple fingerstick drop of blood. Our actions in the first-quarter led to several subsequent key achievements:

- We acquired three regulatory approvals of the DPP COVID-19 System in our targeted global testing market: an Emergency Use Authorization, or EUA, granted by the U.S. Food and Drug Administration, or FDA, in April 2020; an approval for emergency use issued by Brazil's Agência Nacional de Vigilância Sanitária, or ANVISA, in April 2020, and a CE Marking for the European Union obtained in early May 2020.
- Stony Brook Medicine selected the DPP COVID-19 System to help identify persons who have recovered from COVID-19 for use in an FDA-approved investigation to determine if those persons' convalescent blood plasma can help treat patients with an active COVID-19 infection.
- We began shipping the DPP COVID-19 System to fulfill a $4 million purchase order from Bio-Manguinhos, a long-standing customer that is a subsidiary of the foundation responsible for the development and production of vaccines, diagnostics and biopharmaceuticals for Brazil's national public health system.
- We initiated commercial shipments of the DPP COVID-19 System to customers in the United States.
- We strengthened our balance sheet by raising $28.4 million in a secondary public offering in May 2020.
- We stablished a non-exclusive distribution relationship with Thermo Fisher Scientific's healthcare channel for the distribution of Chembio's DPP COVID-19 System in the U.S.

In addition, in June 2020 our DPP platform received further U.S. regulatory approval upon the FDA's granting of a 510(k) for our DPP Zika IgM System, which includes both a test for Zika IgM antibodies and a Micro Reader. The development and regulatory submission of the DPP Zika IgM System was funded by the Biomedical Advanced Research and Development Authority, part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (BARDA). The DPP Zika IgM System had previously received an EUA from the FDA. This was the first 510(k) that includes our Micro Reader, which is the same device used with DPP COVID-19 Systems and DPP HIV-Syphilis Systems, the latter which is pending FDA review for a PMA.

However, later in June 2020 the FDA revoked our EUA for the DPP COVID-19 System, which we refer to as the Revocation, and since then we have been focused on revising the COVID-19 System for antibodies (serology) in anticipation of resubmitting it to the FDA for an EUA. Additionally, as announced in early July 2020, we are developing a DPP COVID-19 System for antigen detection with the support of a $0.6 million award from the Biomedical Advanced Research and Development Authority or BARDA, which is part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services.

The diminished focus on our existing product portfolio and extensive economic disruption caused by the COVID-19 pandemic, exacerbated by the Revocation in June 2020 and the related impact on product returns and variable consideration, was reflected in our results for the six months ended June 30, 2020 as compared to the prior year period, as total revenue decreased 35.0% to $12.0 million and product sales decreased 38.3% to $9.5 million.

In order to address challenging economic conditions and accelerate implementation of our new business strategy, we are executing a program to reduce operating expenses and better align our costs with revenues. For a further description of this program, see "—Expense Reduction Program" below. Our cash and cash equivalents totaled $36.4 million at June 30, 2020, compared to $18.3 million at December 31, 2019.

DPP COVID-19 System

We believe we have a proven track record in rapidly responding to global health emergencies. Building upon our extensive experience in developing and manufacturing high-quality HIV tests, we received EUAs for DPP tests related to the global outbreak of Ebola, which began in 2014, and Zika, which commenced in 2015 and was awarded a 510(k) in June 2020 as discussed above. When the novel coronavirus emerged, we were confident that we could leverage our DPP platform and our scientific and operational expertise to create an antibody test that could detect the presence of antibodies indicative of recent infection or past infection generated in response to the virus. DPP technology is an advanced, versatile lateral flow testing platform with the capability to multiplex, or detect multiple biomarkers, from a single patient sample. The speed with which we were able to develop a test for COVID-19 illustrates the DPP platform's applicability to new and emerging infectious diseases.

During the six months ended June 30, 2020, we refocused our business strategy to apply our DPP technology to address the escalating need for COVID-19 diagnostic tests, including tests that can be performed both close to the patient and at a laboratory or hospital. In February 2020 we began the process of shifting substantially all of our resources to the development and commercialization of the DPP COVID-19 IgM/IgG System, which consists of our new serological test for COVID-19 and our Micro Reader analyzer. In the latter half of the first quarter of 2020, we developed, and in preparation for commercialization, began to manufacture the DPP COVID-19 IgM/IgG System.

During the second quarter of 2020, prior to the Revocation, we focused on responding to a substantial number of commercial leads for the DPP COVID-19 IgM/IgG System, establishing and servicing qualified new customers, building a distributor relationship with Thermo Fisher Scientific's healthcare channel, and manufacturing product to meet demand.

The DPP COVID-19 IgM/IgG System detects antibodies in the blood that are produced by the body in response to a novel coronavirus infection. Detection of an acute infection, as determined by the level of IgM antibodies, helps determine if a patient is still infectious. As the infection progresses, the body typically begins to produce IgG antibodies. As the IgG antibody levels increase, the IgM antibody levels will decrease and eventually disappear. IgG antibodies remain, evidencing the earlier infection. It is not currently known how long IgG antibodies to coronavirus remain in the body.

The DPP COVID-19 System offers discrete detection of IgM and IgG antibodies, with high sensitivity and specificity, from a simple fingerstick drop of blood after approximately 15 minutes of reaction time. Our portable Micro Reader analyzer then reports accurate results in approximately 15 seconds. Objective results produced by the Micro Reader reduce the possibility of the types of human error that can be experienced in the visual interpretations required by many other serological tests. The system is portable, provides accurate results from fingerstick blood or other samples, and can detect multiple biomarkers simultaneously and discretely. At the same time, the easy-to-use testing workflow is scalable. Clinicians can run multiple tests at the same time because cartridges are only required to be inserted in the Micro Reader for 15 seconds to obtain results following the 15-minute test incubation period.

The DPP COVID-19 Antigen System that is under development with the support of BARDA is expected to consist of a DPP COVID-19 Antigen Assay and Micro Reader and to use a respiratory specimen, such as a nasal or nasopharyngeal swab, to detect SARS-CoV-2 antigens. Antigen tests such as the one we are developing are important in the overall response against COVID-19 as they can be provided on a decentralized basis, closer to the point of care, at lower cost and with faster results than alternative molecular test options.

Key Developments

While we have been focusing on a test for COVID-19 for a relatively short time, we have achieved several key developments that we believe demonstrate the potential utility and marketability of the DPP COVID-19 System.

Shipment to Brazil. In March 2020 we received a $4 million purchase order for DPP COVID-19 Systems from Bio-Manguinhos, a long-standing customer that is a subsidiary of the foundation responsible for the development and production of vaccines, diagnostics and biopharmaceuticals for Brazil's national public health system. In April 2020 we began shipping DPP COVID-19 Systems to Bio-Manguinhos to fulfill this purchase order.

Issuance of EUA. On April 14, 2020, the FDA issued an EUA for emergency use of the DPP COVID-19 System pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act of 1938. EUA authority allows the FDA, following a declaration of emergency or threat-justifying authorization of emergency use by the Secretary of Health and Human Services, to authorize the introduction into interstate commerce of drugs, devices, or biologics intended for use in an actual or potential emergency involving a biological, chemical, radiological, or nuclear agent. Under this authority, the FDA may authorize such products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by such agents when appropriate findings are made concerning the nature of the emergency, the availability of adequate and approved alternatives, and the quality of available data concerning the effectiveness of the medical product under consideration for emergency use. On February 4, 2020, the Secretary of Health and Human Services determined that the novel coronavirus presented a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and declared that circumstances existed justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus that causes COVID-19. On February 29, 2020, the FDA issued immediately in effect guidance for clinical laboratories, commercial manufacturers and FDA staff to provide a policy to help accelerate the availability of COVID-19 diagnostic tests, and updated that guidance on March 16, 2020 to provide more specific detail to laboratories and commercial manufacturers developing COVID-19 diagnostic tests. To date, the FDA has issued many EUAs for serological tests for use in detecting COVID-19-related antibodies. On May 4, 2020, the FDA further updated its COVID- 19 diagnostic test guidance to require EUA submissions for all serology tests that were previously marketed under FDA enforcement discretion following submission of a notification to FDA. FDA policies regarding diagnostic tests, therapies and other products used to diagnose, treat or mitigate COVID-19 remain in flux as the FDA responds to new and evolving public health information and clinical evidence.

Selection for Use in FDA-Approved Study. In April 2020, Stony Brook Medicine selected the DPP COVID-19 System to assist in the recruitment of patients who have recovered from COVID-19 infections. Stony Brook Medicine is conducting a study intended to determine if convalescent blood plasma from people who have recovered from COVID-19 can help treat hospitalized patients with active COVID-19 infection. Stony Brook University Hospital has received Investigational New Drug approval from the FDA to offer convalescent blood plasma treatment to its patients through a randomized, controlled study and is expected to enroll up to 500 patients from the Long Island, New York area. The DPP COVID-19 System is being used to confirm that patients enrolled in the study had been infected with COVID-19 and now have adequate levels of IgG antibodies to make them eligible to donate convalescent plasma.

Initial Shipments in United States. We made our initial commercial shipments of the DPP COVID-19 System to U.S. customers late in April 2020 and continued to ship product until receipt of the Revocation.

Revocation of EUA. On June 16, 2020, the FDA stated that it was revoking our EUA for the DPP COVID-19 IgM/IgG System was revoked, 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 a National Institutes of Health/National Cancer Institute (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.

Despite the Revocation, we continue to be excited about our opportunities in the market for DPP COVID-19 IgM/IgG Systems, as follows:

- 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
- The FDA's recent identification of the performance criteria for COVID-19 serology tests clarified our path forward in working to revise the DPP COVID-19 IgM/IgG System to meet or exceed current FDA requirements.

Regarding the 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:

- 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.

Targeted Uses and Customers

By changing the way people interact and function in everyday life, the COVID-19 pandemic has created new types of customer needs and has expanded the use cases for diagnostic testing. We believe the DPP COVID-19 System is well-positioned to address both existing and emerging markets by, for example, monitoring infection progression in individuals to improve clinical outcomes, surveilling community populations to determine herd immunity, and facilitating evaluation of potential therapeutic treatments and potential vaccine development processes. Because the DPP COVID-19 System is portable, uses a fingerstick blood sample or other samples, can produce accurate results, and requires approximately 15 minutes for test processing and approximately 15 seconds for results processing, we believe tests can be conducted in a wide variety of settings, including on a decentralized basis without significant infrastructure.

Because the EUA issued by the FDA for emergency use of the DPP COVID-19 System was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, to perform moderate and high complexity tests, we are working with the FDA to identify and understand the requirements and guidelines that would be applicable to receiving a certificate of waiver under CLIA with respect to the DPP COVID-19 System. CLIA generally regulates laboratories that test human specimens and ensures laboratories produce accurate, reliable, and timely patient test results, regardless of where the test is performed. As defined by CLIA, waived tests are categorized as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. A CLIA-waived test can be performed as a point-of-care test at any laboratory with a Certificate of Waiver without need for a highly trained laboratory technician to administer the test, which makes the test more accessible and economical. This would include many physician offices, health clinics and urgent care centers, pharmacies and nursing homes. In the event that FDA approves our application for waived status under CLIA, we anticipate that a diverse customer base will be interested in using the DPP COVID-19 System, based on the DPP COVID-19 System's portability, accuracy, speed, cost-effectiveness and ease of use.

If we are granted an EUA for the revised DPP COVID-19 System and, until the FDA authorized waived status under CLIA, we will focus our sales efforts on target hospitals, moderately complex physician office labs, urgent care clinics and state and city health departments authorized to perform moderate and high complexity tests in regions that have been most effected by the pandemic. Outside the known health care arena, we anticipate there will be increasing interest from larger institutions and employers as the world evaluates its path back to work and whether individuals may have been exposed to COVID-19 and may have immunity.

Legacy Infectious Disease Product Portfolio

We are a leading provider of diagnostic tests for infectious diseases with a broad portfolio of infectious disease products. We refer to our infectious disease products, other than the DPP COVID-19 System, as our legacy products. As described above under "—DPP COVID-19 System," in the six months ended June 30, 2020 we began the process of shifting substantially all of our resources to the development and commercialization of the DPP COVID-19 System. As a result, and as illustrated by our results for the six months ended June 30, 2020, we expect to generate a diminished amount of revenue from our legacy products for the foreseeable future, while we continue to focus on the manufacture and commercialization of the DPP COVID-19 System. Thereafter, we intend to recommence the development, marketing, manufacture and sale of the legacy product portfolio consistent with market demand.

Nearly all of our legacy infectious disease products are based on our DPP technology. They require only a single drop of blood from the fingertip or other samples, and provide results in approximately 15 minutes. These products feature:

- enhanced sensitivity and specificity;
- advanced multiplexing; and
- when used with our Micro Reader, accurate results processed in approximately 15 seconds.

Regulatory Approvals

We have obtained FDA approvals and, directly or through our partners, international regulatory approvals for legacy infectious disease tests as follows:

Product	U.S.	International
DPP COVID-19 IgM/IgG System		✓
DPP HIV 1/2 Assay	✓	✓
DPP HIV-Syphilis System	Pending FDA Approval	✓
DPP Syphilis Screen & Confirm Assay		✓
DPP ZCD IgM/IgG System		✓
DPP Dengue NS1 Antigen System		✓
DPP Dengue IgM/IgG System		✓
DPP Zika IgM System	✓	✓
DPP Zika IgM/IgG System		✓
DPP Chikungunya System		✓
DPP Ebola Antigen System	✓ EUA	
DPP Leishmaniasis Assay		✓
HIV 1/2 STAT-PAK Assay	✓	✓
Chagas STAT-PAK Assay		✓
SURE CHECK HIV 1/2 Assay	✓	✓
SURE CHECK HIV Self-Test		✓

Historically, we have sought to leverage our FDA approvals and, directly or through our partners, international regulatory approvals for infectious disease tests as follows:

- our registration of existing and new products in unchartered countries and regions, such as selected countries in Latin America and Southeast Asia;
- our entry into new market segments, such as international HIV self-testing; and
- advances in our product pipeline in infectious disease with key products, including a multiplex test for HIV and Syphilis targeted for sale in the United States and tests for Chikungunya, Dengue and Zika for sale internationally.

Legacy Products

Our legacy products include both stand-alone and multiplex tests for sexually transmitted infectious diseases, such as HIV and Syphilis. HIV and Syphilis continue to be major global public health issues. According to estimates of the World Health Organization, or WHO:

- HIV has claimed more than 35 million lives, including 770,000 in 2018. Approximately 37.9 million people were living with HIV at the end of 2018, and 1.7 million were newly infected during 2018.
- There were 18.0 million prevalent cases of Syphilis as of 2012, and 5.6 million new infections were estimated to occur annually.
- Elimination of mother-to-child transmission, or MTCT, of both HIV and Syphilis is a global health priority. In 2013, 1.9 million pregnant women were infected with Syphilis worldwide. Congenital syphilis contributes significantly to infant mortality, accounting for 305,000 annual perinatal deaths worldwide in 2013. Globally, more than 1.4 million pregnant women were infected with HIV as of 2015, and MTCT of HIV is estimated to have resulted in over 150,000 infant cases in 2015.

We have sought to address the global concerns related to HIV and Syphilis co-infection through the development of a novel, multiplex test for both HIV and Syphilis. We developed a DPP HIV-Syphilis multiplex test and received regulatory approvals covering a number of international markets, including Brazil, Europe, Malaysia and Mexico. In February 2020, we received a “not approvable” letter from the FDA with respect to our Premarket Approval, or PMA, application on our DPP HIV-Syphilis multiplex test for commercial use in the United States. The FDA requested the repeat of the reproducibility study, as one of the sites in the trial reported greater variability compared to the other sites. We completed and submitted the repeat study to the FDA in April 2020 and are awaiting its formal review. When appropriate and subject to issuance of the PMA, we will continue the pursuit of the associated CLIA waiver. We believe we continue to be well-positioned to be the first company to introduce a multiplex, rapid test for HIV and Syphilis in the United States.

Our legacy products also include tests for selected fever and tropical diseases such as Chagas, Ebola, Leishmaniasis and Zika. The market for lateral flow tests for mosquito-borne diseases includes established markets for diseases such as Dengue and Malaria, which WHO estimates collectively account for more than 600 million annual infections worldwide. There are also a number of emerging markets for lateral flow tests for infectious diseases such as Burkholderia, Chikungunya, Dengue, lassa, leptospirosis, Marburg, Rickettsia and Zika. Though certain of these have not been commercialized, our legacy products include tests using our DPP platform to detect all of the aforementioned fever and tropical diseases, as stand-alone or multiplex tests.

Our investments in these products are attracting international attention. In April 2020, we received a second $1.5 million purchase order from UNICEF for multiplex Zika, Chikungunya and Dengue (DPP ZCD) Systems, including tests and Micro Readers. The orders follow the successful completion of conditions set forth in the previously announced long term arrangement (LTA). Along with the firm purchase commitment of $1.5 million, the LTA includes additional potential purchases of up to $2.0 million, for a total potential amount of up to $3.5 million. Along with the previous UNICEF order for Chembio’s multiplex Zika IgM/IgG System announced in February 2020, the combined LTAs contemplate up to $7.0 million in potential orders. Shipments under these orders commenced during the quarter ended June 30, 2020 and will scheduled for delivery through 2021.

Our DPP ZCD System can accurately detect three unique viral infections, all of which are transmitted by the same type of mosquito, have similar symptoms and are often associated with co-infections. We believe that testing for these viruses in combination will be critical in addressing these co-circulating pathogens. This novel multiplex test will enhance both surveillance capabilities and clinical response efforts, providing significant advantages over current lab-based tests by allowing healthcare providers to take rapid action.

Chembio’s multiplex DPP ZCD System allows simultaneous and discrete detection of antibodies for both active (IgM) and prior exposure (IgG) to Zika, Chikungunya and Dengue viruses. The DPP ZCD System has received approval from ANVISA in Brazil and is CE Marked.

Third-Party Funding

Since 2015, we have received over $12.2 million of funding from some of the world's leading health organizations, which has helped us accelerate the expansion of our pipeline of infectious disease tests. Our collaborators have included: the Bill & Melinda Gates Foundation; The Paul G. Allen Family Foundation, or Paul Allen Foundation; The Oswaldo Cruz Foundation (Fiocruz); and the Foundation for Innovative New Diagnostics, or FIND, as well as U.S. government agencies such as the Centers for Disease Control and Prevention, or CDC, the Biomedical Advanced Research and Development Authority of the U.S. Department of Health and Human Services, or BARDA, and the U.S. Department of Agriculture.

Legacy Products Under Development

Several tests in our infectious disease pipeline are approaching commercialization, and several have received initial regulatory approvals:

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification & Validation	Phase IV Clinical & Regulatory	Phase V Commercial Launch
DPP HIV-Syphilis System (US)	Self-funded	✓	✓	✓	✓	PMA pending
DPP Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Dengue NS1 Antigen System	Self-funded	✓	✓	✓	✓	CE and ANVISA pending
DPP Chikungunya IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Zika Chikungunya Dengue IgM/IgG System	Self-funded	✓	✓	✓	✓	CE and ANVISA
DPP Ebola Antigen System	CDC	✓	✓	✓	✓	FDA-EUA
DPP Fever Assay Asia	FIND	✓	✓	✓	✓	
DPP Fever Assay Africa	Paul Allen Foundation	✓	✓	✓		
DPP Fever Assay Malaysia	Self-funded	✓	✓	✓	✓	

Sales Channels

We believe our deep experience with infectious diseases, including our development of tests that can multiplex as many as eight different diseases with a single drop of blood and deliver accurate results with our Micro Readers, illustrates our ability to expand our DPP technology into a broader range of tests. Our initial focus for the DPP COVID-19 System is in the United States and in fulfilling existing orders from Brazil, but we expect to expand our sales efforts to include Europe and elsewhere, as demand determines.

There is a diverse customer base interested in using the DPP COVID-19 System. This potential group includes various hospital departments, state and city health departments, ambulatory surgery centers, physician offices, health clinics and urgent care centers, pharmacies, and nursing homes. Outside the known health care arena, we anticipate there will be increasing interest from larger institutions and employers as the world evaluates its path back to work and whether individuals may have been exposed to COVID-19 and may have immunity. We are focusing our initial sales efforts for the DPP COVID-19 System principally on hospitals, physician offices with moderately complex labs, urgent care clinics and state and city health departments in the regions that have been most affected by the pandemic, while monitoring existing and escalating demand throughout the United States and internationally.

Our broader infectious disease portfolio of products is sold globally, both directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies and consumers. Historically, we marketed and sold our products only in a small number of countries and regions. While we are focusing substantially on the market for the DPP COVID-19 System, we intend to maintain our relationships with the United Nations Children's Fund, or UNICEF, and other organizations and agencies that influence market decisions for our legacy products and products under development.

To support our commercial efforts and support future growth, we are also adding to our marketing and customer service teams in a manner that is aligned with our growth expectations.

Manufacturing

In April 2020, we initiated a retrenchment of our Malaysian facility that was completed during the second quarter of 2020 and that included termination of employment of our Malaysian workforce. We now manufacture all of our tests in the United States and Brazil and all of our Micro Readers in Germany.

In 2018, we began process of automating some of our manufacturing processes and expanding our manufacturing capacity in the United States. We initiated the process of automating our U.S. manufacturing processes because we believe the reduced variable costs associated with automated manufacturing lines will improve product gross margins.

As described under "—Business Update—DPP COVID-19 System" above, since February 2020 we have been shifting resources to develop and commercialize the DPP COVID-19 System. Accordingly, and in connection with receipt of an EUA from the FDA for the DPP COVID-19 System, during the three months ended March 31, 2020 we began the process of shifting substantially all of our test manufacturing capacity to the DPP COVID-19 System. This shift included investment totaling approximately $0.8 million to increase tooling capacity, advance our automated manufacturing, and begin recruiting additional workers to expand capacity and supplement absenteeism associated with employee self-quarantines as the result of the COVID-19 pandemic.

During the initial period of expected high demand for COVID-19 tests such as the DPP COVID-19 System, the ultimate duration of which we continue to evaluate, we worked to scale both our manual and automated processes for the assembly of tests for the DPP COVID-19 System. We have designed, and will seek to implement, a capacity growth plan intended to ramp production. Our actual growth in capacity will be tied to market demand, and our ability to ramp capacity will be subject to our ability to fund, manage and execute our internal manufacturing requirements and to continue to have the necessary support of our supply chain and other vendors.

Research & Development Services

Our commercially available products employ either our proprietary DPP technology or traditional lateral flow technology. In recent years, we have, while concurrently developing our own products, executed a strategy to leverage DPP intellectual property, as well as our scientific and operational expertise, through our Research & Development Services program of collaborative projects.

Research & Development Services develops tests for third parties using our DPP platform and, in limited cases, other platforms in projects that we believe have the potential to create value for the rest of our business. Research and development, or R&D, costs related to these collaborations are fully funded by our collaborators. We believe that, in addition to providing revenue to support our R&D organization, these activities further validate the DPP platform's ability to provide superior diagnostic performance compared with products that utilize traditional lateral flow technology. The projects also expand the know-how of our R&D team, which we seek to leverage in the development of our own products.

Examples of projects performed by Research & Development Services include the following:

- In January 2015 we entered into an agreement with the Concussion Science Group Division of Perseus Science Group LLC, or Perseus, to develop a rapid diagnostic test for traumatic brain injury utilizing both our DPP and optical analyzer technologies.
- In October 2017 we signed a biomarker development project agreement with AstraZeneca plc, or AstraZeneca, utilizing both our DPP and optical analyzer technologies.
- In April 2018, we entered into a collaboration agreement with LumiraDx to develop new rapid diagnostic tests for infectious diseases. Under terms of the agreement, we receive funding from LumiraDx, subject to satisfying certain milestones, to develop certain neibiw rapid infectious disease tests. Following the regulatory approval and commercialization of tests in accordance with the agreement, we will both sell reagents to, and receive royalty payments from, LumiraDx on sales of all products developed through this collaboration.
- In July 2019 we entered into a collaboration agreement with Shire, a subsidiary of Takeda Pharmaceutical to develop a novel rapid diagnostic test to detect an undisclosed biomarker.
- In March 2020 we completed the technical feasibility phase for a potential companion/compatible diagnostic test being developed in collaboration with Shire. The program is focused within Takeda's Rare Diseases Therapeutic Area Unit, which aspires to transform the treatment of rare diseases in immunology, hematology, metabolic and lysosomal storage disorders. Based on the progress, in March 2020 Takeda provided the next tranche of funding for the next phase of the program.
- We entered into agreements with LumiraDx in March 2020 (as amended in April 2020) to, among other things, develop a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies on the LumiraDx platform.
- In July 2020, we were selected to conduct a second research and development services program for Takeda utilizing our DPP technology and Micro Reader analyzers.

We believe leading global healthcare organizations and others have chosen to collaborate with us based on our deep scientific expertise with our DPP technology platform and capabilities, our successful record of developing DPP tests with a diverse set of collaborators, including global commercial companies, governments and non-governmental organizations, and our extensive experience in obtaining regulatory approvals from various regulatory authorities in the United States, Brazil, the European Union, and Mexico, as well as prequalifications from WHO.

The following table illustrates the status of work within our Research & Development Services program:

Product	Collaborator	Phase I Feasibility	Phase II Development	Phase III Verification &Validation	Phase IV Clinical/ Regulatory	Phase V Commercial Launch
DPP Rare Disease (undisclosed biomarker)	Takeda	✓	✓			
DPP (undisclosed biomarker)	Takeda	✓				
DPP COVID-19 Antigen System	BARDA	✓				
COVID-19 Test	LumiraDx	✓	✓	✓		
Infectious Disease Portfolio	LumiraDx	✓	✓			
DPP Biomarker Development Project (undisclosed biomarker)	AstraZeneca	✓	✓	✓		CE Mark*
DPP TBI	Perseus	✓	✓			

*For use in pharmaceutical research

Competition

General

Many of our competitors are significantly larger than us, and they may have market presence, engineering, technical and marketing capabilities and financial, personnel and other resources substantially greater than our own. Important competitive factors include product quality, analytical performance, ease of use, price, customer service and reputation. Industry competition is based on these and the following additional factors:

- patent protection;
- scientific expertise;
- ability to develop and market products and processes;
- ability to obtain required regulatory approvals;
- ability to manufacture cost-effective products that meet applicable regulatory requirements;
- access to adequate capital; and,
- ability to attract and retain qualified personnel.

Our ability to develop and market other products is in large measure dependent on our having additional resources and collaborative relationships. Some of our product development efforts have been funded by a third party on a project or milestone basis. We believe our proprietary know-how relating to our DPP technology has been instrumental in obtaining collaborations. We believe our patent protection enhances our ability to develop new, more profitable collaborative relationships.

DPP COVID-19 System

Competition is, and will likely continue to be, particularly intense in the market for COVID-19 diagnostic tests. Numerous companies in the United States and internationally have announced their intention to offer new products, services and technologies that could be used in substitution for the DPP COVID-19 System. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than our company. Existing and potential competitors in the market for COVID-19 diagnostic tests include developers of antigen, serological and molecular tests.

We expect competition to continue to increase as other established and emerging companies enter the market, as customer requirements evolve, and as new products, services and technologies are introduced. The entrance of new competitors is being encouraged by governmental authorities, who are offering funding to support development of testing solutions for COVID-19. For example, on April 29, 2020, the U.S. National Institutes of Health announced it would be using a portion of its $1.5 billion in federal stimulus funding to fund a $500 million national challenge designed to help the agency identify the best candidates for an at-home or point-of-care test for COVID-19. Some of our existing or new competitors may have strong relationships with current and potential customers, including governmental authorities, and, as a result, may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer requirements. In addition, during the time period between the Revocation and resubmission we anticipate for EUA, competitors have gained progress in their commercialization efforts, and customers have gained experience in using competitive product.

We believe we will be able to compete successfully based upon (a) the capabilities and attributes of the DPP COVID-19 System, which can provide, for a competitive price, rapid and accurate test results for both IgM and IgG antibodies through portable, close-to-the-patient tests and analyzers, (b) our extensive experience in developing rapid tests to respond to the HIV crisis and the Ebola and Zika global outbreaks.

Expense Reduction Program

During the six months ended June 30, 2020, we began implementing a multi-faceted expense reduction program to reduce operating expenses and facilitate profitable growth. We undertook actions to adjust the size and composition of our organization, including by removing positions that were non-essential in light of our new business strategy, and to remove other expenses, all of which we expect will provide savings throughout, and after, 2020. Certain actions were taken with a view to facilitating our new focus on the development, manufacture and commercialization of the DPP COVID-19 System.

In light of market dynamics, we also completed a retrenchment of our Malaysian operations, including the termination of employment of our Malaysian workforce during the three months ended June 30, 2020. We will maintain our Malaysian subsidiary and facility and sustain the product registrations that were obtained throughout southeast Asia, with the benefit of having that entity to preserve the opportunity to restart operations there in the future when market conditions warrant.

Based on these activities, the Company recorded a restructuring charge ranging of $0.4 million during the three months ended June 30, 2020.

Consolidated Results of Operations

Three Months Ended June 30, 2020 Versus Three Months Ended June 30, 2019

Our results of operations for the three months ended June 30, 2020 and 2019 were as follows (dollars in thousands):

	June 30, 2020		June 30, 2019	
TOTAL REVENUES	**$ 5,111**	**100%**	$ 9,888	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**5,671**	**111%**	6,990	71%
Research and development expenses	**1,922**	**38%**	2,101	22%
Selling, general and administrative expenses	**4,397**	**41%**	4,097	43%
Severance and restructuring costs	**388**	**0%**	-	0%
	12,378		13,188	
LOSS FROM OPERATIONS	**(7,267)**		(3,300)	
OTHER (EXPENSE) INCOME, NET	**(712)**		6	
LOSS BEFORE INCOME TAXES	**(7,979)**	**(156)%**	(3,294)	(36)%
Income tax benefit	**(135)**		(107)	
NET LOSS	**$ (7,844)**		$ (3,187)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the three months ended June 30, 2020 were $5.1 million, a decrease of $4.8 million, or 48.3%, compared to the three months ended June 30, 2019. As discussed above, in the second quarter, we executed the initial steps to implement our new business model and focus our resources on the development and commercialization of COVID-19 testing products. At the same time, the customers of our legacy infectious disease tests also focused much of their resources on COVID-19 management.

The Revocation had a significant negative impact on our product revenues by triggering the recall of unused tests from customers in the United States. In addition, given the uncertainty of the regulatory environment outside the U.S., we did not recognize net revenue in the second quarter for our shipments of the COVID-19 System outside the U.S.

Gross Product Margin

Cost of product revenue is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses.

Gross product margin is net product revenue less cost of product revenue, and gross product margin percentage is gross product margin as a percentage of net product revenue. Gross product margin during the three months ended June 30, 2020 decreased by $3.7 million, or 205%, from the comparable period of 2019. The gross product margin reduction resulted from losses related to the Revocation during the second quarter, which triggered the return of COVID-19 Systems that were produced and sold to customers in the U.S. It also resulted from cost of product revenue including the cost of COVID-19 Systems that were produced and shipped outside the U.S., but for which revenue was not recognized due to the requirement of GAAP that we have a high degree of confidence that it is probable that a significant reversal in revenue will not occur. Many factors can affect that consideration, including, as examples, things outside our influence, actions of third parties, and evidence from similar situations. After considering all the information available to us, we were not able to recognize the product revenue from those shipments in the second quarter due to the hurdle that requires a high degree of confidence that it is probable that a significant reversal in revenue will not occur.

The following schedule calculates gross product margin (dollars in thousands):

	For the Three Months Ended June 30		Favorable/(Unfavorable)	
	2020	2019	**$ Change**	**% Change**
Net product sales	**$ 3,792**	$ 8,785	$ (4,993)	56.8%
Less: Cost of product sales	**(5,671)**	(6,990)	1,319	18.9%
Gross product margin	**$ (1,879)**	$ 1,795	$ (3,674)	204.7%
Gross product margin percentage	**(49.6)%**	20.4%		

The $3.7 million decrease in gross product margin was composed of the following:

- $1 million unfavorable product sales volume as described above, together with
- $2.6 million unfavorable product margins related to the cost of returned product and product shipped outside the U.S.

We believe the our investment in automation will reduce our reliance on manual labor and contribute to improved product gross margins.

Research and Development

This category includes costs incurred for clinical and regulatory affairs and other R&D as follows (dollars in thousands):

	For the Three Months Ended June 30		Favorable/(Unfavorable)	
	2020	2019	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 178**	$ 323	$ 145	44.9%
Other research and development	**1,744**	1,778	34	1.9%
Total research and development	**$ 1,922**	$ 2,101	$ 179	8.5%

The decrease in R&D costs for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily associated with the reduction in clinical trial cost related to the DPP HIV-Syphilis System during 2019, offset by costs related to the development of the DPP COVID-19 System.

Selling, General and Administrative Expense

Selling, general and administrative expense includes administrative expenses, sales and marketing costs (including commissions), and other corporate items.

The $0.3 million, or 7.3%, increase in selling, general and administrative expense for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 is primarily related to one-time period costs and equity compensation costs.

Other Income (Expense), net

Other expenses/income, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the three months ended June 30, 2020 compared to comparable period in 2019 due to interest accruing on long-term debt incurred on September 3, 2019, of which $20 million (carrying value of $17.9 million) was outstanding at June 30, 2020. For a description of this long-term debt, please see "—Liquidity and Capital Resources—Sources of Funds—Credit Agreement" below.

Income Tax Benefit

During the three months ended June 30, 2020, we recognized a tax benefit of $0.1 million related to losses generated by our foreign subsidiaries. As of June 30, 2020 and 2019, our U.S. deferred tax assets included a full valuation allowance.

Six Months Ended June 30, 2020 versus Six Months Ended June 30, 2019

The results of operations for the six months ended June 30, 2020 and 2019 were as follows (dollars in thousands):

	June 30, 2020		June 30, 2019	
TOTAL REVENUES	**$ 11,971**	**100%**	$ 18,430	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	**10,045**	**84%**	12,002	65%
Research and development expenses	**3,881**	**32%**	4,318	23%
Selling, general and administrative expenses	**8,554**	**71%**	8,110	44%
Severance and restructuring costs	**1,111**	**9%**	-	0%
Acquisition costs	**64**	**1%**	396	2%
	23,655		24,827	
LOSS FROM OPERATIONS	**(11,684)**		(6,396)	
OTHER (EXPENSE) INCOME, NET	**(1,374)**		13	
LOSS BEFORE INCOME TAXES	**(13,058)**	**(109)%**	(6,383)	(35)%
Income tax benefit	**(215)**		(380)	
NET LOSS	**$ (12,843)**		$ (6,003)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the six months ended June 30, 2020 were $12 million, a decrease of $6.5 million, or 35% compared to the six months ended June 30, 2019. As discussed above, in the second quarter, we executed the initial steps to implement our new business model and focus our resources on the development and commercialization of COVID-19 testing products. At the same time, the customers of our legacy infectious disease tests also focused much of their resources on COVID-19 management. The Revocation had a significant negative impact on our net product revenues by triggering the recall of unused tests from customers in the United States. In addition, given the uncertainty of the regulatory environment outside the U.S., we did not recognize revenue in the second quarter for our shipments of the COVID-19 System outside the U.S. Total revenues for the six months ended June 30, 2020 was also adversely affected by our shift in focus from offering and selling legacy products to developing and beginning to commercialize the DPP COVID-19 System.

Gross Product Margin

Cost of product sales is primarily composed of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses.

Gross product margin is net product revenue less cost of product revenue, and gross product margin percentage is gross product margin as a percentage of net product revenue. Gross product margin during the six months ended June 30, 2020 decreased by $4 million, or 116%, from the comparable period of 2019. The gross product margin reduction resulted from losses related to the revocation during the second quarter, which triggered the return of COVID-19 Systems that were produced and sold to customers in the U.S. It also resulted from cost of product revenue including the cost of COVID-19 Systems that were produced and shipped outside the U.S., but for which revenue was not recognized due to the requirement of GAAP that we have a high degree of confidence that it is probable that a significant reversal in revenue will not occur. Many factors can affect that consideration, including, as examples, things outside our influence, actions of third parties, and evidence from similar situations. After considering all the information available to us, we were not able to recognize the product revenue from those shipments in the second quarter due to the hurdle that requires a high degree of confidence that it is probable that a significant reversal in revenue will not occur.

The following schedule calculates gross product margin (dollars in thousands):

	For the Six Months Ended		**Favorable/(Unfavorable)**	
	June 30, 2020	June 30, 2019	**$ Change**	**% Change**
Net product sales	**$ 9,508**	$ 15,409	$ (5,901)	38.3%
Less: Cost of product sales	**10,045**	(12,002**)**	1,957	16.3%
Gross product margin	**$ (537)**	$ 3,407	$ (3,944)	115.8%
Gross product margin percentage	**(5.6)%**	22.1**%**		

The $3.9 million decrease in gross product margin was composed of the following:

- $1.3 million unfavorable product sales volume as described above, together with
- $2.6 million unfavorable product margins related to the cost of returned product and product shipped outside the U.S.

We believe our investment in automation will reduce our reliance on manual labor and contribute to improved product gross margins.

Research and Development

This category includes costs incurred for clinical and regulatory affairs and other research and development, as follows (dollars in thousands):

	For the Six Months Ended		Favorable/(Unfavorable)	
	June 30, 2020	June 30, 2019	**$ Change**	**% Change**
Clinical and regulatory affairs	**$ 500**	$ 763	$ 263	34.5%
Other research and development	**3,381**	3,555	174	4.9%
Total Research and Development	**$ 3,881**	$ 4,318	$ 437	10.1%

The decrease in R&D costs for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily associated with the reduction externally funded programs and clinical trial costs related to the DPP HIV-Syphilis System during 2019, offset by costs related to the development of the DPP COVID-19 System.

Selling, General and Administrative Expense

Selling, general and administrative expense includes administrative expenses, sales and marketing costs (including commissions), and other corporate items.

The $0.4 million, or 5.5%, increase in selling, general and administrative expense for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 related to one-time period costs and equity compensation costs.

Other (Expense) Income, net

Other expenses/income, net consists principally of interest expense, net of interest income earned on our deposits, which increased in the six months ended June 30, 2020 compared to comparable period in 2019 due to interest accruing on long-term debt incurred on September 3, 2019, of which $20 million (carrying value of $17.9 million) was outstanding at June 30, 2020. For a description of this long-term debt, please see “—Liquidity and Capital Resources —Sources of Funds—Credit Agreement” below.

Income Tax Benefit

During the six months ended June 30, 2020, we recognized a tax benefit of $0.2 million related to losses generated by our foreign subsidiaries. As of June 30, 2020 and 2019, our U.S. deferred tax assets included a full valuation allowance.

Liquidity and Capital Resources

During the six months ended June 30, 2020 we have funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used $7.3 million of cash, and we received proceeds on issuance of stock of $28.5 million (net of expenses). As of June 30, 2020, we had outstanding debt (excluding leases) in the amount of $20.1 million (carrying amount of $17.9 million), consisting of loans of $20.0 million under a credit agreement entered into on September 3, 2019 and $0.1 million under a seller-financed note payable incurred in connection with our purchase of automated manufacturing equipment.

We continually evaluate our liquidity requirements, capital needs and availability of capital resources based on our operating needs and our planned growth initiatives, particularly in the light of our shift in business focus to the DPP COVID-19 System. We believe our existing cash and cash equivalents and our cash flow from operating activities will be sufficient to meet our anticipated cash needs for at least the next twelve months. Our future working capital needs will depend on many factors, including the timing of our planned submission of the revised DPP COVID-19 System for an EUA and a successful award of such by the FDA; the rate of our business and revenue growth, particularly if we are able to resume commercialization of the DPP COVID-19 System; the timing of our continuing automation of U.S. manufacturing; and the timing of investment in our research and development as well as sales and marketing. If we are unable to increase our revenues and manage our expenses in accordance with our operating plan, we may need to reduce the level or slow the timing of the growth plans contemplated by our operating plan, which would likely curtail or delay the growth in our business contemplated by our operating plan and could impair or defer our ability to achieve profitability and generate cash flow, or to seek to raise additional funds through debt or equity financings, strategic relationships, or other arrangements.

Sources of Funds

The following table sets forth selected working capital information:

	June 30, 2020
	(in thousands)
Cash and cash equivalents	$ 36,427,468
Accounts receivable, net of allowance for doubtful amounts	2,610,587
Inventories, net	14,131,540
Prepaid expenses and other current assets	742,908
Total current assets	53,912,503
Less: Total current liabilities	14,296,153
Working capital	$ 39,616,350

We received net proceeds of $28.4 million from an underwritten public offering of Common Stock in May 2020.

On April 20, 2020, we entered into an agreement with the U.S Small Business Administration for a loan of $3 million under the Paycheck Protection Program. The loan bears a 1% interest rate and has a two-year term beginning on the date of disbursement. Principal and interest is due at maturity. This loan was returned on May 2020.

On April 24, 2020, we were awarded a grant of $1.0 million from Empire State Development to be used as working capital for the development and production of IgM/IgG serology tests for COVID-19 for sale in the State of New York. Of that total, $0.5 million was funded during the three months ended June 30, 2020.

Our cash and cash equivalents at June 30, 2020, which included a restricted amount of $3.3 million, was held for working capital purposes. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends. We have not entered into, and do not expect to enter into, investments for trading or speculative purposes. Our accounts receivable and investory balances fluctuate from period to period, which affects our cash flow from operating activities. Fluctuations vary depending on cash collections, client mix, and the timing of shipment of our products and the invoicing of our research and development activities.

Uses of Funds

Our operations used $7.3 million of cash during the six months ended June 30, 2020, reflecting a net loss adjusted for non-cash items of $11.2 million (which included $1.1 million of severance and restructuring costs and $0.1 million of acquisition costs), a $1.1 million decrease in accounts receivable, offset by a $4.5 million increase in inventory, a $3.3 million increase in accounts payable and accrued liabilities and a $4.0 million increase in deferred revenue.

During the six months ended June 30, 2020, we continued to invest in manufacturing equipment, leasehold improvements and other fixed assets, particularly in the light of our shift in business focus to our DPP COVID-19 System. Our capital expenditures totaled $2.4 million in the six months ended June 30, 2020.

Off-Balance Sheet Arrangements

As of June 30, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K under the Securities Exchange Act of 1934, or the Exchange Act.

Significant Accounting Policies and Critical Accounting Estimates

The following description of our significant accounting policies and critical accounting estimates augments the disclosure set forth under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

Revenue Recognition

We recognize revenue for product sales in accordance with FASB ASC 606, *Revenue from Contracts with Customers*. Revenues from product sales are generally recognized when the customer obtains control of our product, which occurs at a point in time, typically upon tendering to the customer, subject to variable consideration and other provisions of ASC 606. We expense incremental costs of obtaining a contract as and when incurred because the expected amortization period of the asset that it would have recognized is one year or less or the amount is immaterial. Freight and distribution activities on products are performed after the customer obtains control of the goods. We have made an accounting policy election to account for shipping and handling activities that occur either when or after goods are tendered to the customer as a fulfillment activity, and therefore recognizes freight and distribution expenses in Cost of Product Sales. We exclude certain taxes from the transaction price (e.g., sales, value added and some excise taxes).

For certain contracts, we recognize revenue from research and development, milestone and grant revenues when earned. Grants are invoiced after expenses are incurred. Revenues from projects or grants funded in advance are deferred until earned. For certain collaborative research projects, we recognize revenue by defining milestones at the inception of the agreement and applying judgement and estimates in recognizing revenue for relevant contracts.

Recently Issued Accounting Pronouncements

A discussion of recent accounting pronouncements was included in our 2019 Form 10-K and is updated in subsection (v) of note 2 to the condensed consolidated financial statements included elsewhere in this report.

ITEM 4. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures**. Under the supervision and with the participation of our senior management, consisting of our principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this report. Based on this evaluation, our management, including our principal executive officer and principal financial officer, concluded that as of June 30, 2020 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in our Exchange Act reports is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) **Changes in Internal Control over Financial Reporting**. There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or Rule 15d-15 under the Exchange Act that occurred during the three months ended June 30, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Employee Litigation

John J. Sperzel, our former chief executive officer, has asserted a right to exercise certain options to purchase, for an aggregate exercise price of $943,126, a total of 266,666 shares of common stock that were vested when he resigned on January 3, 2020. Under their terms, those options were exercisable for a period of thirty days after his service to our company ended. The compensation committee of the board, acting in its discretion in accordance with the terms of the underlying equity incentive plans, has determined that Mr. Sperzel failed to exercise the options in a timely manner prior to their expiration. Chembio intends to vigorously defend against any claim by Mr. Sperzel that he continues to have a right to exercise any options.

Stockholder Litigation

As of July 31, 2020, four purported class action lawsuits had been filed by alleged stockholders of our company 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; and (4) Ken Hayes v. Chembio Diagnostics, Inc., Richard L. Eberly, Gail S. Page, Katherine L. Davis, Mary Lake Polan, and John G. Potthoff, 1:20-cv-02918, filed on July 1, 2020, or Hayes.

The Chernysh, Gowen and Bailey complaints are brought by purported individual stockholders of our company 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 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. We and the plaintiffs in Chernysh, Gowen and Bailey have entered into a stipulation, approved by the Court on July 17, 2020, relieving the defendants from the obligation to respond to the complaints in the cases pending the designation of a lead plaintiff. Pursuant to the stipulation, within ten days following the entry of an order by the Court appointing a lead plaintiff and a lead plaintiff's counsel, counsel for the defendants and the lead plaintiff are to confer and submit to the Court a proposed schedule for the filing of a consolidated amended complaint and the defendants' response to that pleading.

The Hayes complaint purports to state claims for violations of Section 14(a) of the Securities Exchange Act of 1934 and Rule 14a-9 promulgated thereunder by the Securities and Exchange Commission, declaratory relief, and state law claims for breach of fiduciary duty, brought by plaintiff on behalf of himself and all of our other public stockholders against our company and directors to remedy alleged misstatements of material information in the proxy statement disseminated by Chembio in advance of our Annual Meeting of Stockholders held on July 28, 2020, or the Annual Meeting. The Hayes plaintiff alleges that the Schedule 14A Proxy Statement we filed on June 16, 2020 with the Securities and Exchange Commission, or the Proxy Statement, in which we were soliciting stockholder approval of, inter alia, a proposal to change our state of incorporation from the State of Nevada to the State of Delaware (the "Reincorporation Proposal"), contained misstatements of Nevada and Delaware law. The Hayes plaintiff sought a declaration that the Proxy Statement was false and misleading and entry of an order enjoining the stockholder vote on the Reincorporation Proposal until such time as the Proxy Statement has been corrected as well as an order finding our directors liable for breaching their fiduciary duties and awarding plaintiff the costs and disbursements of the action, including attorneys' and expert fees. On July 8, 2020, we filed an amended proxy statement correcting, among other things, the issues raised in the Hayes complaint. As a consequence of the supplementation, the plaintiff withdrew its motion for a preliminary injunction. On July 23, 2020, weo and the plaintiff entered into a stipulation to the dismissal of the action, with prejudice as to the claims of the named plaintiff. The stipulation was subject to plaintiff's reservation of the right to apply for an award of attorneys' fees and expenses from us within 45 days after entry of an order approving the stipulation in the event the parties are unable to reach agreement on plaintiff's claim for entitlement to fees. Also, on July 23, 2020, the plaintiff filed a notice dismissing the named plaintiff's claims, with prejudice, as to the individual defendants. On July 27, 2020, the Court entered an order closing the case and providing that plaintiff shall have until September 28, 2020 to move to reopen the case if the attorneys' fee issue has not been resolved.

ITEM 1A. RISK FACTORS

Except as set forth below, there have been no material changes to the risk factors described in the section captioned Part I, Item 1A, "Risk Factors," in our 2019 Form 10-K. In addition to the other information set forth in this report, you should carefully consider the factors discussed in the section captioned Part I, Item 1A, Risk Factors," in our 2019 Form 10-K, which could materially affect our business, financial condition, or future results. Moreover, you should interpret many of the risks identified in our 2019 Form 10-K as being heightened as a result of the ongoing and numerous adverse impacts of the COVID-19 pandemic. The risks described in our 2019 Form 10-K and in this report are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may have a material adverse effect on our business, financial condition, and/or operating results.

For purposes of the following risk factors, we refer to our DPP COVID-19 IgM/IgG Systems and DPP COVID-19 Antigen Systems collectively as DPP COVID-19 Systems.

Risks Related to Our Business

We have refocused our business strategy to respond to COVID-19, which is a new and rapidly developing market, making it difficult to evaluate our business and future prospects.

The market for COVID-19 diagnostic testing is new and rapidly developing, which makes it difficult to evaluate our business and future prospects. We have encountered, and will continue to encounter, risks and difficulties frequently experienced in rapidly changing industries, including those related to:

- our ability to compete with companies that are currently in, or may in the future enter, the market for our products;
- our ability to control costs, including our operating expenses;
- our ability to successfully expand our business;
- our ability to meet customer demand;
- the amount and timing of operating expenses, particularly sales and manufacturing expenses, related to the maintenance and expansion of our business, operations and infrastructure; and
- general economic and political conditions in our markets.

Given the unpredictable nature of the COVID-19 pandemic, the potential size of this market and the timing of its development is highly uncertain. Our future success is dependent on the manner in which the market for COVID-19 diagnostics develops. If the market develops in a manner that does not facilitate the inclusion of our products, or fails to grow in the manner in which we expect, our business may not continue to grow.

We are allocating substantially all of our resources to the production of our DPP COVID-19 Systems for the foreseeable future, and our long-term business success could be negatively impacted by our diversion of resources from our legacy business of diagnostic testing for other infectious diseases.

We are committing substantially all of our financial and personnel resources to the development, manufacturing and commercialization of DPP COVID-19 Systems. This resource allocation may negatively impact our legacy product portfolio, as we expect to spend limited funds and time on updating pre-existing products and regulatory approvals or on completing products that were in development prior to our strategic decision to focus on DPP COVID-19 Systems. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could dissipate; there is no guarantee that current or anticipated demand will continue, or if demand does continue, that we will be able to produce in quantities to meet the demand. We intend to reestablish our legacy business in the future, but there can be no assurance that we will be able to successfully recommence the development and commercialization of our legacy products and products under development.

Our near-term success is highly dependent on the success of our DPP COVID-19 Systems, and we cannot be certain that it will attain market acceptance or be successfully commercialized in the United States or elsewhere.

Even if we are able to obtain an EUA for either of our revised DPP COVID-19 Systems, that product may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. We have conducted our own research into the markets for our product candidates, including our DPP COVID-19 Systems; however, we cannot guarantee market acceptance of our product, and have somewhat limited information on which to estimate our anticipated level of sales. Our products will require healthcare providers and doctors to accept and adopt our technology. Our industry is susceptible to rapid technological developments and there can be no assurance that we will be able to match any new technological advances. If we are unable to match the technological changes in the needs of our customers the demand for our products will be reduced. Acceptance and use of any products we market will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;
- limitation on use or warnings required by FDA in our product labeling;
- cost-effectiveness of our products relative to competing products;
- convenience and ease of administration;
- potential advantages of alternative treatment methods;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect virtually all of our product revenues for the foreseeable future to be generated from sales of our current products and DPP COVID-19 Systems in particular, the failure of these products to find market acceptance would substantially harm our business and would adversely affect our revenue. If our DPP COVID-19 Systems are not as successfully commercialized as expected, we may not be able to generate sufficient revenue to become profitable. Any failure of either of our DPP COVID-19 Systems to be successfully commercialized in the United States may have a material adverse effect on our business, operating result financial condition and cash flows, and could result in a substantial decline in the price of our common stock.

Our Revised DPP COVID-19 IgM/IgG System may not gain wide industry acceptance, and industry adoption of alternative technology could negatively impact our ability to compete successfully.

Of the 171 manufacturers and commercial laboratories to receive an EUA for COVID-19 diagnostics as of July 31, 2020, 35 were for serology tests, 134 were for molecular tests, and 2 were for antigen tests. Customers or the industry as a whole could adopt alternative technologies for testing, including molecular point-of-care testing, which could result in lower demand for our serological test. Various advances in the treatment and monitoring of patients could cause lower demand for our revised DPP COVID-19 IgM/IgG System or for serological testing for COVID-19 as a whole.

The diagnostic testing market, particularly with respect to COVID-19, is highly competitive, and many of our competitors are larger, better established and have greater technical and marketing capabilities and financial and other resources than we have.

The diagnostics market, particularly with respect to COVID-19 diagnostic tests, is highly competitive and we face substantial competition based on factors such as product quality, analytical performance, ease of use, price, customer service and reputation. Industry competition is also based the following additional factors:

- patent protection;
- scientific expertise;
- ability to develop and market products and processes;
- ability to obtain required regulatory approvals;
- ability to manufacture cost-effective products that meet applicable regulatory requirements;
- access to adequate capital; and
- ability to attract and retain qualified personnel.

Numerous companies in the United States and internationally have announced their intention to offer new products, services and technologies that could be used in substitution for the DPP COVID-19 Systems. Many of those competitors are significantly larger, and have substantially greater financial, engineering and other resources, than us. In addition, our competitors may have or may develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. If we are unable to compete effectively, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be harmed. In addition, the production of an efficacious vaccine or other treatment for COVID-19 may reduce the demand for diagnostic products. The success or failure, or perceived success or failure, of other companies may adversely impact our ability to obtain any future funding, or to ultimately commercialize our DPP COVID-19 Systems.

The failure to comply with the terms of our Credit Agreement and Guaranty could result in a default under its terms and, if uncured, could result in action against our pledged assets and dilution of our stockholders.

On September 3, 2019, we entered into a Credit Agreement and Guaranty, or Credit Agreement, with Perceptive Credit Holdings II, LP, or Perceptive. Under the Credit Agreement, we received a $20,000,000 senior secured term loan credit facility, which was drawn in full on September 4, 2019. The credit agreement is secured by a first priority, perfected lien on substantially all of our property and assets, including our equity interests in our subsidiaries.

The Credit Agreement contains covenants that restrict our ability to finance future operations or capital needs or to engage in other business activities. The Credit Agreement restricts our ability and the ability of our restricted subsidiaries to:

- incur, assume or guarantee additional Indebtedness (as defined in the Credit Agreement);
- repurchase capital stock;
- make other restricted payments including, without limitation, paying dividends and making investments;
- create liens;
- sell or otherwise dispose of assets, including capital stock of subsidiaries;
- enter into agreements that restrict dividends from subsidiaries;
- enter into mergers or consolidations; and
- enter into transactions with affiliates

The Credit Agreement provides for specified quarterly minimum consolidated net revenue covenants of us and our subsidiaries for the trailing twelve-month period ended on each such calculation date during the term of the Credit Agreement. The Credit Agreement also contains covenants requiring us and our subsidiaries to maintain cash and cash equivalents held in one or more accounts subject to the first priority perfected security interests of the lenders under the Credit Agreement of not less than $3,000,000. The breach of any of these covenants would result in a default under the Credit Agreement. We failed to meet the specified quarterly minimum consolidated net revenue covenant for the quarter ended June 30, 2020, and we were required to obtain a waiver from Perceptive in order to avoid an event of default. If we fail to meet such covenant for a future quarter, we may not be able to obtain a waiver from Perceptive, which has total discretion in deciding whether to grant a waiver, and we may incur an event of default. If an event of default occurs, Perceptive could elect to declare all amounts outstanding thereunder, together with accrued interest, to be immediately due and payable. If we were unable to pay such amounts, Perceptive could proceed against the collateral pledged to them. We have pledged our inventory, accounts receivable, cash, securities, other general intangibles and the capital stock of certain subsidiaries to the lenders. In such an event, we cannot assure you that we would have sufficient assets to pay amounts due under the Credit Agreement.

Shareholder litigation could negatively impact our business, operating results and financial condition.

We may incur additional costs in connection with the defense or settlement of existing and any future shareholder litigation, including four shareholder lawsuits to date that have been brought against us. See Part II, Item 1. “Legal Proceedings” above for additional information regarding these lawsuits. These lawsuits or other future litigation may adversely affect the ability of our technical and management personnel, and our directors, to perform their normal responsibilities. We could incur significant costs in connection with any such litigation lawsuits, including costs associated with the indemnification of obligations to our directors.

We expect competition to with respect to testing solutions for COVID-19 to continue to increase and our success will depend on widespread market acceptance of our products.

We expect competition to continue to increase as other established and emerging companies enter the market, as customer requirements evolve, and as new products, services and technologies are introduced. The entrance of new competitors is being encouraged by governmental authorities, which are offering funding to support development of testing solutions for COVID-19. Some of our existing or new competitors may have strong relationships with current and potential customers, including governmental authorities, and, as a result, may be able to respond more quickly to new or changing regulatory requirements, new or emerging technologies, and changes in customer requirements. Our products may not compete favorably, and we may not be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

Our use of third-party suppliers, some of which may constitute our sole supply source, for certain important product components and materials presents risks that could have negative consequences for our business.

We purchase certain HIV antigens, a syphilis antigen, COVID-19 antigens, the nitrocellulose, and certain other critical components used in our STAT-PAK, STAT-VIEW, SURE CHECK and DPP product lines from a sole or limited number of sources. If for any reason these suppliers become unwilling or unable to supply our antigen, nitrocellulose, or other critical component needs, we believe that alternative supplies could be obtained at a competitive cost. However, a change in any of the antigens, nitrocellulose or other critical components used in our products would require additional development work and approval by the FDA and other regulatory agencies. In addition, it may be difficult to find such an alternate supply source in a reasonable time period or on commercially reasonable terms, if at all. As a result, the termination or limitation of our relationship with one or more of these suppliers could require significant time to complete, increase our costs, and disrupt or discontinue our ability to manufacture and sell the affected products. In addition, governmental purchasers or funding programs in a particular country may require that we purchase key components from suppliers in that country, which could significantly limit our ability to obtain the components with the quality, and at the price, we seek.

With some of these suppliers, we do not have long-term agreements and instead purchase components and materials through a purchase order process. As a result, these suppliers may stop supplying us components and materials, limit the allocation of supply and equipment to us due to increased industry demand, or significantly increase their prices at any time with little or no advance notice. Our reliance on a limited number of suppliers could also result in delivery problems, reduced control over product pricing and quality, and our inability to identify and qualify another supplier in a timely manner.

Moreover, some of these suppliers may experience financial difficulties that could prevent them from supplying us with components or subassemblies used in the design and manufacture of our products. In addition, these suppliers may experience manufacturing delays or shut downs due to circumstances beyond their control, such as complications related to COVID-19, labor issues, political unrest or natural disasters.

Any supply chain deficiencies could materially and adversely affect our ability to fulfill customer orders and our results of operations. The availability of critical components and materials from sole- or limited source suppliers could reduce our control over pricing, quality and timely delivery, increase our costs, could disrupt our ability to manufacture and sell, and preclude us from manufacturing and selling, certain of our products into one or more markets. Any such event could have a material adverse effect on our results of operations, cash flow and business.

The COVID-19 pandemic could continue to spread rapidly and affect our suppliers and employees, and cause disruptions in current and future plans for operations and expansion.

The COVID-19 pandemic may directly and indirectly adversely impact our business, financial condition and operating results. The extent to which this will continue will depend on numerous evolving factors that are highly uncertain, rapidly changing and cannot be predicted with precision or certainty at this time.

Our business may be disrupted due to the costs incurred as a result of additional necessary actions and preparedness plans to help ensure the health and safety of our employees and continued operations, including enhanced cleaning processes, protocols designed to implement appropriate social distancing practices, and/or adoption of additional wage and benefit programs to assist employees. We may also have difficulty meeting demand for our products if our employees are affected by COVID-19, or if we do not have adequate space to produce our product with social distancing practices implemented. We also cannot predict the effect of COVID-19 pandemic on our supply chain's reliability and costs,

In addition, our business and operations, and the operations of our suppliers, may be adversely affected by the COVID-19 pandemic. The pandemic, including the related response, could cause disruptions due to potential suspension or slowdown of activities at our third-party suppliers, or increased prices implemented by our suppliers. The adverse effect on our employees or suppliers could have an adverse impact on our business, results of operations and financial condition.

We base our estimates or judgments relating to critical accounting policies on assumptions that can change or prove to be incorrect.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States and our discussion and analysis of financial condition and results of operations is based on such statements. The preparation of financial statements requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We continuously evaluate significant estimates used in preparing our financial statements, including those related to (i) revenue recognition, including uncertainties related to variable consideration and milestones; (ii) stock-based compensation; (iii) allowance for uncollectible accounts receivable; (iv) inventory reserves and obsolescence; (v) customer sales returns and allowances; (vi) contingencies; and (vii) income taxes, (viii) goodwill and intangibles, (ix) business acquisition, and (x) research and development costs.

For example, for the quarter ended June 30, 2020, our cost of product sales included the cost of COVID-19 systems that were produced and shipped outside the U.S., but for which revenue was not recognized in the quarter. We decided we were unable to recognize the revenue from those shipments in the second quarter due to the GAAP requirement that we have a high degree of confidence that it is probable that a significant reversal in revenue will not occur in the future. Many factors can affect such a decision, including, for example, actions of third parties and other considerations that are outside our influence or control. As a result, we recognized negative gross margin in the quarter.

Our estimates are based on historical experience and various other assumptions that we believe to be reasonable, as set forth in our discussion and analysis of financial condition and results of operations, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these and other estimates if our assumptions change or if actual circumstances differ from those in our assumptions. If our operating results fall below the expectations of securities analysts and investors, the price of our Common Stock may decline.

We are subject to governmental export controls that could impair our ability to compete in international markets.

The United States and various foreign governments have imposed controls, export license requirements and restrictions on the export of certain products and technologies. We must export our products in compliance with export controls in the United States, including the Commerce Department's Export Administration Regulations and various economic and trade sanctions established by the Treasury Department's Office of Foreign Assets Controls. We may not always be successful in obtaining necessary export licenses, and our failure to obtain required import or export approval for our products or limitations on our ability to export or sell our products imposed by these laws may harm our international and domestic sales and adversely affect our revenue. Noncompliance with these laws could have negative consequences, including government investigations, penalties and reputational harm.

If the United States government imposes restrictions on the export of DPP COVID-19 Systems, or any of our other products, such restrictions could have a material impact on our ability to sell our products to existing or potential customers outside of the United States and harm our ability to compete internationally. Any change in export regulations or legislation, or change in the countries, persons or technologies targeted by export regulations, could decrease our ability to export or sell our products outside the United States or to existing or potential customers with international operations. Changes in our ability to sell our products outside the United States could negatively impact our business prospects and adversely affect our business and results of operations.

Third-party reimbursement policies and potential cost constraints could negatively affect our business.

The potential end-users of our products include hospitals, physicians and other healthcare providers. If these end-users do not receive adequate reimbursement for the cost of our products from their patients' healthcare insurers or payors, the use of our products could be negatively impacted. Furthermore, the net sales of our products could also be adversely affected by changes in reimbursement policies of government or private healthcare payors.

Hospitals, physicians and other healthcare providers who purchase diagnostic products in the United States generally rely on third-party payors, such as private health insurance plans, Medicare and Medicaid, to reimburse all or part of the cost of the product. Due to the overall escalating cost of medical products and services, especially in light of the COVID-19 outbreak and its straining of healthcare systems across the globe, there is increased pressure on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in the United States, available levels of reimbursement may change for our existing products or products under development. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, current reimbursement amounts may be decreased in the future and future legislation, and regulation or reimbursement policies of third-party payors, may reduce the demand for our products or our ability to sell our products on a profitable basis.

Risks Related to Regulations

COVID-19 diagnostic tests, including our DPP COVID-19 Systems, are subject to changes in CLIA, FDA, ANVISA and other regulatory requirements.

Our DPP COVID-19 Systems are subject to regulations of the U.S. Food and Drug Administration, or FDA, International Organization for Standards and other regulatory requirements, including Agência Nacional de Vigilância Sanitária or ANVISA, Brazil's health regulatory agency. The regulations regarding the manufacture and sale of DPP COVID-19 Systems may be unclear and are subject to change. Newly promulgated regulations could require changes to DPP COVID-19 Systems, necessitate additional procedures, or make it impractical or impossible for us to market DPP COVID-19 Systems for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to impose new or additional requirements relating to DPP COVID-19 Systems. The implementation of such changes or new or additional requirements may result in a substantial additional costs and could delay or make it more difficult or complicated to sell our products.

The FDA issued, and then revoked, an Emergency Use Authorization, or EUA, for emergency use of the DPP COVID-19 IgM/IgG System. Such revocation precludes the sale of DPP COVID-19 IgM/IgG Systems in the United States unless and until a further regulatory approval or authorization is obtained. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.

We are currently working to obtain EUAs for our DPP COVID-19 IgM/IgG Systems and approvals for waived statuses under CLIA, which would permit any laboratory with a Certificate of Waiver, including physician offices and urgent care clinics, to perform the tests. The time required to obtain marketing authorizations and other approvals from regulatory authorities is unpredictable. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can change, and does often change, during development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of FDA regulatory review.

Because we may not be able to obtain or maintain the necessary regulatory approvals for some of our products, we may not generate revenues in the amounts we expect, or in the amounts necessary to continue our business. Our existing products as well as our manufacturing facilities must meet quality standards and are subject to inspection by a number of domestic regulatory and other governmental and non-governmental agencies, as well as certain customers.

All of our proposed and existing products are subject to regulation in the U.S. by the U.S. Food and Drug Administration or FDA, the U.S. Department of Agriculture, and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products. The process of obtaining required approvals or clearances varies according to the nature of, and uses for, a specific product. These processes can involve lengthy and detailed laboratory testing, human or animal clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for that product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. As an example, the time required to obtain an Emergency Use Authorization, or EUA, from the FDA for COVID-19 tests has lengthened markedly over the past months due to, among other things, application volume. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may determine to devote our resources to different products.

Changes or developments in government regulations, policies or interpretations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. For example, on June 16, 2020, the FDA revoked the EUA it had granted for our DPP COVID-19 IgM/IgG System based in part on performance criteria identified after the Emergency Use Authorization was granted on April 14, 2020. Moreover, FDA regulations, policies and procedures with respect to COVID-19 tests may be significantly impacted by the future development of one or more proposed vaccines for COVID-19.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business. We are, for example, expending resources to modify the design of our DPP COVID-19 IgM/IgG System to achieve performance targets consistent with the FDA's performance criteria issued subsequent to the granting of our original EUA.

We can manufacture and sell our products only if we comply with regulations and quality standards established by government agencies such as the FDA and the U.S. Department of Agriculture as well as by non-governmental organizations such as the ISO and WHO. We have implemented a quality control system that is intended to comply with applicable regulations. Although FDA approval is not required for the export of our products, there are export regulations promulgated by the FDA that specifically relate to the export of our products that require compliance with FDA QSRs and that also require meeting certain documentary requirements regarding the approval of the product in export markets. We also may be subject to import regulations in connection with international sourcing of components and materials incorporated in the manufacturing of our products.

If we do not comply with FDA or other regulatory requirements, we may be required to suspend production or sale of our products or institute a recall, which could result in higher costs and a loss of revenues.

Regulations of the FDA and other federal, state and foreign regulatory agencies have significant effects on many aspects of our operations, and the operations of our suppliers and distributors, including packaging, labeling, manufacturing, adverse event reporting, recalls, distribution, storage, advertising, promotion and record keeping. We are subject to routine inspection by the FDA and other agencies to determine compliance with QSRs and FDA regulatory requirements in the United States and other applicable regulations worldwide, including but not limited to ISO standards. We believe that our facilities and procedures are in material compliance with the FDA requirements and ISO standards, but the regulations may be unclear and are subject to change, and we cannot be sure that the FDA or other regulators will agree with our compliance with these requirements. The FDA and foreign regulatory agencies may require post-marketing testing and surveillance to monitor the performance of approved or cleared products or impose conditions on any product clearances or approvals that could restrict the distribution or commercial applications of those products. Regulatory agencies may impose restrictions on our or our distributors' advertising and promotional activities or preclude these activities altogether if a noncompliance is believed to exist.

In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product or additional regulatory actions, including withdrawal of the product from the market.

Our inability to comply with the applicable requirements of the FDA can result in, among other things, 483 notices, warning letters, administrative or judicially imposed sanctions such as injunctions, recall or seizure of products, civil penalties, withdrawal of product registrations, total or partial suspension of production, refusal to grant premarket clearance for devices, a determination that a device is not approvable, marketing clearances or approvals, or criminal prosecution. For example, in February 2020, we received a “not approvable” letter from the FDA with respect to our premarket approval submission on our DPP HIV-Syphilis multiplex test for commercial use in the United States and in June 2020 we received notice from the FDA that the EUA for our DPP COVID-19 IgM/IgG System had been revoked. The ability of our suppliers to supply critical components or materials and of our distributors to sell our products could also be adversely affected if their operations are determined to be out of compliance. Such actions by the FDA and other regulatory bodies could adversely affect our revenues, costs and results of operations.

We must frequently make judgment decisions with respect to compliance with applicable laws and regulations. If regulators subsequently disagree with how we have sought to comply with these regulations, we could be subjected to substantial civil and criminal penalties, as well as product recall, seizure or injunction with respect to the sale of our products. Our reputation could be substantially impaired if we are assessed any civil and criminal penalties and limit our ability to manufacture and market our products which could have a material adverse effect on our business.

Our inability to respond to changes in regulatory requirements could adversely affect our business.

We believe that our existing products and procedures are in material compliance with all applicable FDA regulations, ISO requirements, and other applicable regulatory requirements, but the regulations regarding the manufacture and sale of our products, the QSR and ISO requirements, and other requirements may be unclear and are subject to change. Newly promulgated regulations could require changes to our products, necessitate additional clinical trials or procedures, or make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all. The FDA and other regulatory authorities also have the ability to change the requirements for obtaining product approval and/or impose new or additional requirements as part of the approval process. These changes or new or additional requirements may occur after the completion of substantial clinical work and other costly development activities. The implementation of such changes or new or additional requirements may result in additional clinical trials and substantial additional costs and could delay or make it more difficult or complicated to obtain approvals and sell our products. In addition, the FDA may revoke an Emergency Use Authorization under which our products are sold, where it is determined that the underlying health emergency no longer exists or warrants such authorization. Such revocation would preclude the sale of our affected products unless and until a further regulatory approval or authorization is obtained. For example, For example, on June 16, 2020, the FDA revoked the EUA it had granted for our DPP COVID-19 IgM/IgG System based in part on performance criteria identified after the Emergency Use Authorization was granted on April 14, 2020, and since that time we have been expending resources to modify the design of our DPP COVID-19 IgM/IgG System to achieve performance targets consistent with the FDA's performance criteria. We cannot anticipate or predict the effect, if any, that these types of changes might have on our business, financial condition or results of operations.

Demand for our products may be affected by FDA regulation of laboratory-developed tests and genetic testing.

Regulatory responsibility over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories is covered by the FDA, including our Micro Reader analyzer. The FDA has previously taken the position that it has regulatory authority over laboratory-developed tests, or LDTs, but has exercised enforcement discretion by not regulating most LDTs performed by high complexity CLIA-certified laboratories. LDTs are tests designed, developed, and performed in-house by a laboratory. These laboratories are subject to CLIA regulation but such laboratories have previously not been subject to regulation by the FDA under the agency's medical device requirements.

However, the FDA has announced that it would begin regulating LDTs, and in October 2014 the FDA issued proposed guidance on the regulation of LDTs for public comment. But, on November 18, 2016, the FDA announced that it would not finalize the proposed guidance prior to the end of the Obama administration. On January 13, 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining a possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. We cannot predict what policies the Trump administration will adopt with respect to LDTs. If the FDA increases regulation of LDTs, it could make it more difficult for laboratories and other customers to continue offering LDTs that involve genetic or molecular testing. This, in turn, could reduce demand for our products and adversely impact our revenues.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved, authorized, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear, approve, or authorize new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for medical devices or modifications to be cleared or approved, medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

ITEM 6. EXHIBITS

Number	Description
1.1	Underwriting Agreement dated May 7, 2020 between Chembio Diagnostics, Inc. and Robert W. Baird & Co. Incorporated, as representative of the several underwriters named therein
10.1†	Amendment No. 1, dated June 16, 2020, to the letter agreement dated January 17, 2020 between Chembio Diagnostics, Inc. and Gail S. Page
10.2†‡	Letter agreement dated June 15, 2020 between Chembio Diagnostics, Inc. and Gail S. Page
10.3†	Amendment No. 1, dated June 30, 2020, to the letter agreement dated June 15, 2020 between Chembio Diagnostics, Inc. and Gail S. Page
31.1	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover page formatted as Inline XBRL and contained in Exhibit 101

† Indicates management contract or compensatory plan or arrangement.

* The certifications attached as Exhibit 32.1 accompany the Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

‡ Certain sensitive personally identifiable information in this exhibit was omitted by means of redacting a portion of the text and replacing it with [***].

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Chembio Diagnostics, Inc.

Date: August 7, 2020

By: /s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President

Date: August 7, 2020

By: /s / Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and Executive Vice President

Exhibit 10.1

AMENDMENT TO LETTER AGREEMENT

This Amendment to Letter Agreement dated June 16, 2020 (this "*Amendment*") is entered into between Chembio Diagnostics, Inc., a Nevada corporation (the "*Company*"), and Gail S. Page ("*Page*"), with respect to their Letter Agreement dated as of January 17, 2020 (the "*Agreement*").

In consideration of the mutual agreements herein contained, the parties hereby covenant, promise and agree to and with each other as follows:

1. Compensation. In addition to the compensation contemplated by Section 3 of the Agreement, the Company shall pay to Ms. Page, within fifteen days after the date hereof, a cash bonus of $150,000 with respect to her services rendered to the Company as interim chief executive officer, including her assistance in identifying and recruiting a permanent Chief Executive Officer and President without engagement of an executive search firm.

2. Transition Period. Section 5(a) of the Agreement is amended to provide that the Transition Period (as defined in the Agreement) shall be deemed to have extended through June 14, 2020.

3. Miscellaneous. Except as set forth herein, the terms of the Agreement are unchanged and shall remain in full force and effect. This Amendment, and its validity, interpretation and enforcement, shall be governed by the laws of the State of New York, excluding conflict of laws principles

IN WITNESS WHEREOF, each of the parties has executed, or caused to be executed, this Amendment as of the date first written above.

GAIL S. PAGE

/s/ Gail S. Page

CHEMBIO DIAGNOSTICS, INC.

By: /s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President

Exhibit 10.2

Chembio Diagnostics Inc.
555 Wireless Blvd.
Hauppauge, New York 11788

June 15, 2020

Ms. Gail S. Page
[***]
[***]

Dear Gail:

On behalf of Chembio Diagnostics Inc. (the "*Company*"), I am pleased to provide you with this letter agreement (this "*Agreement*") setting forth the principal terms of the compensation package to be provided to you by the Company for your services as Executive Chair ("*Executive Chair*") of the Company's Board of Directors (the "*Board*"), which terms are effective as of June 15, 2020 and will continue up to the time of the Company's 2021 Annual Meeting of Stockholders (the "*Term*").

1. Duties. You agree to serve the Company faithfully, diligently and competently and, except as determined in accordance with Section 1(b), to devote approximately one-half of your full working time to the performance of the duties and responsibilities set forth in this Section 1.

(a) *Basic Chair Duties*. During the Term, you will have all of the duties, responsibilities and authority commensurate with the position of Chair of the Board during the Term, including:

(i) to chair meetings of the Board, and otherwise administer affairs of the Board, in a manner that will foster a collective decision-making process for the Board's actions and responsibilities;

(ii) to serve as the primary liaison between the Board and members of management of the Company, including to ensure an effective communication flow from management to the Board and its committees;

(iii) as otherwise set forth from time to time in the charter and bylaws of the Company or in the corporate law of the jurisdiction in which the Company has been incorporated; and

(iv) as otherwise may be requested of you by the Board from time to time consistent with the position of Chair of the Board.

(b) *Supplemental Executive Chair Duties.* As Executive Chair you will have the following additional duties, responsibilities and authority through at least December 31, 2020:

(i) to the extent specifically requested by the Chief Executive Officer and President of the Company (the "*CEO*"), advise the CEO on a strategic level with respect to operations and finance and advise other members of the Company's management as the CEO specifies; and

(ii) serve as mentor to the CEO by providing advice, counseling and supervision to the CEO when and as specifically requested by the CEO and seeking to motivate and support the CEO in the execution of his duties and responsibilities.

In December 2020, you, the Compensation Committee of the Board (the "*Committee*") and the CEO will discuss and mutually evaluate the nature and extent of the duties, responsibilities and authority that you will have under this Section 1(b) during the remainder of the Term, commencing on January 1, 2021, in light of then-existing conditions and circumstances. The Committee reserves the right, based on such discussion and evaluation, to modify the duties, responsibilities and authority set forth in the first sentence of this Section 1(b) for such remainder of the Term, except that no such modification may, without your prior consent, increase the hours required for the performance of your duties and responsibilities as Executive Chair in 2021 to exceed one-half of your full working time.

(c) *Clarification of Scope of Duties*. Your duties and responsibilities as Executive Chair shall consist exclusively of actions taken to help the Board to fulfill its duties and responsibilities. As Executive Chair, you shall provide leadership to the Board and not to the Company, which is the responsibility of the CEO. Your duties, responsibilities and authority as Executive Chair shall not include any duties, responsibilities and authority associated with the position of CEO or of any other management position, and the provisions of Section 1(b) shall not be interpreted in a manner that, whether at the request of the CEO or otherwise, would result in your performing any duties or responsibilities, or exercising any authority, associated with the position of CEO or of any other management position. For purposes of clarity, it is understood that your duties, responsibilities and authority as Executive Chair during the Term will be more limited than those you have been fulfilling during the transition period following your service as the Company's interim chief executive officer, including the portion of such transition period during which you served as Executive Chair prior to the date hereof. As examples (but not an exclusive list) of actions and activities that you will no longer be required or authorized to perform as of the commencement of the Term, you shall not participate in (i) executive leadership team or other management meetings, except as may be requested by the CEO for a specific, limited issue or purpose or (ii) investor or public relations activities, except as contemplated by the Company's written communications policies and procedures for director interaction with stockholders and other market participants (for which purpose the Company confirms that an updated statement of such policies and programs will be implemented on or before June 30, 2020). The Committee shall, after consulting with the Executive Chair and the CEO, have full power and authority to rule on any question or uncertainty that arises with respect to the interpretation of the subject matter of this Section 1(c).

(d) *Other Board Duties*. It is expected that you will continue as a member of the Board throughout the Term, subject to your re-election to the Board at the Company's 2020 Annual Meeting of Stockholders. During the Term, you will not serve as a member of any of the standing committees of the Board (that is, the Audit Committee, the Compensation Committee, or the Nominating and Corporate Governance Committee). You may, at the invitation of the appropriate Chairs of those standing committees, elect to attend meetings of any or all of those committees to the extent you determine that it will help you to fulfill your duties and responsibilities as Executive Chair.

(e) *Unrelated Activities*. You may serve in any capacity with one or more other public or private organizations during the Term, *provided* that any such activities do not, at the time the activities commence or thereafter, (i) create an actual or potential business or fiduciary conflict of interest with your services as Executive Chair, (ii) individually or in the aggregate, interfere materially with the performance of your duties to the Company in your capacity as Executive Chair, or (iii) violate or breach any written policy or program of the Company applicable in your capacity as a member of the Board.

2. Term. Notwithstanding any other provision of this Agreement, the Term will terminate immediately upon the expiration or termination of your service as a member of the Board for any reason prior to the Company's 2021 Annual Meeting of Stockholders.

3. Compensation.

(a) *Retainer.* The Company will pay you a cash retainer at an annualized rate of $175,000 for your time commitment of one-half of your full time during the Term, less applicable withholdings for taxes, payable in accordance with the Company's historical practice for Board-related retainers or with such other mutual agreement as may be agreed upon by the parties.

(b) *Equity Awards.* You will not be entitled to receive any equity award from the Company during the Term solely in connection with your service as Executive Chair. For purposes of clarity, your currently outstanding equity awards will continue to vest during the Term in accordance with their terms, without any change as the result of this Agreement.

(c) *Reimbursements.* The Company will reimburse you for reasonable out-of-pocket business, entertainment and travel expenses in connection with the performance of your duties under this Agreement that are incurred and submitted in accordance with the Company's expense reimbursement policy from time to time in effect with respect to directors generally.

(d) *Bonuses.* Cash or equity bonuses, if any, for your services as Executive Chair will be at the sole discretion of the Committee and shall be agreed upon by you and the Committee in advance when and if determined by the Committee to be appropriate.

4. Independent Contractor. You shall be an independent contractor, and not an employee, of the Company.

5. Confidential Information and Company Records.

(a) *Confidentiality.* During the Term and continuing thereafter, you agree that you will not, whether alone or in association with any other person, directly or indirectly, knowingly divulge, furnish or make accessible to any third person or organization other than in the regular course of the Company's business any confidential information concerning the Company or its subsidiaries or its or their business, including confidential methods of operation and organization, confidential sources of supply and customer or other mailing lists.

(b) *Records.* All records, files, documents and the like, or abstracts, summaries or copies thereof, relating to the business of the Company or the business of any subsidiary or affiliated companies, which the Company or you prepare or use or come into contact with, will remain the sole property of the Company or the affiliated or subsidiary company, as the case may be, and will be promptly returned upon termination of the Transition Period or at such earlier time as may be requested by the Board.

(c) *Enforcement.* The provisions of this Section 5 shall survive the end of the Term and the end of the Transition Period. You acknowledge that any remedy at law for a breach or threatened breach of any of the provisions of this Section 5 may be inadequate and that accordingly the Company shall be entitled to an injunction or specific performance or any other mode of equitable relief without the necessity of showing any actual damage, posting a bond or furnishing other security.

6. Company Policies. You will be bound by and comply fully with the Company's standard confidentiality agreement (a form of which was been provided to you), insider trading policy, code of business conduct and ethics, and any other policies and programs adopted by the Company regulating the behavior of its employees, as such policies and programs may be amended from time to time to the extent the same are not inconsistent with this Agreement.

7. Indemnification. To the maximum extent permitted by law, you will be indemnified under the Company's charter and bylaws while serving as Executive Chair, and you will continue to be named as an insured on the director and officer liability insurance policy currently maintained by the Company, or as may be maintained by the Company from time to time.

8. Miscellaneous.

(a) *Notices.* Notices under this Agreement must be in writing and will be deemed to have been given when personally delivered or two days after mailed by U.S. registered or certified mail, return receipt requested and postage prepaid. Mailed notices to you will be addressed to you at the home address that you have most recently communicated to the Company in writing. Notices to the Company will be addressed to the CEO at the Company's corporate headquarters. Either party hereto may change its address for the purpose of this Section 8(a) by written notice similarly given.

(b) *Successors.* This Agreement is binding on and may be enforced by the Company and its successors and permitted assigns and is binding on and may be enforced by you and your heirs and legal representatives.

(c) *Waiver.* No provision of this Agreement may be modified or waived except in writing signed by you and a duly authorized officer of the Company.

(d) *Severability.* The invalidity, illegality or unenforceability of any provision or provisions of this Agreement shall not affect any other provision of this Agreement, which shall remain in full force and effect, nor shall the invalidity, illegality or unenforceability of a portion of any provision of this Agreement affect the balance of such provision. In the event that any one or more of the provisions contained in this Agreement or any portion thereof shall for any reason be held to be invalid, illegal or unenforceable in any respect, this Agreement shall be reformed, construed and enforced as if such invalid, illegal or unenforceable provision had never been contained in this Agreement.

(e) *Survival.* The provisions of this Agreement shall survive the expiration or termination of the Term for any reason to the extent necessary to enable the parties to enforce their respective rights under this Agreement.

(f) *Entire Agreement.* This Agreement constitutes the entire understanding and agreement you and between the Company regarding your service as Executive Chair. This Agreement supersedes all prior negotiations, discussions, correspondence, communications, understandings and agreements between you and the Company relating to such service.

(g) *Modifications.* This Agreement may not be modified or amended, nor may any rights under it be waived, except in a writing signed and agreed to by both you and the Committee.

(h) *Interpretation.* For purposes of this Agreement:

(i) headings used in this Agreement are for convenience of reference only and shall not, for any purpose, be deemed a part of this Agreement;

(ii) the word "including" as used in this Agreement shall not be construed so as to exclude any other thing not referred to or described; and

(iii) this Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted.

(i) *Governing Law.* THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED IN THAT STATE, WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAW.

If the foregoing correctly sets forth your understanding of our agreement, please so indicate by signing and returning to us a copy of this Agreement.

CHEMBIO DIAGNOSTICS INC.

By: /s/ Richard L. Eberly
Chief Executive Officer and President

Accepted and agreed:
GAIL S. PAGE
/s/ Gail S. Page

Exhibit 10.3

AMENDMENT TO LETTER AGREEMENT

This Amendment to Letter Agreement dated June 30, 2020 (this "*Amendment*") is entered into between Chembio Diagnostics, Inc., a Nevada corporation (the "*Company*"), and Gail S. Page ("*Page*"), with respect to their Letter Agreement dated as of June 15, 2020 (the "*Agreement*"). Capitalized terms used in the Amendment and defined in the Agreement shall have the respective meanings ascribed to them in the Agreement.

On June 25, 2020, Page advised the Company that she no longer intended to stand for reelection as a member of the Board at the Company's 2020 Annual Meeting of Stockholders (the "*Annual Meeting*"). The parties are entering into this Amendment in order to, among other things, facilitate a smooth and professional transition of matters with which Page has been involved as a member of the Board, including as Executive Chair.

In consideration of the mutual agreements herein contained, the parties hereby covenant, promise and agree to and with each other as follows:

1. Term. Notwithstanding any provision of the Agreement, the Term shall terminate as of 5:00 p.m., Eastern daylight saving time, on June 30, 2020, and Page's performance of, and compensation for, services as Executive Chair shall terminate as of such time.

2. Board Service and Compensation. Page shall serve as a member of the Board until her term expires at the Annual Meeting. During the period from the end of the Term until the Annual Meeting: (a) Page shall be entitled to receive a retainer fee for service as a member of the Board, in accordance with the policy in effect as of the date of the Amendment with respect to non-employee members of the Board generally; (b) Page's currently outstanding equity awards shall continue to vest in accordance with their terms, without any change as the result of this Agreement, and she shall be entitled to elect to net exercise some or all of her outstanding vested options, consistent with the terms of the options and the Company's past practices; and (c) the Company shall reimburse Page for her reasonable out of-pocket expenses that are incurred and submitted in accordance with the Company's expense reimbursement policy from time to time in effect with respect to non-employee members of the Board generally.

3. Covenants. Section 5 of the Agreement is deleted in its entirety and is amended and restated as set forth below:

"5. Confidential Information, Company Records, Non-Disparagement and Trading Restrictions.

(a) *Confidentiality.*

(i) Page acknowledges that, in the course of her services (her "*Services*") as interim Chief Executive Officer of the Company, as a consultant to the Company during the Transition Period and as a member of the Board (including certain of the committees of the Board), Page has and will come to know general and specific information (collectively, "*Confidential Information*") that is confidential and proprietary to the Company and/or its subsidiaries (collectively, the "*Company Entities*"). Confidential Information includes oral and written information about, relating to or concerning the Company Entities that the Company has, by its policies or otherwise, indicated (A) should be kept confidential, (B) should reasonably be deemed confidential by Page whether or not it was designated as confidential, or (C) if disclosed could be injurious to any of the Company Entities. Confidential Information includes business plans, concepts, strategies, proposals, processes, methods, internal procedures, financial statements, projections, technical specifications, data, supplier lists, marketing plans, sales strategies, product designs, customer information, and other confidential operational information of any of the Company Entities. Without limiting the generality of the foregoing, Confidential Information specifically includes the Company Entities': personnel lists and files, and related confidential information; hiring plans and strategies; compensation data and strategies; talent management plans and strategies; and sales and marketing strategies.

(ii) Page agrees that Confidential Information is the sole and exclusive property of the Company Entities, and Page agrees to hold, in a fiduciary capacity for the benefit of the Company Entities, all Confidential Information acquired by Page during the period of her Services (including the time from the date of this Amendment to the date of the Annual Meeting). Page agrees and covenants that, other than as required by law, she shall not use to the detriment of any Company Entity or divulge, publicly or privately, any specified or other Confidential Information regarding any aspect of the business and operations of the Company Entities acquired during or as a result of her Services. Furthermore, to the extent that disclosure of any Confidential Information is controlled by statute, regulation or other law, Page agrees that she is bound by such laws and that the Agreement, as amended by this Amendment, shall not operate as a waiver of any such non-disclosure requirement.

(iii) Page agrees that, during the six-month period following the Annual Meeting, she shall refrain from making any statements, whether privately or publicly and whether implied or expressed, concerning any of the Company Entities, their respective businesses or operations, or any of their respective directors, officers, employees or service providers (including accountants, attorneys, financial advisers, and lenders and other creditors) other than as required by law, except (A) with respect to communications, on a confidential basis, with her accountants, attorneys, financial advisers and credit providers or her immediate family members or (B) with prior written permission from the Company and in cooperation with the Company's internal personnel and investor relations firm. The requirements of this paragraph (iii) are in addition to the requirements of Section 5(c).

(b) *Records*. All records, files, documents and the like, or abstracts, summaries or copies thereof relating to the business of any Company Entity, which such Company Entity or Page prepares or uses or with which she has come into contact, shall remain the sole property of such Company Entity and shall be promptly returned upon termination of the Page's membership on the Board or at such earlier time as may be requested by the Board. The Company may issue to Page a list of items to be returned, detailing due dates and requesting she work with any assigned vendor to retrieve any electronic files belonging to any Company Entity stored on any personal computers or any mobile or other devices such as tablets or telephones, and Page shall use her reasonable efforts to comply promptly with such requests. Additionally, in order that the Company can implement a smooth and professional transition of all matters with which Page was involved during the period of her Services, Page agrees to cooperate by being reasonably responsive to any questions conveyed by the CEO by email or telephone regarding any issues and commitments that she managed, oversaw or played a role in during the period of her Services.

(c) *Non-Disparagement.* Page agrees that, at all times following her signing of this Amendment, Page shall not engage in any vilification of any of the Company Entities or any of their respective directors, officers, employees or service providers (including accountants, attorneys, financial advisers, and lenders and other creditors) and shall refrain from making any false, negative, critical. defamatory or disparaging statements, implied or expressed, concerning any of the Company Entities or any of their respective directors, officers, employees or service providers (including as aforesaid), including with respect to management or communication style, methods of doing business, quality of products and services, or role in the community. Page further agrees to do nothing that would damage the business reputation or goodwill of any of the Company Entities or any of their respective directors, officers, employees or service providers (including as aforesaid). The Company agrees that, promptly following the Annual Meeting, its Chair of the Board shall instruct the members of the Board and the Company's Executive Leadership Team that they shall refrain, and such individuals shall at all times thereafter refrain, from making any false, negative, critical, defamatory or disparaging statements, implied or expressed, concerning Page that would damage her reputation.

(d) *Trading Restrictions*. Page acknowledges and agrees that she (i) shall not buy or sell any securities of the Company during the period from the date of this Amendment until the commencement of the second trading day on the NASDAQ Stock Market after the date on which the Company publicly issues its earnings release for the quarter ending June 30, 2020, other than any shares of common stock acquired from the Company pursuant to exercises of options for cash, and (ii) shall comply in all respects with applicable federal securities laws pertaining to "insider trading" with respect to securities of the Company.

(e) *Enforcement.* The provisions of this Section 5 shall survive the termination of Page's service as a member of the Board. Page acknowledges that any remedy at law for a breach or threatened breach of any of the provisions of this Section 5 may be inadequate and that accordingly the Company shall be entitled to an injunction or specific performance or any other mode of equitable relief without the necessity of showing any actual damage, posting a bond or furnishing other security."

4. Cooperation in Legal Matters. Upon reasonable notice by the Company, Page shall voluntarily provide thorough and accurate information and truthful testimony to and on behalf of the Company regarding (a) any litigation, arbitration, or government or other administrative investigations or proceedings initiated by, or brought or threatened against, any Company Entity or in which any Company Entity is an indemnifying party, including participating in meetings with counsel representing any Company Entity and testifying at depositions, trials or other proceedings or (b) any dispute between any Company Entity and any other entity or person (other than Page) arising from or related to any act or omission by Page that actually or allegedly occurred during the period of her Services. In making any request for cooperation or assistance under this Section 4, a Company Entity shall attempt to work with Page to arrange times that reasonably accommodate her, and in responding to any such request, Page shall reasonably accommodate her schedule to the needs of such Company Entity. Except as may be required by law, Page shall not disclose to or to discuss with anyone who is not directing or assisting such Company Entity in any such litigation, arbitration or investigation, other than Page's own attorney, the fact of or subject matter of the litigation, arbitration or investigation. If the services described above are requested, Page will be compensated at the rate of $218.75 per hour for such services as an independent contractor and will be reimbursed (consistent with the Company's expense reimbursement policies and procedures) for reasonable out-of-pocket expenses, including travel expenses but excluding legal fees and expenses, incurred by her in connection with her compliance with this Section 4), provided that (i) Page shall not be entitled to receive any compensation or expense reimbursement pursuant to this Section 4 with respect to any litigation, arbitration, or government or other administrative proceeding (y) to which Page is a party or (z) for which, pursuant to the indemnification provisions of the Company's charter and bylaws or a director and officer liability insurance policy maintained by the Company, Page either is eligible to receive expense reimbursements or is disqualified, under such indemnification provisions or insurance policy, from receiving expense reimbursements solely as the result of acts or omissions by her and (ii) in no event shall Page be entitled to any compensation for time spent testifying at depositions, trials or other proceedings.

5. Indemnification. Section 7 of the Agreement is deleted in its entirety and is amended and restated as set forth below:

"7. Indemnification. To the maximum extent permitted by law, Page will be indemnified under the Company's charter and bylaws for claims and liabilities arising out of her Services, and Page will continue to be named as an insured on the director and officer liability insurance policy currently maintained by the Company, or as may be maintained by the Company from time to time, for a period of no less than six years after the date of the Annual Meeting.

6. Miscellaneous. Except to the extent set forth herein, the terms of the Agreement are unchanged and shall remain in full force and effect. This Amendment, and its validity, interpretation and enforcement, shall be governed by the laws of the State of New York, excluding conflict of laws principles

IN WITNESS WHEREOF, each of the parties has executed, or caused to be executed, this Amendment as of the date first written above.

GAIL S. PAGE

/s/ Gail S. Page

CHEMBIO DIAGNOSTICS, INC.

By: /s/ Richard L. Eberly
Richard L. Eberly
Chief Page Officer and President

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Richard L. Eberly, certify that:

1. I have reviewed this quarterly report Form 10-Q of Chembio Diagnostics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(e) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

Date: August 7, 2020

/s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Neil A. Goldman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Chembio Diagnostics, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls.

Date: August 7, 2020

/s/ Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and Executive Vice President
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Chembio Diagnostics, Inc. for the quarterly period ended June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge on the date hereof:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Chembio Diagnostics, Inc. for the period presented therein.

Date: August 7, 2020

/s/ Richard L. Eberly
Richard L. Eberly
Chief Executive Officer and President
(Principal Executive Officer)

Date: August 7, 2020

/s/ Neil A. Goldman
Neil A. Goldman
Chief Financial Officer and Executive Vice President
(Principal Financial Officer)

The foregoing certification is being furnished solely pursuant to 18 U.S.C. § 1350 and is not being filed as part of the Report or as a separate disclosure document.