CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES

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Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Chembio Diagnostics, Inc.
Hauppauge, New York

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Chembio Diagnostics, Inc. (the “Company”) and subsidiaries as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders’ equity, and cash flows the years then ended, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2019 and 2018, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 13, 2020 expressed an unqualified opinion thereon.

Change in Accounting Principle

On January 1, 2019, the Company changed its method of accounting for leases due to the adoption of Accounting Standards Codification Topic 842, Leases. The effects of the adoption are described in Note 3 to the consolidated financial statements.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2011.

Melville, NY
March 13, 2020

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

	December 31, 2019	December 31, 2018
- ASSETS -		
CURRENT ASSETS:		
Cash and cash equivalents	**$ 18,271,352**	$ 12,524,551
Accounts receivable, net of allowance for doubtful accounts of $62,000 and $42,000 at December 31, 2019 and 2018, respectively	**3,661,325**	7,373,971
Inventories, net	**9,598,030**	7,851,222
Prepaid expenses and other current assets	**693,013**	702,010
TOTAL CURRENT ASSETS	**32,223,720**	28,451,754
FIXED ASSETS:		
Property, plant and equipment, net	**5,933,569**	2,873,920
Finance lease right-of-use assets, net	**210,350**	–
OTHER ASSETS:		
Operating right-of-use assets, net	**7,030,744**	–
Intangible assets, net	**3,914,352**	3,884,831
Goodwill	**5,872,690**	4,983,127
Deposits and other assets	**543,539**	717,551
TOTAL ASSETS	**$ 55,728,964**	$ 40,911,183
- LIABILITIES AND STOCKHOLDERS' EQUITY -		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	**$ 5,526,243**	$ 5,888,681
Deferred revenue	**125,000**	422,905
Note payable	**180,249**	207,694
Finance lease liabilities	**41,894**	–
Operating lease liabilities	**568,294**	–
TOTAL CURRENT LIABILITIES	**6,441,680**	6,519,280
OTHER LIABILITIES:		
Long-term operating lease liabilities	**6,969,603**	–
Long-term finance lease liabilities	**171,953**	–
Note payable	**–**	171,821
Long-term debt net of debt discount and issuance costs	**17,644,149**	–
Deferred tax liability	**466,326**	892,308
TOTAL LIABILITIES	**31,693,711**	7,583,409
COMMITMENTS AND CONTINGENCIES (Note 12)		
STOCKHOLDERS' EQUITY:		
Preferred stock – 10,000,000 shares authorized, none outstanding	**–**	–
Common stock - $.01 par value; 100,000,000 shares authorized, 17,733,617 and 17,166,459 shares issued and outstanding at December 31, 2019 and 2018, respectively	**177,335**	171,664
Additional paid-in capital	**95,433,077**	90,953,788
Accumulated deficit	**(71,585,003)**	(57,909,874)
Accumulated other comprehensive income	**9,844**	112,196
TOTAL STOCKHOLDERS' EQUITY	**24,035,253**	33,327,774
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 55,728,964**	$ 40,911,183

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

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

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the years ended	
	December 31, 2019	December 31, 2018
Net loss	**$ (13,675,129)**	$ (7,865,649)
Other comprehensive loss:		
Foreign currency translation adjustments	**(102,352)**	(66,752)
COMPREHENSIVE LOSS	**$ (13,777,481)**	$ (7,932,401)

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2019, AND 2018

	Common Stock		Additional Paid-in-Capital	Accumulated Deficit	AOCI	Total
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2017	**12,318,570**	**$ 123,185**	**$ 62,821,288**	**$ (50,044,225)**	**$ 178,948**	**$ 13,079,196**
Common Stock:						
New stock from offerings	4,509,760	45,098	27,431,162	–	–	27,476,260
Restricted stock issued	266,839	2,668	(2,668)	–	–	–
Restricted stock compensation	–	–	281,249	–	–	281,249
Options:						
Exercised	71,290	713	71,201	–	–	71,914
Stock option compensation	–	–	351,556	–	–	351,556
Comprehensive loss	–	–	–	–	(66,752)	(66,752)
Net loss	–	–	–	(7,865,649)	–	(7,865,649)
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 issued	**381,908**	**3,819**	**(128,081)**	**–**	**–**	**(124,262)**
Restricted stock compensation	**–**	**–**	**1,394,812**	**–**	**–**	**1,394,812**
Issuance of common stock for business acquired	**153,707**	**1,537**	**441,754**	**–**	**–**	**443,291**
Options:						
Exercised	**31,543**	**315**	**32,171**	**–**	**–**	**32,486**
Stock option compensation	**–**	**–**	**261,088**	**–**	**–**	**261,088**
Warrants and Other:						
Warrant on Term Debt	**–**	**–**	**1,196,093**	**–**	**–**	**1,196,093**
Contingent Earnout for business acquired	**–**	**–**	**1,281,452**	**–**	**–**	**1,281,452**
Comprehensive loss	**–**	**–**	**–**	**–**	**(102,352)**	**(102,352)**
Net loss	**–**	**–**	**–**	**(13,675,129)**	**–**	**(13,675,129)**
Balance at December 31, 2019	**17,733,617**	**$ 177,335**	**$ 95,433,077**	**$ (71,585,003)**	**$ 9,844**	**$ 24,035,253**

See accompanying notes to consolidated financial statements

CHEMBIO DIAGNOSTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED

	December 31, 2019	December 31, 2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Cash received from customers and grants	**$ 37,930,172**	$ 29,804,273
Cash paid to suppliers and employees	**(45,655,562)**	(41,624,299)
Cash paid for operating and finance leases	**(640,844)**	–
Interest and taxes, net	**(689,272)**	38,585
Net cash used in operating activities	**(9,055,506)**	(11,781,441)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of businesses, net of cash acquired	**(100,000)**	(5,491,204)
Acquisition of and deposits on fixed assets	**(3,502,540)**	(1,467,192)
Patent Application Costs	**(297,006)**	–
Working capital adjustments related to business combination	**145,760**	–
Net cash used in investing activities	**(3,753,786)**	(6,958,396)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from option exercises	**32,486**	71,914
Principal payments for finance leases	**(19,875)**	–
Payments on debt issuance costs	**(186,313)**	–
Payments on note payable	**(181,822)**	(64,481)
Proceeds from issuance of long-term debt, net	**18,850,000**	–
Proceeds from sale of common stock, net	**–**	27,476,260
Net cash provided by financing activities	**18,494,476**	27,483,693
Effect of exchange rate changes on cash	**61,617**	(9,607)
INCREASE IN CASH AND CASH EQUIVALENTS	**5,746,801**	8,734,249
Cash and cash equivalents - beginning of the period	**12,524,551**	3,790,302
Cash and cash equivalents - end of the period	**$ 18,271,352**	$ 12,524,551
RECONCILIATION OF NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:		
Net Loss	**$ (13,675,129)**	$ (7,865,649)
Adjustments:		
Depreciation and amortization	**1,916,194**	902,505
Share based compensation	**1,655,900**	632,805
Benefit from deferred tax liability	**(513,715)**	(78,432)
Provision for doubtful accounts	**20,000**	–
Changes in assets and liabilities, net of effects from acquisitions:		
Accounts receivable	**3,764,045**	(5,150,072)
Inventories	**(1,457,612)**	(3,077,104)
Prepaid expenses and other current assets	**64,355**	(118,293)
Deposits and other assets	**(90,624)**	–
Accounts payable and accrued liabilities	**(441,015)**	2,599,894
Deferred revenue	**(297,905)**	372,905
Net cash used in operating activities	**$ (9,055,506)**	$ (11,781,441)
Supplemental disclosures for non-cash investing and financing activities:		
Deposits on manufacturing equipment transferred to fixed assets	**$ 430,000**	$ 257,455
Deposits and other assets transferred to intangible assets	**–**	118,899
Seller-financed equipment purchases	**–**	326,110
Issuance of common stock for net assets of business acquired	**443,291**	–
Contingent liability earnout	**1,225,000**	–

See accompanying notes to consolidated financial statements

NOTE 1 — DESCRIPTION OF BUSINESS:

Chembio Diagnostics, Inc. and its subsidiaries (collectively, the "Company" or "Chembio"), develop, manufacture, and commercialize point-of-care diagnostic tests that are used to detect and diagnose diseases. The Company is pursuing three corporate priorities: (1) expand its commercialization, (2) advance its research and development pipeline, and (3) prepare for future growth.

All products that are currently being developed are based on the Company's patented DPP® technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology.

The Company's product commercialization and product development efforts are focused on infectious disease testing and technology collaborations. In infectious disease, the Company is commercializing tests for HIV and Syphilis, Zika virus, and developing tests for malaria, dengue virus, chikungunya virus, ebola, lassa, Marburg, leptospirosis, *Rickettsia typhi*, *Burkholderia pseudomallei*, and *Orientia tsutsugamushi*, individually or as part of fever panel tests. Through technology collaborations, the Company is developing tests for concussion, bovine tuberculosis, a rare disease in collaboration with Takeda Pharmaceutical, and a biomarker development project in collaboration with AstraZeneca.

Large and growing markets have been established for these kinds 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 to medical laboratories and hospitals, governmental and public health entities, non-governmental organizations, medical professionals and retail establishments, both domestically and internationally, under the Company's STAT PAK®, SURE CHECK®, STAT-VIEW® or DPP® registered trademarks, or under the private labels of the Company's marketing partners.

The Company routinely enters into arrangements with governmental and non-governmental organizations for the funding of certain research and development efforts.

NOTE 2 — ACQUISITIONS:

Orangelife

On November 25, 2019, pursuant to a quote purchase agreement, the Company acquired all of the outstanding shares of Orangelife Comercio e Industria Ltda., or Orangelife, a privately-held Brazilian company, which 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 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 our common stock.
- Issuance of 316,456 shares of our common stock to Dr. Manco Collovati, the founder and former CEO of Orangelife, based on the transfer and approval of certain of our product registration in Brazil prior to November 25, 2022. All of the shares may be deliverable in the event of change in control of our company. The number of shares issued is subjected to adjustments based upon Orangelife's working capital at closing. The fair value of the shares on the date of the acquisition are recorded in equity.

The purchase consideration is subject to routine post-closing adjustments. The acquisition of Orangelife will allow us to expand our commercial presence by offering our products to the state, private, and pharmacy markets in Brazil, in addition to providing local support to our long time customer Bio-Manguinhos, the subsidiary of the Oswaldo Cruz Foundation (Fiocruz) that oversees development and production of vaccines, diagnostics, and biopharmaceuticals, primarily 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.

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 fair value of the fixed assets based on the net book value of Orangelife as that approximates fair value. 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 will be 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 Consolidated Statements of Operations for the year ended December 31, 2019 include $325,853 of transaction costs related to the Orangelife acquisition.

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 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 Chembio Diagnostics and Orangelife on a combined and consolidated basis.

	Unaudited Proforma 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)

opTricon

On November 6, 2018, pursuant to a share purchase agreement, the Company acquired all of the outstanding shares of opTricon GmbH (“opTricon”), a privately-held Germany based developer and manufacturer of handheld analyzers for rapid diagnostic tests, for $5.5 million in cash, subject to routine post-closing adjustments. Since 2015, the Company and opTricon have been parties to an agreement under which the Company has collaborated in developing its DPP Micro Reader, a handheld, battery-operated analyzer that uses an innovative image sensor to provide, when combined with the Company’s DPP tests, a quantitative interpretation of diagnostic results. The Company purchased opTricon because it believes it will enable it to promote DPP tests and DPP Micro Readers more actively across global markets. The results of opTricon operations have been reflected in the consolidated financial statements since November 6, 2018.

As a result of the consideration paid exceeding the fair value of the net assets acquired, goodwill in the amount of $3,290,888 was recorded in connection with this acquisition, none of which will be deductible for tax purposes. In addition, the Company recorded $2,260,000 in intangible assets associated with the addition of opTricon’s developed technology and customer base. The Consolidated Statements of Operations for the year ended December 31, 2019 and 2018 includes $395,612 and $337,645 of transaction costs related to the opTricon acquisition, respectively.

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 6, 2018:

	Amount
Net current assets	$ 404,204
Property, plant and equipment	125,000
Goodwill	3,383,112
Deferred tax liability	(681,112)
Other intangible assets (estimated useful life):	
Developed technology (7 years)	1,900,000
Customer contracts / relationships (10 years)	360,000
Total consideration	$ 5,491,204

The Company calculated the fair value of the fixed assets based on the net book value of opTricon as that approximates fair value. The developed technology and customer contracts/relationships were based on discounted cash flows using management estimates.

The following represents unaudited pro forma operating results for the year ended December 31, 2018 as if the operations of opTricon had been included in the Company’s Consolidated Statements of Operations as of January 1, 2018:

	Proforma December 31, 2018
Total revenues	$ 36,614,995
Net loss	$ (8,394,074)
Net loss per common share	$ (0.58)
Diluted net loss per common share	$ (0.58)

The pro forma financial information includes business combination accounting effects from the acquisition including amortization charges from acquired intangible assets of opTricon approximately $351,000 for the year ended December 31, 2018. The unaudited pro forma information as presented above is for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of fiscal 2018. Included in the proforma table above are opTricon’s net revenues and pre-tax loss for the year ended December 31, 2018 which were approximately $2,214,000 and $213,000, respectively. opTricon’s results of operations from the date of acquisition through December 31, 2018 are immaterial to the Company’s Consolidated Statements of Operations.

NOTE 3 — SIGNIFICANT ACCOUNTING POLICIES:

(a) ***Principles of Consolidation:***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany transactions and balances are eliminated in consolidation.

(b) ***Use of Estimates:***

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make assumptions and estimates that affect the amounts reported in the consolidated financial statements and accompanying 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 pursuant to milestones, useful lives of intangible and fixed assets, stock-based compensation, 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 value for cash and cash equivalents, accounts receivable, and accounts payable, approximate fair value due to the immediate or short-term maturity of these financial instruments. Included in cash and cash equivalents is $16.0 million and $4.7 million as of December 31, 2019 and 2018, respectively, of money market funds that are Level 1 fair value measurements under the hierarchy. The fair value of the Company's notes payable approximates the recorded value as the rate is based upon the current rates offered to the Company for similar financial instruments.

Fair value measurements of all financial assets and liabilities that are being 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.

(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 FDIC 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) ***Inventories:***

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost and net realizable value. Cost is determined on the first-in, first-out method. The Company's policy is to periodically evaluate the market value of the inventory and the stage of product life cycle, and record a write-down for any inventory considered slow moving or obsolete.

(g) ***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.

(h) ***License Agreements:***

The Company records up-front payments related to license agreements as prepaids and amortizes them over their respective economic life. As of December 31, 2019 and 2018, total prepaids were $100,000 and $100,000, respectively.

Amortization expenses for the licenses above for the years ended December 31, 2019, and 2018 were $0, and $0, respectively.

(i) ***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 years ended December 31, 2019 and 2018.

(j) ***Revenue Recognition:***

In May 2014, the Financial Accounting Standards Board ("FASB") issued converged guidance on recognizing revenue in contracts with customers, Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers*. The intent of the new standard is to improve financial reporting and comparability of revenue globally. The core principle of the standard is for a company to recognize revenue in a manner that depicts the transfer of goods or services to customers in an amount that reflects the consideration which the company expects to receive in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions include capitalization of certain contract costs, consideration of the time value of money in the transaction price, and in certain circumstances, allowing estimates of variable consideration to be recognized before contingencies are resolved. The guidance also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from an entity's contracts with customers.

The new revenue standards became effective for the Company on January 1, 2018 and were adopted using the modified retrospective method. The adoption of the new revenue standards as of January 1, 2018 did not change the Company's revenue recognition as its revenues continue to be recognized when the customer takes control of its product. As the Company did not identify any material accounting changes that impacted the amount of reported revenues with respect to its product revenue, license and royalty revenue, and R&D, milestone and grant revenues, no adjustment to retained earnings was required upon adoption.

The Company adopted the standards to contracts that were not completed at the date of initial application (January 1, 2018).

Under the new revenue standards, the Company recognizes revenues when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. The Company recognizes revenues following the five-step model prescribed under ASU No. 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 revenues when (or as) the Company satisfies the performance obligation.

Product Revenues

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 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).

Our 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 feasibility studies. Revenues from sale of products are recognized point-in-time and revenues from R&D feasibility studies are recognized ratably, over the period of the agreement.

Judgement is required to determine the stand-alone selling price ("SSP") for each distinct performance obligation. SSP is directly observable and we can use a range of amounts to estimate SSP, as we sell 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 currently does not have agreements in which multiple performance obligations are sold combined.

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 and the specific facts and circumstances of each arrangement. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, 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 earnings in the period of adjustment.

Royalty Revenues

The Company receives royalty revenues on sales by its licensee of products covered under patents that it owns. The Company does not have future performance obligations under this license arrangement. The Company records these revenues based on estimates of the sales that occurred during the relevant period as a component of license and royalty revenues. 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 revenues 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 licensee.

R&D and grant revenue

All such contracts 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 ASC 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. Performance obligation is the feasibility study which encompasses various phases of product development processes: design feasibility & planning, product development & design optimization, design verification, design validation & process validation, and pivotal studies.

In June 2018, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (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 Topic 958, "Not-for-Profit Entities," of the FASB's Accounting Standards Codification (ASC) 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 clarifies the guidance used by entities other than not-for-profits to identify and account for contributions made.

Disaggregation of Revenue

The following tables disaggregate Total Revenues for the year ended December 31, 2019, by type of transaction and by geography:

	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	$ 28,844,997	$ –	$ 28,844,997
R&D, milestone and grant revenue	3,321,031	1,359,251	4,680,282
License and royalty revenue	938,753	–	938,753
	$ 33,104,781	$ 1,359,251	$ 34,464,032

Exchange transactions are recognized in accordance with ASC 606, while non-exchange transactions are recognized in accordance with ASU No. 2018-08.

	Total
Africa	$ 7,564,360
Asia	888,800
Europe & Middle East	6,498,995
Latin America	11,808,768
United States	7,703,109
	$ 34,464,032

The following tables disaggregate Total Revenues for the year ended December 31, 2018, by type of transaction and by geography:

	Exchange Transactions	Non-Exchange Transactions	Total
Net product sales	$ 27,913,209	$ –	$ 27,913,209
R&D, milestone and grant revenue	2,687,210	3,032,248	5,719,458
License and royalty revenue	948,773	–	948,773
	$ 34,581,440	$ 3,032,248	$ 34,581,440

Exchange transactions are recognized in accordance with ASC 606, while non-exchange transactions are recognized in accordance with ASU No. 2018-08.

	Total
Africa	$ 8,838,632
Asia	1,404,982
Europe & Middle East	4,895,273
Latin America	12,546,083
United States	6,896,470
	$ 34,581,440

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 December 31, 2018, the Company reported $422,905 in deferred revenue of which $422,905 was earned and recognized as R&D, milestone and grant revenue during the year ended December 31, 2019. At December 31, 2019, the Company reported $125,000 in deferred revenue which is expected to be recognized during the first quarter of 2020.

In April 2017, the Company entered into a $1.1 million agreement with FIND to develop a simple, point-of-care fever panel assay that can identify multiple life-threatening acute febrile illnesses common in the Asia Pacific region. The Company earned $0.2 million and $1.1 million for the year ended December 31, 2019, and from inception through December 31, 2019, respectively as R&D, milestone and grant revenue in the Company's Consolidated Statements of Operations.

In August 2016, the Company was awarded a grant of $5.9 million from BARDA, which is part of the U.S. Department of Health And Human Resources to develop a rapid Zika virus assay. The Company earned $0.6 million and $5.9 million for the year ended December 31, 2019 and from inception through December 31, 2019, respectively, as R&D, milestone and grant revenue in the Company's Consolidated Statements of Operations.

(k) ***Research and Development:***

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

(l) ***Stock-Based Compensation:***

The fair value of restricted stock and restricted stock unit awards are their fair value on the date of grant. Stock-based compensation expense for stock options is calculated using the Black-Scholes valuation model based on awards ultimately expected to vest together with the fair value of restricted stock and restricted stock unit awards, are, reduced for actual forfeitures, and, expensed on a straight-line basis over the requisite service period of the grant. During 2018, the Company adopted ASU 2016-09, "Improvements to Employee Share-Based Payment Accounting".

(m) ***Income Taxes:***

The Company accounts for income taxes under an asset and liability approach that recognizes deferred tax assets and liabilities based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse.

The Company follows a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. The guidance relates to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. Any interest and penalties accrued related to uncertain tax positions are recorded in tax expense.

The Company assesses the realizability of its net deferred tax assets on an annual basis. If, after considering all relevant positive and negative evidence, it is more likely than not that some portion or all of the net deferred tax assets will not be realized, the Company will reduce the net deferred tax assets by a valuation allowance. The realization of net deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of net operating loss carryforwards.

(n) ***Loss Per Share:***

Basic loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period including outstanding restricted stock that by its terms is includible in the calculation. Diluted loss per share for the years ended December 31, 2019, and 2018 reflects the potential dilution from the exercise or conversion of other securities into common stock, if dilutive.

There were 666,197, and 732,906 options outstanding as of December 31, 2019 and 2018, respectively, which were not included in the calculation of diluted income per share for the years ended because their effect would have been anti-dilutive.

(o) ***Goodwill and Intangible Assets:***

Goodwill represents the excess of the purchase price the Company paid over the fair value of the net tangible and identifiable intangible assets acquired in the Company's acquisition of opTricon in November 2018, Chembio Diagnostics Malaysia in January 2017 and Orangelife in November 2019. Goodwill is not amortized but rather is tested annually as of the first day of the fiscal fourth quarter, or sooner if the Company believes that indicators of impairment exist. The Company makes a qualitative evaluation about the likelihood of goodwill impairment, which is based on a number of applicable factors. If the Company concludes that it is more likely than not that the carrying value of the applicable reporting unit is greater than its fair value, then it would recognize an impairment charge for the amount by which the carrying value exceeds the reporting unit's fair value, provided the impairment charge does not exceed the total amount of goodwill allocated to the reporting unit.

For the year ended December 31, 2019 and 2018, there was no impairment of goodwill and other intangible assets.

Following is a table that reflects changes in Goodwill:

Beginning balance January 1, 2019	$	4,983,127
Acquisition of Orangelife		986,058
Chembio Diagnostics GmbH measurement period adjustment		(99,648)
Changes in foreign currency exchange rate		3,153
Balance at December 31, 2019	$	5,872,690

Intangible assets consist of the following at:

		December 31, 2019			December 31, 2018		
	Weighted Average Remaining Life	**Cost**	**Accumulated Amortization**	**Net Book Value**	Cost	Accumulated Amortization	Net Book Value
Intellectual property	6	$ 1,418,681	$ 299,232	$ 1,119,449	$ 1,089,688	$ 173,633	$ 916,055
Developed technology	6	1,922,682	266,550	1,656,132	1,910,315	–	1,910,315
Customer contracts/relationships	7	1,325,521	270,902	1,054,619	1,121,600	151,929	969,671
Trade names	8	114,946	30,794	84,152	108,521	19,731	88,790
		$ 4,781,830	$ 867,478	$ 3,914,352	$ 4,230,124	$ 345,293	$ 3,884,831

Amortization expense for the year ended December 31, 2019 and 2018 was $515,263 and $233,734, respectively, and is recorded within COGS, R&D and Selling, General and Administrative expenses. Amortization expense, subject to changes in currency exchange rates, is expected to be approximately $590,000 per year from 2020 through 2024, and total $1 million for all of the years thereafter.

(p) ***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.

(q) ***Acquisition Costs:***

Acquisition costs include period expenses, primarily professional services, related to acquisition activities.

(r) ***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 income. Foreign transaction gains/losses are immaterial.

(s) ***Recent Accounting Pronouncements Affecting the Company:***

In February 2016, the FASB issued ASU No. 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 requires the entity to recognize the assets and liabilities for the rights and obligations created by leased assets. Leases will be classified as either finance or operating, with classification affecting expense recognition in the income statement. In July 2018 the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, and ASU 2018-11, *Leases (Topic 842) Targeted Improvements*, which provide supplemental adoption guidance and clarification to ASU 2016-02, and must be adopted concurrently with the adoption of ASU 2016-02, cumulatively referred to as "Topic 842". Topic 842 was effective for the Company in the first quarter of 2019, with early adoption permitted, and was applied using either a modified retrospective approach, or an optional transition method which allows an entity to apply the new standard at the adoption date with a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption.

As further discussed on Note 12(c) – Leases, the Company adopted Topic 842 on January 1, 2019 under the optional transition method and elected the short-term lease exception and available practical expedients. Under the transition method, the Company did not adjust its comparative period financial information or make the new required lease disclosures for periods before the effective date. The impact of adoption of right-of-use assets and liabilities on January 1, 2019 was $0.8 million, and $0.8 million, respectively.

In March 2016, the FASB issued authoritative guidance under ASU 2016-09, *Compensation-Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting*. ASU 2016-09 provides for simplification of several aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The Company adopted ASU 2016-09 on January 1, 2017. As the Company has a full valuation allowance against its U.S. net deferred tax assets, the adoption of this standard for recognition of the tax effect of deductions for employee share awards in excess of compensation costs ("windfall") did not have a material impact on its consolidated financial statements and related disclosures. See Note 8 – Income Taxes, for additional information. Should the full valuation allowance be reversed in future periods, the adoption of this new guidance could introduce more volatility in the calculation of the Company's effective tax rate, depending on the Company's share price at exercise or vesting of share-based awards as compared to grant date. The other provisions of ASU 2016-09 did not have a material impact on the Company's consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which provides guidance related to cash flows presentation. The Company adopted ASU 2016-15 in the first quarter of 2018. The guidance in ASU 2016-15 is generally consistent with the Company's current cash flow classifications, and did not have a material impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which requires an entity to no longer perform a hypothetical purchase price allocation to measure goodwill impairment. Instead, impairment will be measured using the difference between the carrying amount and the fair value of the reporting unit. This update will be effective for annual and interim periods in fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company adopted ASU 2017-04 in the fourth quarter of 2017. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, to provide clarity to which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company adopted ASU 2017-09 in the first quarter of 2018. Adoption did not have a material effect on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Per the ASU, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The ASU is effective for public entities for fiscal years beginning after December 15, 2018 and the Company adopted it effective January 1, 2019. This ASU is applicable to the stock warrants issued as part of the Credit Agreement, as further discussed in Note 14 – Warrants.

In July 2018, 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* to clarify the accounting guidance related to contributions made or received. This guidance primarily affects not-for-profit entities, although it also applies to businesses to the extent that they make or receive contributions, including grants. ASU 2018-08 clarifies and improves the scope and accounting guidance for both contributions received and made in order to assist entities in evaluating if those transactions should be accounted for as contributions under the scope of Topic 958, or as an exchange transaction subject to other guidance. Public entities are required to apply the amendments on contributions received and contributions made to annual periods beginning after June 15, 2018, and December 15, 2018, respectively, each including interim periods within those annual periods. Early adoption is permitted, and the Company adopted ASU 2018-08 effective as of January 1, 2018. The impact of adoption was immaterial.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. This standard simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill and allocating consolidated income taxes to separate financial statements of entities not subject to income tax. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. Upon adoption, the Company must apply certain aspects of this standard retrospectively for all periods presented while other aspects are applied on a modified retrospective basis through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. The Company is currently evaluating the impact of this new standard on its consolidated financial statements.

In June 2016, the FASB issued a new standard to replace the incurred loss impairment methodology under current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. We will be required to use a forward-looking expected credit loss model for accounts receivables, loans, and other financial instruments. Credit losses relating to available-for-sale debt securities will also be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. The standard will be effective for us beginning July 1, 2020, with early adoption permitted beginning July 1, 2019. Adoption of the standard will be applied using a modified retrospective approach through a cumulative-effect adjustment to retained earnings as of the effective date to align our credit loss methodology with the new standard. We are currently evaluating the impact of this standard in our consolidated financial statements, including accounting policies, processes, and systems.

NOTE 4 — INVENTORIES:

Inventories consist of the following at December 31, 2019:

	December 31	
	2019	2018
Raw Materials	**$ 2,901,319**	$ 2,803,677
Work in Process	**793,343**	263,043
Finished Goods	**5,903,368**	4,784,502
	$ 9,598,030	$ 7,851,222

NOTE 5 — FIXED ASSETS:

Fixed assets consist of the following at December 31, 2019:

	December 31	
	2019	2018
Machinery and Equipment	**$ 7,955,511**	$ 6,070,137
Furniture and Fixtures	**21,477**	35,287
Computer Equipment	**416,359**	435,348
Leasehold Improvements	**3,038,469**	2,334,512
Enterprise Business Systems	**1,830,925**	462,420
Less: Accumulated Depreciation and Amortization	**(7,329,173)**	(6,463,784)
	$ 5,933,569	$ 2,873,920

Depreciation expense for the 2019 and 2018 years totaled $933,558 and $634,261, respectively.

As of December 31, 2019 and 2018, the Company has purchased manufacturing equipment that is not yet in use and therefore has not been depreciated, aggregating $1,400,181 and $428,859, respectively.

NOTE 6 — ACCOUNTS PAYABLE AND ACCRUED LIABILITIES:

Accounts payable and accrued liabilities consist of the following at December 31, 2019:

	December 31	
	2019	2018
Accounts Payable - suppliers	**$ 3,144,098**	$ 3,622,765
Accrued Commissions & Royalties	**931,760**	867,344
Accrued Payroll	**231,753**	48,867
Accrued Vacation	**410,199**	264,789
Accrued Bonuses	**215,000**	494,318
Accrued Expenses - Other	**593,433**	590,598
	$ 5,526,243	$ 5,888,681

NOTE 7 — DEFERRED RESEARCH AND DEVELOPMENT REVENUE:

The Company recognizes income from R&D milestones when those milestones are reached and non-milestone contracts and grants when earned. These projects are invoiced after expenses are incurred. Any projects or grants funded in advance are deferred until earned. As of December 31, 2019 and 2018, there were $125,000 and $422,905 unearned advanced revenues, respectively.

NOTE 8 — INCOME TAXES:

The components of (loss) before income taxes consisted of the following:

	Year Ending December 31,	
	2019	2018
United States operations	**$ (12,504,780)**	$ (7,137,428)
International operations	**(1,670,641)**	(795,742)
(Loss) before taxes	**$ (14,175,421)**	$ (7,933,170)

The (benefit from) provision for income taxes for the years ended December 31, 2019 and 2018 is comprised of the following:

	Year Ending December 31,	
	2019	2018
Current		
Federal	**$ –**	$ –
State	**9,790**	10,911
Foreign	**3,633**	–
Total current (benefit) provision	**13,423**	10,911
Deferred		
Federal	**–**	–
State	**–**	–
Foreign	**(513,715)**	(78,435)
Total deferred (benefit) provision	**(513,715)**	(78,435)
Total (benefit) provision	**$ (500,292)**	$ (67,521)

A reconciliation of the Federal statutory rate to the effective rate applicable to loss before income taxes is as follows:

	Year Ending December 31,	
	2019	2018
Federal income tax at statutory rates	**21.00%**	21.00%
State income taxes, net of federal benefit	**(0.05)%**	(0.10)%
Nondeductible expenses	**(1.00)%**	(1.58)%
Foreign rate differential	**0.45%**	0.36%
Change in valuation allowance	**(17.51)%**	(18.44)%
Other	**0.64%**	(0.39)%
Income tax benefit	**3.53%**	0.85%

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low-taxed income (“GILTI”) provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations. The guidance allows companies to make an accounting policy election to either (1) account for GILTI as a component of tax expense in the period in which they are subject to the rules (the period cost method), or (ii) account for GILTI in the Company’s measurement of deferred taxes (the deferred method). After completing the analysis of the GILTI provisions, the Company elected to account for GILTI using the period cost method.

The Company had an ownership change as described in Internal Revenue Code Sec. 382 during 2004 (“2004 change”). As a result, the Company’s net operating losses prior to the 2004 change of $5,832,516 were subject to an annual limitation of $150,608 and for the first five (5) years are entitled to a BIG (Built-In-Gains) of $488,207 per year. These net operating losses expire in 2020 through 2024.

The Company had a second ownership change during 2006 (“2006 change”). The net operating losses incurred between the 2004 change and the 2006 change of $8,586,861 were subject to an annual limitation of $1,111,831 and for the first five (5) years are entitled to a BIG of $1,756,842 per year. These net operating losses expire in 2024 through 2026.

After applying the above limitations, at December 31, 2019, the Company has post-change net operating loss carry-forwards of approximately $27,235,494 which expire between 2020 and 2037 and $16,242,683 which do not expire. In addition the Company has research and development tax credit carryforwards of approximately $1,679,495 for the year ended December 31, 2019, which expire between 2020 and 2036.

The Company has state net operating loss carryforwards of approximately $1,912,798 which generally expire between 2035 and 2039. The Company has foreign net operating loss carryforwards of approximately $3,355,645 which generally expire between 2025 and 2026.

	2019	2018
Inventory reserves	**$ 196,193**	$ 204,206
Accrued expenses	**105,323**	175,168
Net operating loss carry-forwards	**10,079,317**	7,122,576
Research and development credit	**1,679,495**	1,696,870
Stock-based compensation	**581,053**	215,797
Lease obligations	**1,646,584**	–
Depreciation	**44,993**	139,362
Total deferred tax assets	**14,332,958**	9,553,979
Right-of-use assets	**(1,538,129)**	–
Intangibles	**(921,807)**	(968,849)
Total deferred tax liabilities	**(2,459,936)**	(968,849)
Net deferred tax assets before valuation allowance	**11,873,022**	8,585,130
Less valuation allowances	**(12,339,348)**	(9,477,438)
Net noncurrent deferred tax liabilities	**$ (466,326)**	$ (892,308)

The Company does not provide for U.S. income taxes on unremitted earnings of foreign subsidiaries as its present intention is to reinvest the unremitted earnings in the Company’s foreign operations. At December 31, 2019 there were no unremitted earnings of foreign subsidiaries.

Interest and penalties, if any, related to income tax liabilities are included in income tax expense. As of December 31, 2019, the Company does not have a liability for uncertain tax positions.

The Company files Federal and state income tax returns, Chembio Germany files in Germany, Chembio Brazil files in Brazil and Chembio Malaysia files in Malaysia and has been on tax holiday which expired on December 31, 2018. With few exceptions, tax years for fiscal 2016 through 2019 are open and potentially subject to examination by federal, state and foreign taxing authorities.

NOTE 9 — STOCKHOLDERS' EQUITY:

(a) ***Common Stock***

During 2019, options to purchase 54,343 shares of the Company's common stock were exercised for 31,543 shares of common stock at exercise prices ranging from $3.48 to $4.35. During 2018, options to purchase 144,947 shares of the Company's common stock were exercised for 71,290 shares of common stock at exercise prices ranging from $3.48 to $5.64 by surrendering options and shares of common stock already owned.

In November 2018, the Company closed on an underwritten public offering of 2,726,000 shares of its common stock, including the underwriter's exercise of its overallotment of 355,565 shares, at $6.75 per share. The net proceeds of the offering, after deducting the underwriter's discounts and other offering expenses payable by the Company, was approximately $16.5 million.

In February 2018, the Company closed on an underwritten registered public offering of 1,783,760 shares of its common stock at $6.75 per share. The net proceeds of the offering, after deducting the underwriter's discounts and other offering expenses payable by the Company, was approximately $10.9 million.

(b) ***Preferred Stock***

The Company has 10,000,000 shares of preferred stock authorized and none outstanding. These shares can become issuable upon an approved resolution by the board of directors and the filing of a Certificate of Designation with the state of Nevada.

(c) Options, Restricted Stock, and Restricted Stock Units

The Board of Directors or its Compensation Committee may issue options, restricted stock, and restricted stock units pursuant to employee stock incentive plans that have been approved by the Company's stockholders.

(d) ***Warrants***

As of December 31, 2019, the Company has 550,000 warrants outstanding to purchase shares of common stock as further discussed in Note 14 – Warrants.

NOTE 10 — EQUITY INCENTIVE PLANS:

Effective June 3, 2008, the Company's stockholders voted to approve the 2008 Stock Incentive Plan ("SIP"), with 625,000 shares of common stock available to be issued. At the Annual Stockholder Meeting on September 22, 2011 the Company'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 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 ("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 December 31, 2019, there were 0 options exercised, and at December 31, 2019, 0 options were outstanding and no Equity Award Units were available to be issued under the SIP.

Effective June 19, 2014, the Company's stockholders voted to approve the 2014 Stock Incentive Plan ("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 become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2019, there were 54,343 options exercised, and at December 31, 2019, 642,625 options were outstanding and 148,667 Equity Award Units were still available to be issued under the SIP14.

Effective June 18, 2019, the Company's stockholders voted to approve the 2019 Omnibus Incentive Plan ("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, expires, or is 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 unit, or other stock-based award under the 2019 Plan (collectively, 2019 Equity Units). The awards become vested at such times and under such conditions as determined by the Board or its Compensation Committee. Cumulatively through December 31, 2019, there were 375,000 2019 Equity Units awarded under the 2019 Plan, and 2,025,000 2019 Equity Units available to be awarded.

The Company's results for the years ended December 31, 2019 and 2018 include stock-based compensation expense totaling $1,655,900 and $632,805, respectively. Such amounts have been included in the Consolidated Statements of Operations within cost of product sales ($10,806 and $25,615, respectively), research and development ($228,597 and $78,831, respectively) and selling, general and administrative expenses ($1,416,497 and $528,360, respectively).

Stock option compensation expense in the years ended December 31, 2019 and 2018 represents the estimated fair value of options outstanding, which is being amortized on a straight-line basis over the requisite vesting period of the entire award. The stock compensation expense were $261,088 and $351,556 in December 31, 2019 and 2018, respectively.

No stock options were issued during 2019. The weighted average estimated fair value of stock options granted in the year ended December 31, 2018 was $3.76 per share. The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The expected volatility is based upon historical volatility of the Company's stock and other contributing factors. The expected term is based on the Company's historical experience with similar type options.

The weighted-average assumptions made in calculating the fair values of options are as follows for the respective years ended December 31:

	2019	2018
Expected term (in years)	n/a	4.96
Expected volatility	n/a	39.91%
Expected dividend yield	n/a	n/a
Risk-free interest rate	n/a	2.70%

The following table provides stock option activity for the years ended December 31, 2019 and 2018:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	810,670	$ 5.18	3.69 years	$ 2,477,853
Granted	93,750	9.80		
Exercised	144,947	4.83		523,327
Forfeited/expired/cancelled	47,505	8.82		
Outstanding at December 31, 2018	711,968	$ 5.62	3.33 years	$ 687,364
Exercisable at December 31, 2018	396,799	$ 4.70	2.66 years	$ 568,956
Outstanding at December 31, 2018	711,968	$ 5.62	3.33 years	$ 687,364
Granted	–	$ 0.00		–
Exercised	54,343	$ 3.60		172,242
Forfeited/expired/cancelled	15,000	$ 5.68		–
Outstanding at December 31, 2019	**642,625**	**$ 5.79**	**2.57 years**	**$ 285,925**
Exercisable at December 31, 2019	**493,958**	**$ 5.22**	**2.20 years**	**$ 285,925**

The following table summarizes information about stock options outstanding at December 31, 2019:

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Shares Outstanding	Average Remaining Contract Life (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Shares Exercisable	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	–	–	$ –	$ –	–	$ –	$ –
2.8 to 4.59999	250,000	1.20	3.42	285,925	250,000	3.42	285,925
4.6 to 6.39999	137,875	2.44	5.87	–	87,125	5.89	–
6.4 to 8.19999	207,875	4.05	7.31	–	138,083	7.22	–
8.2 to 12	46,875	3.60	11.45	–	18,750	11.45	–
Total	642,625	2.57	$ 5.79	$ 285,925	493,958	$ 5.22	$ 285,925

The average remaining contract life for the shares exercisable is 2.2 years, as of December 31, 2019.

As of December 31, 2019, there was $432,746 of net unrecognized compensation cost related to stock options that are not vested, which is expected to be recognized over a weighted average period of approximately 2.00 years. The total fair value of shares vested during the year ended December 31, 2019, was $469,032.

The following table summarizes information about restricted stock and restricted stock units outstanding as of December 31, 2019:

	Number of Shares & Units	Weighted Average Grant Date Fair Value
Unvested at December 31, 2018	287,564	$ 9.65
Granted	375,000	5.80
Vested	(116,578)	9.65
Forfeited/expired/cancelled	–	–
Unvested at December 31, 2019	545,986	7.47

As of December 31, 2019, there was $3,273,929 of net unrecognized compensation cost related to restricted stock and restricted stock units that are not vested, which is expected to be recognized over a weighted average period of approximately 1.4 years. Stock based compensation cost related to restricted stock and restricted stock units recognized during the years ended December 31, 2019 and 2018 was $1,394,814 and $281,249, respectively.

NOTE 11 — 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 business segment. Net product sales by geographic area are as follows:

	Year Ending December 31,	
	2019	2018
Africa	**$ 7,564,360**	$ 8,838,632
Asia	**888,800**	1,404,982
Europe & Middle East	**3,781,761**	2,208,063
Latin America	**11,808,767**	12,546,083
United States	**4,801,309**	2,915,449
	$ 28,844,997	$ 27,913,209

Long-lived assets by geographic area are as follows:

	2019	2018
Asia	**$ 393,299**	$ 466,185
Europe & Middle East	**165,029**	123,752
Latin America	**60,527**	–
United States	**5,314,715**	2,283,983
	$ 5,933,569	$ 2,873,920

NOTE 12 — COMMITMENTS, CONTINGENCIES AND CONCENTRATIONS:

a) Employment Contracts:

The Company has multi-year contracts with two key employees. The contracts call for salaries presently aggregating $730,000 per year, and they expire in March 2020 and December 2021. The following table is a schedule of future minimum salary commitments:

2020	$ 365,000
2021	365,000

Chembio's President & CEO, the key employee whose agreement was set to expire in March 2020, resigned effective as of January 3, 2020.

b) Pension Plan:

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% (or 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $93,892 and $94,544 for the years ended December 31, 2019 and 2018, respectively.

c) Leases:

Chembio's leases have historically been limited to its facilities in New York, Germany, Malaysia & Brazil. As of December 31, 2019, the Company was a party to eight leases. One of the leases is subject to a sublease for the remainder of its term, as further described below.

The Company's leases generally include optional renewal periods. Upon entering into a new 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 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 ("ROU") asset and lease liability. In January 2019 the Company recognized $0.8 million and $0.8 million of right-of-use assets and liabilities, respectively. During 2019, the Company entered into a new lease agreement for its new headquarter location in Hauppauge, NY. The right-of-use asset acquired in exchange for right-of-use liabilities was approximately $6.5 million.

The Company's leases generally include fixed rental payments with defined annual increases. While certain of the Company's leases are gross leases, the majority of the Company's 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 nonlease 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:

	Year Ended December 31, 2019
Operating lease expense	$ 1,655,573
Finance lease cost	
Amortization of right-of-use assets	$ 23,372
Interest on lease liabilities	7,892
Total finance lease expense	$ 31,265

Rent expense was $653,155 for the year ended December 31, 2018.

Supplemental cash flow and other information related to leases were as follows:

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows for operating leases	$ 632,952
Operating cash flows for finance leases	7,892
Financing cash flows for finance leases	19,875
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	$ 7,030,744
Finance leases	210,350

Supplemental balance sheet information related to leases was as follows:

	December 31, 2019
Operating Leases	
Operating lease right-of-use assets	**$ 7,030,744**
	–
Current portion of operating lease liability	**568,294**
Operating lease liabilities	**6,969,603**
Total operating lease liabilities	**$ 7,537,897**
Finance Leases	
Finance lease right of use asset	**$ 233,722**
Accumulated depreciation	**(23,372)**
Finance lease right of use asset, net	**$ 210,350**
Current portion of finance lease liability	**41,894**
Finance lease liability	**171,953**
Total finance lease liabilities	**$ 213,847**
Weighted Average Remaining Lease Term	
Operating leases	9.3 years
Finance leases	4.8 years
Weighted Average Discount Rate	
Operating leases	8.67%
Finance leases	7.00%

During 2019, the Company executed an operating sublease related to its former Holbrook, New York facility. The sublease runs conterminously with the base lease in Holbrook, for which the Company remains primarily responsible. In addition, the Company entered into a finance lease agreement relating to office furniture in June 2019. The Company recognized the corresponding lease asset and liability effective June 30, 2019 and recorded related depreciation starting on July 1, 2019. Monthly payments towards this lease commenced in July 2019.

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 public debt. In September 2019, the Company entered into a credit agreement for a $20 million term loan as described on Note 13 - Long Term Debt.

Maturities of lease liabilities as of December 31, 2019 were as follows.

	Operating Leases	Finance Leases
2020	$ 1,205,161	$ 55,536
2021	1,209,787	55,536
2022	1,057,757	55,536
2023	1,026,272	55,536
2024	1,018,875	27,767
Thereafter	5,773,887	–
Total lease payments	$ 11,291,739	$ 249,911
Less: imputed interest	(3,753,842)	(36,064)
Total	$ 7,537,897	$ 213,847

As previously disclosed in the Company's 2018 Annual Report on Form 10-K, and under the previous lease accounting standard, future minimum lease payments for operating leases having initial or remaining non-cancellable lease terms in excess of one year would have been as follows for the years ending December 31:

2019	$	384,308
2020		88,576
2021		–
	$	472,884

d) Economic Dependency:

Customers are considered major customers when net sales exceed 10% of the Company's total net sales for period or outstanding trade receivables exceed 10% of accounts receivable. The Company had the following major customers for the respective periods:

	For the years ended				Accounts Receivable	
	December 31, 2019		December 31, 2018		December 31, 2019	December 31, 2018
	Net Sales	% of Net Sales	Net Sales	% of Net Sales		
Customer 1	$ 11,263,573	39%	$ 11,333,767	33%	$ 941,962	$ 3,499,340
Customer 2	5,782,543	20%	4,346,640	13%	16,033	1,033,824

The following table delineates purchases the Company had with vendors in excess of 10% of total purchases for the periods indicated:

	For the years ended				Accounts Payable	
	December 31, 2019		December 31, 2018		December 31, 2019	December 31, 2018
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	*	*	1,646,614	16%	*	164,312

In the tables above, an asterisk (*) indicates that purchases from the vendor did not exceed 10% for the period indicated.

The Company purchases materials pursuant to intellectual property rights agreements that 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 and a possible loss of sales, which could adversely affect operating results.

e) Litigation:

From time to time, the Company is involved in certain legal actions arising in the ordinary course of business. The outcomes of such actions, either individually or in the aggregate, are not expected to have a material adverse effect on the Company's future financial position or results of operations.

f) Governmental Regulation:

All of the Company's existing and proposed diagnostic products are regulated by the U.S. Food and Drug Administration, 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, Chembio 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 money penalties, injunctions, and criminal prosecution.

NOTE 13 — LONG-TERM DEBT:

In September 2017, the Company 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 the Company 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, the Company began making monthly payments of principal and interest of approximately $20,150, at an annual rate of 12% over a twenty-four month period. The remaining balance was entirely short-term as of December 31, 2019.

On September 3, 2019, the Company 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, the Company may use the proceeds (i) for general working capital purposes and other permitted corporate purposes, (ii) to refinance certain of the Company'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 Craig-Hallum Capital Group LLC, the Company'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 December 31, 2019 the interest rate was 11.25%.

No principal repayments are due under the Credit Agreement prior to September 30, 2022, unless the Company 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 eleven months from September 2022 through July 2023, and all remaining principal is payable at maturity on September 3, 2023. The Company 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.

As of December 31, 2019, the loan balance, net of unamortized discounts and debt issuance costs, was $17.6 million, and the company was in compliance with its loan covenants. Our obligations under the Credit Agreement are secured by a first priority, perfected lien on substantially all of our property and assets, including our equity interests in our subsidiaries.

NOTE 14 — WARRANTS:

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

The Warrant was evaluated by the Company and classified to stockholder's equity. Its fair value was estimated using a Black-Scholes option-pricing model using the assumptions below.

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

The fair value of the Warrant was determined to be approximately $1.4 million at $2.49 per share.

As of December 31, 2019, the balance recorded in the Company's Stockholders' Equity for the Warrants, net of allocated issuance costs, was $1.2 million.

As of December 31, 2019, no warrants were exercised and no warrants have expired.