BOWEN JAMES A
Form 3
August 25, 2006

FORM 3

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

OMB APPROVAL	
OMB Number:	3235-0104
Expires:	January 31, 2005
Estimated average burden hours per response...	0.5

INITIAL STATEMENT OF BENEFICIAL OWNERSHIP OF SECURITIES

Filed pursuant to Section 16(a) of the Securities Exchange Act of 1934, Section 17(a) of the Public Utility Holding Company Act of 1935 or Section 30(h) of the Investment Company Act of 1940

(Print or Type Responses)

1. Name and Address of Reporting Person *
Â BOWEN JAMES A
(Last) (First) (Middle)

1001 WARRENVILLE ROAD,Â SUITE 300
(Street)

LISLE,Â ILÂ 60532
(City) (State) (Zip)

2. Date of Event Requiring Statement (Month/Day/Year)
08/25/2006

3. Issuer Name **and** Ticker or Trading Symbol
FIRST TRUST/ABERDEEN EMERGING OPPORTUNITY FUND [FEO]

4. Relationship of Reporting Person(s) to Issuer
(Check all applicable)
__X__ Director _____ 10% Owner
__X__ Officer (give title below) __X__ Other (specify below)
President / Officer-Investment Adviser

5. If Amendment, Date Original Filed(Month/Day/Year)

6. Individual or Joint/Group Filing(Check Applicable Line)
_X_ Form filed by One Reporting Person
___ Form filed by More than One Reporting Person

Table I - Non-Derivative Securities Beneficially Owned

1.Title of Security (Instr. 4)	2. Amount of Securities Beneficially Owned (Instr. 4)	3. Ownership Form: Direct (D) or Indirect (I) (Instr. 5)	4. Nature of Indirect Beneficial Ownership (Instr. 5)
Common Shares	0	D	Â

Reminder: Report on a separate line for each class of securities beneficially owned directly or indirectly.

SEC 1473 (7-02)

Persons who respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB control number.

Table II - Derivative Securities Beneficially Owned (*e.g.*, puts, calls, warrants, options, convertible securities)

1. Title of Derivative Security (Instr. 4)	2. Date Exercisable and Expiration Date (Month/Day/Year)	3. Title and Amount of Securities Underlying Derivative Security (Instr. 4)	4. Conversion or Exercise Price of Derivative	5. Ownership Form of Derivative Security:	6. Nature of Indirect Beneficial Ownership (Instr. 5)
		Title			

Date Exercisable	Expiration Date	Amount or Number of Shares	Security	Direct (D) or Indirect (I) (Instr. 5)

Reporting Owners

Reporting Owner Name / Address	Relationships			
	Director	10% Owner	Officer	Other
BOWEN JAMES A 1001 WARRENVILLE ROAD SUITE 300 LISLE,Â ILÂ 60532	Â X	Â	Â President	Officer-Investment Adviser

Signatures

/s/ James A. Bowen, by W. Scott Jardine, attorney-in-fact, pursuant to a Power of Attorney	08/25/2006
**Signature of Reporting Person	Date

Explanation of Responses:

* If the form is filed by more than one reporting person, *see* Instruction 5(b)(v).

** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. *See* 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *See* Instruction 6 for procedure.
Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number.

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.

Stock option compensation expense in each of the periods presented represents the estimated fair value of unvested, outstanding options, amortized on a straight-line basis over the requisite vesting periods of the entire awards.

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

	For the three months ended	
	March 31, 2019	March 31, 2018
Cost of product sales	$ 3,491	$ 8,150
Research and development expenses	59,846	11,920
Selling, general and administrative expenses	284,170	77,180
	$ 347,507	$ 97,250

13

Table of Contents

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

	For the three months ended March 31, 2019	March 31, 2018
Expected term (in years)	N/A	N/A
Expected volatility		
Expected dividend yield		
Risk-free interest rate		

The following table provides stock option activity for the three months ended March 31, 2019:

Stock Options	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
Outstanding at December 31, 2018	711,968	$ 5.62	3.33 years	$ 687,364
Granted	-	-		-
Exercised	-	-		-
Forfeited/expired/cancelled	15,000	5.68		30,286
Outstanding at March 31, 2019	696,968	$ 5.62	3.08 years	$ 647,586
Exercisable at March 31, 2019	466,509	$ 4.62	2.34 years	$ 643,918

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

	Stock Options Outstanding				Stock Options Exercisable		
Range of Exercise Prices	Number of Shares	Average Remaining Contract Term (Year)	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
1 to 2.79999	-	-	$ -	$ -	-	$ -	$ -
2.8 to 4.59999	304,343	1.65	3.45	639,418	304,343	3.45	639,418
4.6 to 6.39999	137,875	3.20	5.87	8,168	77,750	5.87	4,500
6.4 to 8.19999	207,875	4.81	7.31	-	75,041	7.21	-
8.2 to 12	46,875	4.36	11.45	-	9,375	11.45	-
Total	696,968	3.08	$ 5.62	$ 647,586	466,509	$ 4.62	$ 643,918

As of March 31, 2019, there was $630,345 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 2.27 years. The total fair value of shares vested during the three-month periods ended March 31, 2019 and 2018 was $204,567 and $333,845, respectively.

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

	Number of Shares & Units	Weighted Average Grant Date

		Fair Value
Outstanding at December 31, 2018	287,564	$ 9.65
Granted	-	-
Earned/released	-	-
Forfeited/expired/cancelled	-	-
Outstanding at March 31, 2019	287,564	$ 9.65

As of March 31, 2019, there was $1,387,496 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 2.3 years.

14

Table of Contents

g) 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 were as follows:

	For the three months ended March 31, 2019	March 31, 2018
Africa	$ 2,416,300	$ 1,638,530
Asia	121,098	967,574
Europe & Middle East	1,178,025	392,070
Latin America	1,072,066	2,689,893
United States	1,595,497	710,160
	$ 6,382,986	$ 6,398,227

Long-lived assets by geographic area are as follows:

	For the three months ended March 31, 2019	December 31, 2018
Asia	$ 503,327	$ 466,185
Europe & Middle East	111,067	123,752
United States	2,590,149	2,283,983
	$ 3,204,543	$ 2,873,920

h) 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 $4.7 million and $4.7 million as of March 31, 2019 and December 31, 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).

i) Accounts Payable and Accrued Liabilities:

Accounts payable and accrued liabilities consist of:

	March 31, 2019	December 31, 2018

Accounts payable – suppliers	$ 4,226,625	$ 3,622,765
Accrued commissions	510,303	588,131
Accrued royalties / license fees	221,556	279,213
Accrued payroll	293,009	48,867
Accrued vacation	356,464	264,789
Accrued bonuses	236,785	494,318
Accrued expenses – other	529,185	590,598
TOTAL	$ 6,373,927	$ 5,888,681

15

Table of Contents

j) Goodwill Long-Lived Assets 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 and CDM in January 2017. Goodwill is not amortized but rather is tested annually as of the first day of the fiscal fourth quarter for impairment or more frequently 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 the Company recognizes 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.

Following is a table that reflects changes in Goodwill:

Beginning balance December 31, 2018	$4,983,127
opTricon measurement period adjustment	(135,000)
Change in foreign currency exchange rate	6,819
Balance at March 31, 2019	$4,854,946

Intangible assets consist of the following at:

	March 31, 2019				December 31, 2018		
	Weighted Average Useful Life	Cost	Accumulated Amortization	Net Book Value	Cost	Accumulated Amortization	Net Book Value
Intellectual property	10	$1,135,164	$ 203,121	$932,043	$1,089,688	$ 173,633	$916,055
Developed technology	7	1,900,015	76,614	1,823,401	1,910,315	-	1,910,315
Customer contracts/relationships	10	1,113,640	182,940	930,700	1,121,600	151,929	969,671
Trade names	11	108,521	22,439	86,082	108,521	19,731	88,790
		$4,257,340	$ 485,114	$3,772,226	$4,230,124	$ 345,293	$3,884,831

Intellectual property, developed technology, customer contracts/relationships, and trade names are amortized over 10, 7, 10, and 11 years, respectively. Amortization expense for the three months ended March 31, 2019 and 2018 was approximately $139,000 and $45,000, respectively. Amortization expense, subject to changes in currency exchange rates, is expected to be $496,512 per year from 2019 through 2023, and total $1,402,271 for all of the years thereafter.

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 goodwill, long-lived tangible, and intangible assets was recorded for the three months ended March 31, 2019 and 2018.

Table of Contents

k) 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 benefit for the three-month period ended March 31, 2019 was 8.8%, compared to the effective tax rate of 0.0% for the three-month period ended March 31, 2018. The Company's effective tax rates for both periods were affected primarily by a full valuation allowance on domestic net deferred tax assets and the benefit from foreign net operating losses.

l) 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.

m) 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.

n) Acquisition Costs:

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

o) 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 are immaterial.

p) Recent Accounting Pronouncements Affecting the Company:

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases (Topic 842). ASU No. 2016-02 requires the entity to recognize the assets and liabilities for the rights and obligations created by leased assets. Leases are to be classified as either finance or operating, with classification affecting expense recognition in the income statement. In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases, and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which provide supplemental adoption guidance and clarification to ASU No. 2016-02 must be adopted concurrently with the adoption of ASU No. 2016-02, and which are cumulatively referred to as "Topic 842". Topic 842 was effective for the Company in the first quarter of 2019, and is to be 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 at Footnote 5(e) - 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.

17

Explanation of Responses:

Table of Contents

NOTE 4 — STOCKHOLDERS' EQUITY:

No options were exercised during the first quarter of 2019. During the first quarter of 2018, options to purchase 119,947 shares of the Company's common stock were exercised on a cashless basis into 60,372 shares of common stock at an exercise price of $4.71 by the option holder surrendering options and shares of common stock already owned as payment of the exercise price.

NOTE 5 — COMMITMENTS, CONTINGENCIES, AND CONCENTRATIONS:

a) Concentrations:

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

	For the three months ended				Accounts Receivable as of	
	March 31, 2019		March 31, 2018		March 31, 2019	March 31, 2018
	Sales	% of Sales	Sales	% of Sales		
Customer 1	$1,833,590	29 %	$2,409,758	38 %	$2,867,414	$ 1,189,232
Customer 2	*	*	839,399	13 %	*	438,869
Customer 3	*	*	801,625	13 %	-	-

In the table above, an asterisk (*) indicates that product sales to the customer did not exceed 10% for the period indicated.

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

The following table discloses purchases the Company made from each vendor that sold to the Company in excess of 10% of the Company's total purchases for the periods indicated:

	For the three months ended				Accounts Payable as of	
	March 31, 2019		March 31, 2018		March 31, 2019	March 31, 2018
	Purchases	% of Purc.	Purchases	% of Purc.		
Vendor 1	$ *	*	$ 469,357	16 %	$ *	$ 163,538
Vendor 2	*	*	335,105	11 %	*	-

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

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 as the vendors shown in this table. A change in suppliers, however, could cause a delay in manufacturing, either from the logistics of changing suppliers or from product changes attributable to new components, which could result in a possible loss of sales, and which could 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, 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.

c) Employment Contracts:

The Company has multi-year contracts with two key employees that call for salaries presently aggregating $820,000 per year. The contracts expire in March 2020 and December 2021. The following table is a schedule of future minimum salary commitments as of March 31, 2019:

2019	$615,000
2020	478,750
2021	365,000

d) Pension Plan:

The Company has a 401(k) plan established for its employees whereby it matches 40% of the first 5% of salary (or up to 2% of salary) that an employee contributes to the plan. Matching contribution expenses totaled $24,030 and $23,264 for the three months ended March 31, 2019 and 2018, respectively.

18

Table of Contents

e) Leases:

Chembio's leases have historically been limited to its facilities in New York, Germany, and Malaysia. As of March 31, 2019, the Company has entered into five 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, we evaluate the leasehold improvements and regulatory requirements related to our 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, we conclude 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.

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 we make 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 our facility leases.

All leases are operating leases. During the three months ended March 31, 2019, the Company recognized $281,603 rent expense associated with the Company's leases. Of that amount, $83,232, $31,552, and $166,819 have been classified in Cost of product sales, Research and development expenses, and Selling, general and administrative expenses, respectively. During the three months ended March 31, 2019, the Company had $281,603 and $0 of cash and non-cash activities, respectively, associated with its leases. During the three months ended March 31, 2018, the Company recognized $152,237 of rent expense associated with the Company's leases. Of that amount, $128,063, $14,195, and $9,979 have been classified in Cost of product sales, Research and development expenses, and Selling, general and administrative expenses, respectively.

As of March 31, 2019, the deferred rent component of ROU assets totaling $1,173,263 was classified in Prepaid expenses and other current assets.

During the three months ended March 31, 2019, the Company executed an operating sublease related to its former Holbrook, NY facility. The sublease runs conterminously with the base lease in Holbrook, for which the Company remains primarily responsible.

The interest rates implicit in each of the leases are not readily determinable, and the Company does not have an established incremental borrowing rate as its only debt is a seller-financed note for manufacturing equipment. Therefore, the Company used an interest rate based on the marketplace for public debt. The weighted-average discount rate associated with operating leases as of March 31, 2019 is 8.84%.

As of March 31, 2019, the weighted-average lease term for all operating leases is 10 years. The future payments due under operating leases as of March 31, 2019 are as follows:

	Amount
Due in 2019	$474,150
2020	813,444
2021	998,071
2022	1,026,044
2023 and thereafter	7,803,847

	11,115,556
Less: effects of discounting	(4,134,835)
Lease liabilities recognized	$6,980,721

As previously disclosed in our 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

f) 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.

19

Table of Contents

NOTE 6 — NOTE PAYABLE:

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 prepayments 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.

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 March 31, 2019 and December 31, 2018, there were $200,000 and $422,905 unearned advanced revenues, respectively.

Table of Contents

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

You should read the following discussion of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, or our Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this report, particularly in the section titled "Item 1A. Risk Factors" in Part I of our Annual Report. The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of any contingent liabilities at the financial statement date, and reported amounts of revenue and expenses during the reporting period.

Our management's discussion and analysis of financial condition and results of operations is intended to help you understand the business operations and financial condition of the Company as of March 31, 2019, and for the three months ended March 31, 2019. This discussion should be read in conjunction with Item 1. Financial Statements.

The following discussion is presented in six sections:

Executive Overview

Consolidated Results of Operations

Liquidity and Capital Resources

Recent Developments

Significant Accounting Policies and Critical Accounting Estimates

Recently Issued Accounting Pronouncements

Executive Overview

Our Business

Through our wholly owned subsidiaries, Chembio Diagnostic Systems Inc., Chembio Diagnostics Malaysia Sdn Bhd and Chembio Diagnostics GmbH, we develop, manufacture and commercialize point-of-care diagnostic tests that are used to detect or diagnose diseases. All products that are currently being developed are based on our patented DPP technology, a novel point-of-care diagnostic platform that offers certain customer advantages as compared to traditional lateral flow technology. Chembio was formed in 1985.

Business Strategy

We are a leading provider of point-of-care diagnostic products for the detection and diagnosis of infectious diseases. We have been expanding our product portfolio based upon our proprietary DPP technology platform, which uses a small drop of blood from the fingertip to provide high-quality, cost-effective diagnostic results in approximately 15 minutes. We seek to build additional revenue streams by entering into strategic collaborations with leading global healthcare companies in order to leverage the DPP platform.

Compared with traditional lateral flow technology, the DPP technology platform provides enhanced sensitivity and specificity, advanced multiplexing capabilities, and, when used with the DPP Micro Reader, quantitative results. Our DPP HIV test provides sensitivity of 99.8% and specificity of 100%, and has been approved by the U.S. Food and Drug Administration, or FDA, and approved as a waived test under the Clinical Laboratory Improvement Amendments of 1988.

We are pursuing four corporate priorities, aimed at executing on our key building blocks to drive growth and operating efficiency:

- expand our core point-of-care infectious disease business;
- leverage our patented DPP technology and scientific expertise through collaborations;
- broaden our sales channels worldwide; and
- automate our U.S. manufacturing operations to increase capacity and margin.

Our accomplishments in 2019 have included:

- Achieved total revenue of $8.3 million for the three months ended March 31, 2019, an increase of 8% over same period in the prior year
- Commenced automated manufacturing
- Achieved ANVISA Approval in Brazil for Zika/Dengue/Chikungunya multiplex test
- Completed Zika 510(k) study, funded by BARDA
- Signed agreement with Perseus Science to develop a point-of-care test for concussion
- Received US patent for optical analyzer technology

Our product commercialization and product development efforts are focused in two areas: infectious disease, which includes both sexually transmitted and tropical & fever disease; and strategic collaborations with leading global healthcare companies, which leverage the DPP platform to provide us with additional revenue streams. In infectious disease, we are commercializing tests for HIV, Syphilis, Zika virus, dengue virus, and chikungunya virus, and developing tests for hepatitis C, malaria, ebola, lassa, Marburg, leptospirosis, Rickettsia typhi, Burkholderia pseudomallei, and Orientia tsutsugamushi. Certain of these are also being developed as part of fever panel tests. Through strategic collaborations, we are developing tests for a specific form of cancer, concussions, bovine tuberculosis, and for eosinophilic respiratory disease, the latter in collaboration with global biopharmaceutical company 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. Our product development is focused on areas where the availability of rapid POC screening, diagnostic, or confirmatory results can improve health outcomes. More generally, we believe 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.

Our products are sold globally, directly and through distributors, to hospitals and clinics, physician offices, clinical laboratories, public health organizations, government agencies, and consumers.

Table of Contents
Consolidated Results of Operations

Three Months Ended March 31, 2019 versus Three Months Ended March 31, 2018

The results of operations for the three months ended March 31, 2019 and 2018 were as follows (dollars in thousands):

	March 31, 2019		March 31, 2018	
TOTAL REVENUES	$8,301	100%	$7,717	100%
OPERATING COSTS AND EXPENSES:				
Cost of product sales	4,770	57 %	4,118	53 %
Research and development expenses	2,218	27 %	1,847	24 %
Selling, general and administrative expenses	4,013	48 %	2,406	31 %
Acquisition Costs	396	5 %	-	- %
	11,397		8,371	
LOSS FROM OPERATIONS	(3,096)		(654)	
OTHER INCOME	7		2	
LOSS BEFORE INCOME TAXES	(3,089)	(37)%	(652)	(8)%
Income tax provision (benefit)	(272)		-	
NET LOSS	$(2,817)		$(652)	

Percentages in the table reflect the percent of total revenues.

Total Revenues

Total revenues during the quarter ended March 31, 2019 were $8.3 million, an increase of $0.6 million, or 7.6% compared to the quarter ended March 31, 2018. The increase in total net revenues was comprised of the following:

Comparable product sales, reflecting gains in Africa, the United States, and Europe, offset by lower sales in Latin America and Asia. Africa continued to benefit from our winning the single largest tender in our history for the supply of HIV tests to Ethiopia, together with meaningful commercial successes in that region. The United States benefited from winning back a large state program, and Europe reflects both the increasing trend of HIV self-testing and contribution from our acquisition of opTricon (now Chembio Diagnostics GmbH) in November 2018. Latin America declines represented supply chain timing differences.
$0.6 million, or 45% increase in R&D and grant, and license and royalty revenues, reflecting our continued success in securing governmental, non-governmental, and commercial partnerships, in particular associated with our DPP technology platform, and advancing the development work on those programs.

Gross Product Margin

Cost of product sales is primarily comprised of material, labor, manufacturing overhead, depreciation and amortization, and other operating expenses. Gross product margin is net product sales less cost of product sales, and gross product margin percentage is gross product margin as a percentage of net product sales.

Gross product margin decreased by $0.7 million, or 29% compared to 2018. The following schedule calculates gross product margin (dollars in thousands):

	For the three months ended March 31, 2019	March 31, 2018	Favorable/(unfavorable) $ Change	% Change
Net product sales	$ 6,383	$ 6,398	$ (15)	-
Less: Cost of product sales	(4,770)	(4,118)	(652)	(16)%
Gross product margin	$ 1,613	$ 2,280	$ (667)	(29)%
Gross margin percentage	25.3 %	35.6 %		

The $0.7 million decrease in gross product margin was comprised of the following:

comparable product sales volume as described above, and
$0.7 million from unfavorable product margins, related to increased labor (including contract labor) to manually assemble our products and the impact of geographic mix on average selling prices.

The decreases in gross product margin and gross product margin percentage reflect increased labor (including contract labor) costs required to manually assemble our products and the impact of geographic mix on average selling prices. As noted above, we have commenced automated manufacturing on our first line and have two other lines on order. We expect the automation to both reduce our reliance on manual labor and contribute to improving gross product margin.

22

Table of Contents

Research and Development

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

	For the three months ended		Favorable/(unfavorable)	
	March 31, 2019	March 31, 2018	$ Change	% Change
Clinical & regulatory affairs	$439	$484	$ 45	9 %
Other research & development	1,779	1,363	(416)	(31)%
Total Research and Development	$2,218	$1,847	$ (371)	(20)%

The decrease in clinical & regulatory affairs costs for the three months ended March 31, 2019 compared to the three months ended March 31, 2018 is primarily associated with decreased spending on the Company's U.S. clinical trial evaluating its DPP® HIV-Syphilis System. The increase in other research & development costs is primarily associated with an increase in spending on materials & supplies, each corresponding with the growth in R&D and grant revenue-related projects.

Selling, General and Administrative Expense

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

The $1.6 million, or 66.8% increase in SG&A for the three months ended March 31, 2019 compared to the three months ended March 31, 2018, was primarily associated with the inclusion of costs from Chembio Diagnostics GmbH; legal, rent, and other costs related to the lease for our new Hauppauge, NY corporate headquarters, R&D labs, and manufacturing facility; and, higher non-cash equity compenastion costs.

Acquisition Costs

Acquisition costs for the three months ended March 31, 2019 include legal, due diligence, audit, and related costs associated with acquisitions. The $0.4 million increase in acquisition costs for the three months ended March 31, 2019 as compared to 2018 is associated with the acquisition of opTricon in November 2018.

Other Income

Other income consists principally of interest income earned on our deposits, net of interest expense, which remained consistent in the first quarter of 2019 as compared to the first quarter of 2018.

Income Tax Provision

During the first quarter of 2019, we recognized a tax benefit of $0.3 million related to losses generated by our foreign subsidiaries. As of March 31, 2019 and 2018, our United States deferred tax assets included a full valuation allowance.

Table of Contents

Liquidity and Capital Resources

During the three months ended March 31, 2019, we funded our business operations, including capital expenditures and working capital requirements, principally from cash and cash equivalents. Our operations used cash flow of $4.8 million. As of March 31, 2019, we had no outstanding debt other than a $0.3 million seller-financed note payable incurred in connection with our purchase of automated manufacturing equipment.

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 rate of our business and revenue growth, 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 not be able to generate the cash flow needed to fund our automation of U.S. manufacturing and our investment in research and development and sales and marketing at the time contemplated by our operating plan. In such an event, we may elect to reduce the level, or otherwise delay the timing, of such funding and/or such investments, 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.

If we do not elect to reduce or delay such funding or investments, or if we determine to effect one or more acquisitions of businesses, technologies or products, we may be required to seek to raise additional funds through public or private financings, strategic relationships, or other arrangements, to the extent funding would be available to us on acceptable terms or at all. If we were to raise additional funds through the issuance of equity or convertible securities, the issuance could result in substantial dilution to existing stockholders, and the holders of these new securities or debt may have rights, preferences and privileges senior to those of the holders of common stock.

Sources of Funds

Research and Development Awards. We frequently seek research and development programs that may be awarded by government, non-governmental organizations, and non-profit entities, including private foundations. During the three months ended March 31, 2019, we recognized grant revenue totaling $0.9 from government, non-governmental organizations, and non-profit entities.

Working Capital. The following table sets forth selected working capital information:

	March 31, 2019 (in thousands)
Cash and cash equivalents	$ 7,371
Accounts receivable, net of allowance for doubtful amounts	7,718
Inventories, net	9,856
Prepaid expenses and other current assets	2,242
Total current assets	27,187
Less: Total current liabilities	(7,296)
Working capital	$ 19,891

Our cash and cash equivalents at March 31, 2019 were unrestricted and 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 balance fluctuates 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

Cash Flow Used in Operating Activities. Our operations used $4.8 million of cash during the three months ended March 31, 2019, primarily due to the net loss adjusted for non-cash items for the quarter of $2.4 million, a $0.2

million increase in accounts receivable related to the 7.6% increase in total revenue, a $2.0 million increase in inventory associated with supply chain timing, $0.4 million increase in prepaid expenses and other current assets related to prepaid rent and security deposits for our new Hauppauge corporate headquarters facility, offset by a $0.5 million increase in accounts payable and accrued liabilities.
Capital Expenditures. During the three months March 31, 2019, we continued to invest in manufacturing equipment and other fixed assets. Our capital expenditures totaled $0.6 million in the three months ended March 31, 2019.

Effects of Inflation

Inflation and changing prices have not had a material effect on our business, and we do not expect that they will materially affect our business in the foreseeable future. Any impact of inflation on cost of revenue and operating expenses, especially employee compensation costs, may not be readily recoverable in the price of our product offerings.

Off-Balance Sheet Arrangements

We do 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.

Critical Accounting Estimates

There were no significant changes in our critical accounting estimates during the three months ended March 31, 2019 to augment the critical accounting estimates disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, other than those described in the Notes to the condensed consolidated financial statements included in this report.

Recently Issued Accounting Pronouncements

A discussion of recent accounting pronouncements is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and is updated in the Notes to the condensed consolidated financial statements included in this report.

24

Table of Contents

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk.

We do not hold any amounts of derivative financial instruments or derivative commodity instruments and, accordingly, have no material derivative risk to report under this Item. As of March 31, 2019, we did not have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows.

We are exposed to market risks from changes in currency exchange rates and certain commodity prices. All sales from our U.S. subsidiary, regardless of the customer location, are denominated in U.S. dollars. Sales denominated in foreign currencies are associated with the sales from our subsidiaries, Chembio Diagnostics Malaysia Sdn Bhd and Chembio Diagnostics GmbH and comprised approximately 7% of our total revenues for the three months ended March 31, 2019.

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 Securities Exchange Act of 1934, as amended, or 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 March 31, 2019 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 March 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We know of no material, existing or pending legal proceedings against us, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest that is adverse to our interest.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors discussed in Part I, Item 1A, “Risk Factors,” in our Annual Report on Form 10-K for the year ended December 31, 2018. In addition to the other information set forth in this report, you should carefully consider those risk factors, which could materially affect our business, financial condition and future operating results. Those risk factors are not the only risks facing our company. 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 operating results.

Table of Contents

ITEM 6. EXHIBITS

Number	Description
10.1*	Amendment No. 1 dated January 21, 2019 between Chembio Diagnostics, Inc. and Neil A. Goldman, amending the Employment Agreement dated December 18, 2017
10.2*	Amendment No. 1 dated March 20, 2019 between Chembio Diagnostics, Inc. and Javan Esfandiari, amending the Employment Agreement dated March 5, 2016
10.3	Company Lease dated February 1, 2019 between Chembio Diagnostic Systems Inc., as landlord, and Suffolk County Industrial Development Agency, as tenant
10.4	Lease and Project Agreement dated February 1, 2019 between Suffolk County Industrial Development Agency, as landlord, and Chembio Diagnostic Systems Inc., as tenant
10.5	Lease Agreement dated February 5, 2019 between Myra Properties, LLC, as lessor, and Chembio Diagnostic Systems Inc., as lessee
10.6	Agreement of Sublease dated February 5, 2019 between Chembio Diagnostic Systems Inc., as sublessor, and Reliance Communications of New Jersey, LLC, as sublessee
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	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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Definition Linkbase Document
101.LAB	XBRL Taxonomy Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

* Management contract or compensatory plan or arrangement.

Table of Contents

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:	May 2, 2019	By: /s/ John J. Sperzel III John J. Sperzel III Chief Executive Officer and President (Principal Executive Officer)
Date:	May 2, 2019	By: /s / Neil A. Goldman Neil A. Goldman Chief Financial Officer and Executive Vice President (Principal Financial and Accounting Officer)