

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

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2019**

[] TRANSITION REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period ----- to -----

Commission File Number: 0-28666

American Bio Medica Corporation
(Exact name of registrant as specified in its charter)

New York
(State or other jurisdiction of incorporation or organization)

14-1702188
(I.R.S. Employer Identification No.)

122 Smith Road
Kinderhook, New York
(Address of principal executive offices)

12106
(Zip Code)

Registrant's telephone number (including area code): **(518) 758-8158**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ABMC	OTC Markets Pink

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. ☐ Yes ☒ No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

The aggregate market value of 24,745,572 voting Common Shares held by non-affiliates of the registrant was approximately \$1,732,000 based on the last sale price of the registrant's Common Shares, \$.01 par value, as reported on the OTC Pink Open Marketplace on June 30, 2019.

As of June 26, 2020 the registrant had outstanding 35,847,093 Common Shares, \$.01 par value.

Documents Incorporated by Reference:

- (1) Portions of the Registrant's Proxy Statement for the year ended December 31, 2019 in Part III of this Form 10-K
 - (2) Other documents incorporated by reference on this report are listed under Part IV, Item 15(B); Exhibits
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American Bio Medica Corporation

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For the year ended December 31, 2019

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This Form 10-K may contain certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. For this purpose, any statements contained in this Form 10-K that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as “may”, “could”, “should”, “will”, “expect”, “believe”, “anticipate”, “estimate” or “continue” or comparable terminology is intended to identify forward-looking statements. It is important to note that actual results could differ materially from those anticipated from the forward-looking statements depending on various important factors. These important factors include our history of losses, our ability to continue as a going concern, adverse changes in regulatory requirements related to the marketing and use of our products, the uncertainty of acceptance of current and new products in our markets, competition in our markets and other factors discussed in our “Risk Factors” found in Part I, Item 1A.

PART I

ITEM 1. BUSINESS

Form and Year of Organization

American Bio Medica Corporation (the “Company”) was incorporated on April 2, 1986 under the laws of the State of New York under the name American Micro Media, Inc. On September 9, 1992, we filed an amendment to our Articles of Incorporation and changed our name to American Bio Medica Corporation.

Our Business

We manufacture and sell lateral flow immunoassay tests, primarily for the immediate detection of drugs in urine and oral fluid. Our products are accurate, self-contained, cost-effective, user-friendly products that are capable of accurately identifying the presence or absence of drugs in a sample within minutes. The products we manufacture are made 100% in the United States while our competitors manufacture their products outside the United States, primarily in China. One of our drug testing lines is private labeled for another diagnostic company.

We also provide strip manufacturing and assembly and packaging services for a diagnostic test to an unaffiliated third party; that sells this product outside the United States and, we manufacture a diagnostic product that is sold under a private label by an unaffiliated third party.

And finally, we sell (via distribution) a number of other products related to the immediate detection of drugs in urine and oral fluid as well as offering other point of care diagnostic products via distribution. Through the year ended December 31, 2019 (“Fiscal 2019”), we did not derive a significant portion of our revenues from these additional products.

Our Products

Products for the Detection of Drugs in Urine

We manufacture a number of products that detect the presence or absence of drugs in urine. We offer a number of standard configurations, custom configurations on special order, and different cut-off levels for certain drugs. Cut-off levels are concentrations of drugs or metabolites that must be present in urine (or oral fluid) specimens before a positive result will be obtained. Our urine drugs tests are either 510(k) cleared, CLIA Waived and/or OTC cleared (see “Government Regulations” for information on the regulations related to the sale of our drug tests). We currently manufacture the following urine drug testing product lines:

Rapid Drug Screen®: The Rapid Drug Screen, or RDS®, is a patented rapid drug test that detects the presence or absence of 2 to 10 drugs simultaneously in a single urine specimen. The RDS is available as a card only, or as part of a kit that includes a collection cup.

RDS InCup®: The patented RDS InCup is a drug-testing cup that detects the presence or absence of 1 to 12 drugs in a urine specimen. The RDS InCup incorporates collection and testing of a urine sample in a single step. Each RDS InCup contains multiple channels, and each channel contains a drug-testing strip that contains the chemistry to detect a single drug.

Rapid TOX®: Rapid TOX is a cost-effective drug test in a cassette platform that simultaneously detects the presence or absence of 1 to 10 drugs in a urine specimen. Each Rapid TOX contains one or two channels, and each channel contains a drug-testing strip that contains the chemistry to detect 1-5 drugs.

Rapid TOX Cup® II: The patented Rapid TOX Cup II is another drug testing cup that detects the presence or absence of 1 to 16 drugs in a urine specimen. The Rapid TOX Cup II also incorporates collection and testing of the urine sample in a single step. Each Rapid TOX Cup II contains multiple channels and each channel contains a single drug-testing strip that contains the chemistry to detect more than one drug. This product is available in two (2) formats; one of which has a smaller cup and testing strips to be more cost competitive.

Private Label Products

We provide a private labeled version of Rapid TOX to an unaffiliated third party for sale globally. Through Fiscal 2019, sales of these products were not material.

Products for the Detection of Drugs in Oral Fluid:

We manufacture drug tests that detect the presence or absence of drugs in oral fluids. These products are easy to use and provide test results within minutes with enhanced sensitivity and detection. As of the date of this report, our oral fluid drug tests are marketed “for forensic use only” or for “employment use only” as well as in markets outside the United States; (see “Government Regulations” for information on the regulations related to the sale of our drug tests). We currently offer the following oral fluid drug tests:

OralStat®: OralStat is a patented and patent pending, innovative drug test for the detection of drugs in oral fluids. Each OralStat simultaneously tests for 6 or 10 drugs in an oral fluid specimen.

Private Label Products

We do provide a private labeled version of our OralStat product to an unaffiliated third party for sale outside of the United States. Through Fiscal 2019, sales of this product were not material.

Other Products

Throughout the year ended December 31, 2019, we distributed a number of other products related to the detection of substances of abuse as well as products to detect certain infectious disease. We do not manufacture these products. Through Fiscal 2019, we did not derive a significant portion of our revenues from the sale of these products.

Contract Manufacturing

We provide strip manufacturing and assembly and packaging services to non-affiliated diagnostic companies. In Fiscal 2019, we manufactured a test for the detection of RSV (Respiratory Syncytial Virus; the most common cause of lower respiratory tract infections in children worldwide), a test for Malaria (a disease transmitted to humans through bites from infected mosquitoes) and we manufactured a special custom panel of our Rapid TOX as a private label. Fiscal 2019 contract manufacturing sales did not represent a significant portion of our revenue.

Our Markets/Distribution Methods

Rehabilitation/Drug Treatment

The Rehabilitation/Drug Treatment market includes people in both inpatient and outpatient treatment for substance abuse. Drug testing is a positive aspect of treatment as it aids in relapse prevention and encourages honesty both within the patient and with outside interactions. In addition, being able to accurately gauge the current drug use by patients enrolled in a substance abuse program is essential so, urine drug testing is an integral part of treatment programs, including physician office-based programs. There is typically a high frequency of testing in this market. We sell our urine drug tests in this market primarily through our direct sales force and also through a number of distributors.

Pain Management

Drug testing in pain management is one of the major tools of adherence monitoring in the assessment of a patient's predisposition to, and patterns of, misuse/abuse; a vital first step towards establishing and maintaining the safe and effective use of drugs in the treatment of chronic pain. There are many benefits of using an ABMC drug test; these include reducing the risk for toxicity in patients vulnerable to adverse drug effects, detecting patient non-compliance, reducing the risk of therapeutic failure, and avoiding or detecting drug-drug interaction. Additionally, drug testing enhances the physician's ability to use drugs effectively and minimize costs. We currently sell our urine drug tests in this market primarily through our direct sales force and also through a number of distributors.

Other Clinical

Other Clinical markets include emergency rooms/hospitals, family physician offices and laboratories. There are a number of medical emergencies associated with adverse reactions, accidental drug ingestions, and misuse or abuse of prescription drugs and over-the-counter medications. To address this issue, drug testing is performed so healthcare professionals are able to ascertain the drug status of a patient before they administer pharmaceuticals or other treatment. We currently sell our urine drug tests in this market primarily through our direct sales force and also through a number of distributors. We also have a long-term relationship with one of the world's largest clinical laboratories.

Government (including law enforcement and criminal justice)

The Government market includes federal, state, county and local agencies, including police departments, adult and juvenile correctional facilities, pretrial agencies, probation, drug courts and parole departments at the federal and state levels. A significant number of individuals on parole or probation, or within federal, state, county and local correctional facilities and jails, have one or more conditions to their sentence, including but not limited to, periodic drug-testing and substance abuse treatment. We sell our products in this market through our direct sales force.

Employment/Workplace

The Workplace market consists of pre-employment testing of job applicants, as well as random, cause and post-accident testing of employees. Many employers recognize the financial and safety benefits of implementing drug-free workplace programs, of which drug testing is an integral part. In some states, there are workers' compensation and unemployment insurance premium reductions, tax deductions and other incentives for adopting these programs. We sell our products in this market through our direct sales force and through a select network of distributors.

International

The International market consists of various markets outside of the United States. Although workplace testing is not as prevalent outside of the United States as within, the international Government and Clinical markets are somewhat in concert with their United States counterparts. One market that is significantly more prevalent outside of the United States is roadside drug testing. We sell in this market through a select network of distributors.

Competition

We compete on the following factors:

Pricing: The pricing structure in our markets is highly competitive. We offer the only drug testing products that contain testing strips that are 100% manufactured in the US and that is 100% assembled in the United States. Price pressure is the greatest when comparing our pricing with pricing of products manufactured outside of the United States.

Quality: We manufacture, assemble and package our testing strips and products completely in the United States in accordance with quality system regulations set forth by FDA. Many companies in our industry claim their products are manufactured in the United States when in fact; their products are only assembled or packaged in the United States. The testing strips and in most cases the assembly of the product is done outside of the United States; usually in China. Products manufactured outside of the United States are generally manufactured outside of the requirements of quality system regulations set forth by FDA. In our opinion, this results in inferior, sub-par products being offered in the market. Most of our markets require accurate detection near the cut-off level of the test. Our products are manufactured to detect drug use closer to the cut-off level of the test. The majority of the drug tests on the market today are less "aggressive"; meaning they are not as sensitive and they will miss positive results. Missing positive results can be extremely troublesome to customers from both an economic and liability perspective; and in the clinical market, missing positives can be a threat to the health of the individuals being tested. We do offer products manufactured outside of the United States via distribution relationships to those customers that do not require accuracy near or at the cutoff level in their drug testing programs.

Customer and technical support: Our customers often need guidance and assistance with certain issues, including but not limited to, test administration, drug cross reactivity and drug metabolism. We provide our customers with continuous customer and technical support on a 24/7/365 basis; staffed by our employees. We believe that this support gives us a competitive advantage since our competitors do not offer this “employee staffed” extended service to their customers.

Raw Materials and Suppliers

The primary raw materials required for the manufacture of our test strips and our drug tests consist of antibodies, antigens and other reagents, plastic molded pieces, membranes and packaging materials. We maintain an inventory of raw materials. Currently, most raw materials are available from several sources. We own the molds and tooling for our plastic components that are custom and proprietary. The ownership of these molds affords us flexibility and control in managing the supply chain for these components. We do not own the molds and tooling for plastic components that are “stock” items.

Major Customers

One of our customers accounted for 44.8% and 44% of net sales in Fiscal 2019 and the year ended December 31, 2018 (“Fiscal 2018”), respectively.

Patents and Trademarks/Licenses

As of December 31, 2019, we have patented our testing products in 27 countries outside the United States and we hold 11 patents in the United States. As of December 31, 2019, we have 5 foreign patent application pending. We are incurring fees related to these patent applications that will be capitalized over the term of the patents.

As of December 31, 2019, we have 15 trademarks registered in the United States and, 10 trademarks registered in countries/regions such as Canada, Mexico, and the United Kingdom.

Government Regulations

In certain markets, the development, testing, manufacture and sale of our drug tests, and possible additional testing products for other substances or conditions, are subject to regulation by the United States and foreign regulatory agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act, and associated regulations, the United State Food and Drug Administration (“FDA”) regulates the pre-clinical and clinical testing, manufacture, labeling, distribution and promotion of medical devices. When a product is a medical device, a 510(k) marketing application must be submitted to the FDA. A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is safe and effective. Applicants must compare their 510(k) device to one or more similar devices currently being marketed in the United States. Most of our urine-based products are marketed and sold in the Clinical market (in addition to other markets) and therefore, we have obtained 510(k) marketing clearance, CLIA waiver (see below) and/or Over-The-Counter (OTC) marketing clearance on our urine based products. Our oral fluid products are not 510(k) cleared; so we market and sell these products to the forensic market, employment market (under a limited exemption issued by FDA in July 2017) and for export outside the United States.

In order to sell our products in Canada, we must comply with ISO 13485:2003, the International Standards Organization’s Directive for Quality Systems for Medical Devices (MDD or Medical Device Directive), and in order to sell our products in the European Union, we must obtain CE marking for our products (in the European Union, a “CE” mark is affixed to the product for easy identification of quality products). Collectively, these standards are similar to FDA regulations, and are a reasonable assurance to the customer that our products are manufactured in a consistent manner to help ensure that quality defect-free goods are produced. As of the date of this report, we have received approval and the right to bear the CE mark on our Rapid Drug Screen, Rapid ONE, Rapid TOX, RDS InCup, Rapid TOX Cup II, Rapid Reader and OralStat. We are currently certified to I.S. EN ISO 13485:2016 with an expiration date of July 31, 2021.

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 established quality standards for laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. As a result, those using CLIA waived tests are not subject to the more stringent and expensive requirements of moderate or high complexity laboratories. We have received CLIA waiver from the FDA related to our Rapid TOX product line and OTC clearance on our Rapid TOX Cup II product line (The OTC clearance of the Rapid TOX Cup II product line means they are CLIA waived products).

Due to the nature of the manufacturing of our drug tests, the products we offer through contract manufacturing and the raw materials used for both, we do not incur any material costs associated with compliance with environmental laws, nor do we experience any material effects of compliance with environmental laws.

Manufacturing and Employees

Our facility in Kinderhook, New York houses assembly and packaging of the products we manufacture (including the products we supply on a contract manufacturing basis and the products we supply to a third party who markets the products under their own private label). Our warehouse, shipping department and administrative offices are also within our New York facility.

In our Logan Township, New Jersey facility, we manufacture our drug test strips and test strips for unaffiliated third parties. We also perform research and development in our New Jersey facility.

Unaffiliated third parties manufacture the adulteration, alcohol and certain forensic drug testing products we offer. We continue to primarily outsource the printing of the plastic components used in our products, and we outsource the manufacture of the plastic components used in our products.

As of December 31, 2019, we had 48 employees, of which 42 were full-time and 6 were part-time. None of our employees are covered by collective bargaining agreements.

ITEM 1A. RISK FACTORS

We are providing risk factors we believe are applicable to the company and our business even though we are not required to provide this information due to our status as a smaller reporting company.

The drug testing market is highly competitive.

The market for drug tests used at the point of collection is highly competitive. Several companies produce drug tests that compete directly with products and they produce their products outside the United State at a lower cost. Some of our competitors have greater financial resources, allowing them to devote substantially more resources to business and product development and marketing efforts. Our inability to successfully address any competitive risk factors could negatively impact sales and our ability to achieve profitability.

Possible inability to hire and retain qualified personnel.

We need skilled sales and marketing, technical and production personnel to maintain and/or grow our business. If we fail to retain our present staff or hire additional qualified personnel our business could suffer; specifically in the case of sales personnel. An inability to find qualified sales representatives would negatively impact our ability to maintain and/or grow sales.

Any adverse changes in our regulatory framework could negatively impact our business, and costs to obtain regulatory clearance are material.

Although we are unaware of any recent or upcoming changes in regulatory standards related to the marketing of our drug tests, changes in regulatory requirements could negatively impact our business if we are unable to comply with the changes. Typically, the cost to comply with regulatory changes is significant; especially if additional applications for marketing clearance from FDA are required. The cost of filing a 510(k) marketing clearance is material and can have a negative impact on efforts to improve our financial performance. If regulatory standards change in the future, there can be no assurance that we will receive marketing clearances from FDA, if and when we apply for them.

On March 23, 2020, we announced in a press release that we were marketing, via a distribution partnership, a Rapid Test to detect Covid-19 antibodies in whole blood, serum or plasma. The test is being marketed under the March 16, 2020 Emergency Use Authorization (“EUA”) policy set forth by the FDA and on May 29, 2020, an EUA was issued by the FDA. The revocation of the EUA could negatively impact our business and stop any future sales of the Covid-19 antibody tests.

We rely on intellectual property rights and contractual non-disclosure obligations to protect our proprietary information (including customer information). These rights and obligations may not adequately protect our proprietary information, and an inability to protect our proprietary information can harm our business.

We rely on confidentiality procedures and contractual provisions to protect our confidential and proprietary information. Confidential and proprietary information (such as components and product costing, customer pricing structures, customer information, vendor information, internal financial information, production processes, new product developments, product enhancements and other material, non-public information) is protected under non-disclosure agreements with our personnel and consultants. If these individuals do not comply with their obligations under these agreements, we may be required to incur significant costs to protect our confidential information and the use of this information by the breaching individual may cause harm to our business. In fact, throughout Fiscal 2018 and into Fiscal 2019, we were engaged in litigation with Todd Bailey (“Bailey”), a former Vice President, Sales & Marketing/Consultant of the Company. The complaint that we filed against Bailey was related to allegations that Bailey used our confidential and proprietary information to circumvent and interfere with long-standing ABMC customers. This interference resulted in contracts being awarded to Bailey’s company, Premier Biotech Inc., thereby causing harm to our business. We incurred increased legal

fees in Fiscal 2019 and Fiscal 2018 as a result of this litigation and ultimately, the litigation was settled in August 2019. The terms of the settlement remain confidential.

We also rely on a combination of patent, copyright, trademark and trade secret laws. Despite our efforts to protect our intellectual property rights, unauthorized parties may attempt to copy aspects of our products, dilute our trademarks, or otherwise infringe upon our rights. We may be required to incur significant costs to protect our intellectual property right under laws of the United States Patent and Trademark Office. In addition, the laws of some foreign countries do not ensure that our means of protecting our proprietary rights in the United States or abroad will be adequate. Policing and enforcement against the unauthorized use of our intellectual property and other confidential proprietary information could entail significant expenses and could prove difficult or impossible. Such significant expenditures could have a material adverse effect on our results of operations.

One of our customers accounted for more than 10% of our total net sales in Fiscal 2019.

One of our customers accounted for 44.8% and 44% of our net sales in Fiscal 2019 and in Fiscal 2018, respectively. We currently have a contract in place with this long-standing customer that does not expire in the near future. However, there can be no assurance that this customer, or any of our current customers will continue to place orders, or that orders by existing customers will continue at current or historical levels.

We depend on key personnel to manage our business effectively.

We are dependent on the expertise and experience of senior management for our future success. The loss of senior management personnel could negatively impact our business and results of operations. Melissa A. Waterhouse serves as our sole executive officer. She serves as Chief Executive Officer and Principal Financial Officer. We have an employment agreement in place with Ms. Waterhouse, but there can be no assurance that Ms. Waterhouse will continue her employment. The loss of Ms. Waterhouse could disrupt the business and have a negative impact on business results. We also have a number of other individuals in senior management positions. There can be no assurance that they too will continue their employment. We do not currently maintain key man insurance on Ms. Waterhouse.

We rely on third parties for raw materials used in our drug test products and in our bulk test strip contract manufacturing processes.

We currently have approximately 45 suppliers that provide us with the raw materials necessary to manufacture our drug-testing strips, our drug test kits and the products we supply third parties on a contract manufacturing basis. For most of our raw materials, we have multiple suppliers, but there are a few raw materials for which we only have one supplier. The loss of one or more of these suppliers, the non-performance of one or more of their materials or the lack of availability of raw materials could suspend our manufacturing process for one or more product lines. This interruption of the manufacturing process could impair our ability to fill customers' orders as they are placed, putting us at a competitive disadvantage.

We have a significant amount of raw material and "work in process" inventory on hand that may not be used in the year ended December 31, 2020 if the expected configuration of sales orders is not received at projected levels.

We had approximately \$670,000 in raw material components for the manufacture of our products at December 31, 2019. The non-chemical raw material components may be retained and used in production indefinitely and the chemical raw materials components have lives in excess of 20 years. In addition to the raw material inventory, we had approximately \$141,000 in "work in process" (manufactured testing strips) inventory at December 31, 2019. The components for much of this "work in process" inventory have lives of 12-36 months. If sales orders received are not for products that would utilize the raw material components, or if product developments make the raw materials obsolete, we may be required to dispose of these unused raw materials. In addition, since the components for much of the "work in process" inventory have lives of 12-36 months, if sales orders within the next 12-36 months are not for products that contain the components of the "work in process" inventory, we may need to discard this expired "work in process" inventory. We have established an allowance for obsolete or slow moving inventory. At December 31, 2019, this allowance was \$291,000. There can be no assurance that this allowance will continue to be adequate for the year ending December 31, 2020 and/or that it will not have to be adjusted in the future.

Inability to meet our operating plans could have a material adverse effect on our future performance.

If events and circumstances occur such that we do not meet our current operating plans, if we are unable to raise sufficient additional equity or debt financing, or our credit facilities are insufficient or not available, we may be required to further reduce expenses or take other steps which could have a material adverse effect on our future performance.

We incur costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

We incur legal, accounting and other expenses as a result of our required compliance with certain regulations implemented by the United States Securities and Exchange Commission ("SEC"). Our executive management and other personnel devote a substantial amount of time to these compliance requirements, including but not limited to compliance with the Sarbanes-Oxley Act of 2002 that requires, among other things, that we maintain effective internal controls over financial reporting and disclosure controls and procedures. Our management is required to perform system and process evaluation and testing of the effectiveness of our internal controls over financial reporting, as required by Section 404(a) of the Sarbanes-Oxley Act (as a smaller reporting company, we are exempt from the requirements of Section 404(b) of the Sarbanes-Oxley Act requiring auditor's attestation related to internal controls over financial reporting). If we are not able to comply with the requirements of Section 404(a), if we identify deficiencies in our internal controls over financial reporting, or if we are unable to comply with any other SEC regulations or requirements, the market price of our common shares could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Inability to comply with our debt obligations could result in our creditors declaring all amounts owed to them due and payable with immediate effect, or result in the collection of collateral by the creditor; both of which would have an adverse material impact on our business and our ability to continue operations.

We have a credit facility with Crestmark Bank consisting of revolving line of credit (the "Crestmark LOC"). The Crestmark LOC is secured by a first security interest in all of our receivables and inventory and security interest in all other assets of the Company (in accordance with permitted prior encumbrances), (together the "Collateral"). As of December 31, 2019, we were required to comply with a minimum Tangible Net Worth ("TNW") Covenant of \$(600,000). TNW is defined as: Total Assets less Total Liabilities less the sum of (i) the aggregate amount of non-trade accounts receivables, including accounts receivables from affiliated or related persons, (ii) prepaid expenses, (iii) deposits, (iv) net lease hold improvements, (v) goodwill and (vi) any other asset that would be treated as an intangible asset under GAAP; plus Subordinated Debt. Subordinated Debt means any and all indebtedness presently or in the future incurred by the Company to any creditor of the Company entering into a written subordination agreement with Crestmark. On June 22, 2020, we extended the Crestmark LOC and as a result of this extension, the TNW covenant was removed effective with the quarter ending June 30, 2020. We were not in compliance with the TNW covenant at December 31, 2019 and with the exception of the quarter ended June 30, 2019; we have not been in compliance with prior TNW covenants since December 31, 2017. We are in the process of obtaining a waiver from Crestmark Bank in connection with the non-compliance with the TNW covenant at December 31, 2019. If we are not compliant with the TNW covenant for the quarter ending March 31, 2020, we also expect to receive a waiver from Crestmark Bank.

In addition to the Crestmark LOC, we have a loan and security agreement with Cherokee Financial, LLC. ("Cherokee") which is secured by a first security interest in our real estate and machinery and equipment. In addition to general economic, financial, competitive, regulatory, business and other factors beyond our control, our ability to make payments to Cherokee Financial, LLC will depend primarily upon our future operating performance; which has been negatively impacted by the loss of material contracts and the increased price competition in our core markets for drug testing. In February 2020, we extended our loan facilities with Cherokee. (See Note J— Subsequent Event)

A failure to comply with the Crestmark LOC TNW covenant as of December 31, 2019 or March 31, 2020 (that is not waived by Crestmark Bank) and/or repay any of our debt obligations could result in an event of default, which, if not cured or waived, could result in the Company being required to pay much higher costs associated with the indebtedness and/or enable our creditors to declare all amounts owed to them due and payable with immediate effect. If we are forced to refinance our debt on less favorable terms, our results of operations and financial condition could be adversely affected by increased costs and rates. We may also be forced to pursue one or more alternative strategies, such as restructuring, selling assets, reducing or delaying capital expenditures or seeking additional equity capital. There can be no assurances that any of these strategies could be implemented on satisfactory terms, if at all, or that future borrowings or equity financing would be available for the payment of any indebtedness we may have. In addition, in an event of default, our creditors could begin proceedings to collect the collateral securing the debt. This would have a material adverse effect on our ability to continue operations.

We have a history of incurring net losses and as of December 31, 2019, we have a negative stockholders' equity.

Since our inception and throughout most of our history, we have incurred net losses, including but not limited to, a net loss of \$681,000 incurred in Fiscal 2019. As of December 31, 2019, we also reported negative stockholders' equity of \$790,000. We incur substantial expenditures for sales and marketing, general and administrative and research and development purposes. Our ability to achieve profitability in the future will primarily depend on our ability to increase sales of our products. Stockholders' equity improvement will also be dependent on our ability to increase sales which will increase the value of our assets and decrease our liabilities. Future profitability is also dependent on our ability to reduce manufacturing costs and successfully introduce new products or new versions of our existing products into the marketplace. There can be no assurance that we will be able to increase our revenues at a rate that equals or exceeds expenditures. Our failure to increase sales while controlling sales and marketing, general and administrative, and research and development costs (relative to sales) would result in additional losses.

We may need additional funding for our existing and future operations.

Our financial statements for Fiscal 2019 were prepared assuming we will continue as a going concern. If sales do not improve, our current cash balances and cash generated from future operations may not be sufficient to fund operations through June 2021. Future events, including the expenses and difficulties which may be encountered in maintaining a market for our products could make cash on hand and cash available under our line of credit facility insufficient to fund operations. If this happens, we may be required to sell additional equity or debt securities or obtain additional credit facilities. Any equity financing would result in further dilution to existing shareholders. There can be no assurance that any of these financings will be available or that we will be able to complete such financing on satisfactory terms.

Potential issuance and exercise of new options and warrants and, exercise of outstanding options could adversely affect the value of our securities.

We currently have two non-statutory stock option plans, the Fiscal 2001 Non-statutory Stock Option Plan (the "2001 Plan") and the 2013 Equity Compensation Plan (the "2013 Plan"). Both plans have been adopted by our Board of Directors and approved by our shareholders. The common shares underlying the exercise of the stock options under the 2001 Plan have been registered with the SEC; however the common shares underlying the exercise of the stock options under the 2013 Plan have not been registered with the SEC.

Both the 2001 Plan and the 2013 Plan have options available for future issuance. As of December 31, 2019, there were 2,252,000 options issued and outstanding under the 2001 Plan. There were no options issued under the 2013 Plan, making the total issued and outstanding options 2,252,000 as of December 31, 2019. Of the total options issued and outstanding, 2,172,000 are fully vested as of December 31, 2019. As of December 31, 2019, there were 1,465,000 options available for issuance under the 2001 Plan and 4,000,000 options available for issuance under the 2013 Plan. As of December 31, 2019, we had 2,000,000 warrants issued and outstanding, however, the 2,000,000 warrants expired on January 16, 2020.

If outstanding stock options are exercised, the common shares issued will be freely tradable, increasing the total number of common shares issued and outstanding. If these shares are offered for sale in the public market, the sales could adversely affect the prevailing market price by lowering the bid price of our securities. The exercise of these stock options could also materially impair our ability to raise capital through the future sale of equity securities because issuance of the common shares underlying the stock options would cause further dilution of our securities. In addition, in the event of any change in the outstanding shares of our common stock by reason of any recapitalization, stock split, reverse stock split, stock dividend, reorganization consolidation, combination or exchange of shares, merger or any other changes in our corporate or capital structure or our common shares, the number and class of shares covered by the stock options and/or the exercise price of the stock options may be adjusted as set forth in their plans.

Substantial resale of restricted securities may depress the market price of our securities.

There are 11,254,918 common shares presently issued and outstanding as of the date hereof that are “restricted securities” as that term is defined under the Securities Act of 1933, as amended, (the “Securities Act”). These securities may be sold in compliance with Rule 144 of the Securities Act (“Rule 144”), or pursuant to a registration statement filed under the Securities Act. Rule 144 addresses sales of restricted securities by affiliates and non-affiliates of an issuer. An “affiliate” is a person, such as an officer, director or large shareholder, in a relationship of control with the issuer. “Control” means the power to direct the management and policies of the company in question, whether through the ownership of voting securities, by contract, or otherwise. If someone buys securities from a controlling person or an affiliate, they take restricted securities, even if they were not restricted in the affiliate's hands.

A person who is not an affiliate of the issuer (and who has not been for at least three months) and has held the restricted securities for at least one year can sell the securities without regard to restrictions. If the non-affiliate had held the securities for at least six months but less than one year, the securities may be sold by the non-affiliate as long as the current public information condition has been met (i.e. that the issuer has complied with the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”)).

We are subject to reporting requirements of the Exchange Act. Under Rule 144, if a holder of securities is an affiliate of an issuer subject to Exchange Act reporting requirements, the securities must be held for at least six months. In addition, the number of equity securities sold during any three-month period cannot exceed 1% of the outstanding shares of the same class being sold. The securities must be sold in unsolicited, routine trading transactions and brokers may not receive more than normal commission. Affiliates must also file a notice with the SEC on Form 144 if a sale involves more than 5,000 shares or the aggregate dollar amount is greater than \$50,000 in any three-month period. The sale must take place within three months of filing the Form 144 and, if the securities have not been sold, an amended notice must be filed. Investors should be aware that sales under Rule 144 or pursuant to a registration statement filed under the Securities Act might depress the market price of our securities in any market for such shares.

Our securities are currently trading on the OTC Markets Group (under their OTC Pink® Open Market), and are subject to SEC “penny stock,” rules, which could make it more difficult for a broker-dealer to trade our common shares, for an investor to acquire or dispose of our common shares in the secondary market and for us to retain or attract market makers.

The SEC has adopted regulations that define a “penny stock” to be any equity security that has a market price per share of less than \$5.00, subject to certain exceptions, such as any securities listed on a national securities exchange or securities of an issuer in continuous operation for more than three years whose net tangible assets are in excess of \$2 million, or an issuer that has average revenue of at least \$6 million for the last three years. Our common shares are currently trading on the OTC Markets Group, under their OTC Pink Open Market. As of Fiscal 2019, our net tangible assets did not exceed \$2 million, and our average revenue for the last three years was only \$4,147,000, so our securities do not currently qualify for exclusion from the “penny stock” definitions. Therefore, our common shares are subject to “penny stock” rules. For any transaction involving a “penny stock,” unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. For these reasons, a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market. Therefore, broker-dealers may be less willing or able to sell or make a market in our securities because of the penny stock disclosure rules. Not maintaining a listing on a major stock market may result in a decrease in the trading price of our securities due to a decrease in liquidity and less interest by institutions and individuals in investing in our securities, and could also make it more difficult for us to raise capital in the future. Furthermore, listing on OTC Market Group may make it more difficult to retain and attract market makers. In the event that market makers cease to function as such, public trading of our securities will be adversely affected or may cease entirely.

It is still uncertain what the impact of the COVID-19 pandemic will have on the Company and, the degree to which the pandemic will adversely affect our business, revenues, financial condition and results of operations.

In December 2019, an outbreak of a novel strain of coronavirus (COVID-19) spread globally. In March 2020, the World Health Organization declared COVID-19 to be a pandemic. To date, this global pandemic has severely impacted levels of economic activity around the world. In response to this pandemic, governments and public health officials of many countries, states, cities and other geographic regions have taken preventative or protective actions to mitigate the spread and severity of COVID-19, such as imposing restrictions on travel and business operations and advising or requiring individuals to limit or forego their time outside of their homes by imposing shelter-in-place orders. We cannot presently predict the scope and ultimate severity or duration of the coronavirus pandemic and any possible related disruptions to our business, but the coronavirus pandemic and the resulting economic and commercial shutdowns to date have negatively impacted our ability to conduct business in accordance with our plans. Disruptions to our business include restrictions on the ability of our sales and marketing personnel to travel, some disruptions of our global supply chain, and reduced demand and/or suspension of operations by our customers. The primary markets for our DOA products are all negatively impacted by the suspensions (partial or whole) of operation and as of the date of this report, our DOA revenues have declined from the prior year.

We cannot predict the degree to, or the time period over, which our business will be affected by the COVID-19 pandemic. There are numerous uncertainties associated with this outbreak, including the number of individuals who will become infected, whether a vaccine or cure that mitigates the effect of the virus will be synthesized, and, if so, when such vaccine or cure will be ready to be used, the extent of the protective and preventative measures that have been put in place by both governmental entities and other businesses and those that may be put in place in the future, whether the coronavirus' impact will be seasonal and the impact on the U.S. and world economy, and various other uncertainties. Further, even after containment of the virus any significant reduction in employee willingness to return to work would result in a reduction of manufacturing capacity.

On March 23, 2020, we announced in a press release that we were marketing, via a distribution partnership, a Rapid Test to detect Covid-19 antibodies in whole blood, serum or plasma. The test is being marketed under the March 16, 2020 Emergency Use Authorization ("EUA") policy set forth by the FDA and on May 29, 2020, an EUA was issued by the FDA.

We expect COVID-19 will continue to negatively affect customer demand of our DOA products in Fiscal 2021 or at least part of Fiscal 2021, and the duration of this negative impact is uncertain, we do not yet know the full extent of the negative impact of COVID-19 on our DOA business test on our business, financial condition and results of operations. The extent to which the COVID-19 pandemic may impact our business, operating results, financial condition, or liquidity in the future will depend on future developments which are evolving and highly uncertain including the duration of the outbreak, travel restrictions, business and workforce disruptions, the timing of reopening the economic regions in which we and our customers do business and the effectiveness of actions taken to contain and treat the disease. In addition, resurgence in the number of cases of COVID-19 could further negatively impact our business.

And finally, while we expect the marketing of the Covid-19 test to positively impact our revenues in Fiscal 2021, we do not yet know the full extent of the positive impact of COVID-19 test sales on our business, our financial condition and results of operations. The extent to which sales of the COVID-19 test may impact our business, operating results, financial condition, or liquidity in the future will depend on future developments which are evolving and highly uncertain including the duration of the outbreak and the need for antibody testing in the future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We own our property in Kinderhook, New York. The property currently consists of a 30,000 square foot facility with approximately 22 surrounding acres. Our Kinderhook facility houses administration, customer service, inside sales, assembly and packaging, shipping and our warehouse. Our New York facility is encumbered by a lien by Cherokee (as it is collateral for the Loan and Security Agreement with Cherokee).

We lease 5,200 square feet of space in Logan Township, New Jersey that houses our bulk test strip manufacturing and research and development. On December 24, 2019, we amended the term of our lease by extending it through December 31, 2020. Both facilities are currently adequate and meet the needs of all areas of the Company.

ITEM 3. LEGAL PROCEEDINGS

ABMC v. Todd Bailey

On August 5, 2019, we settled litigation with Todd Bailey; a former Vice President, Sales & Marketing and sales consultant of the Company until December 23, 2016; hereinafter referred to as “Bailey”). The litigation was filed by the Company in the Northern District of New York in February 2017. Our complaint sought damages related to profits and revenues that resulted from actions taken by Bailey related to our customers. The settlement also addressed a counter-claim filed by Bailey in October 2017 (filed originally in Minnesota but, transferred to the Northern District of New York in January 2019). Bailey was seeking deferred commissions in the amount of \$164,000 that he alleged were owed to him by the Company. These amounts were originally deferred under a deferred compensation program initiated in 2013; a program in which Bailey was one of the participants. We believed the amount sought was not due to Bailey given the actions indicated in our litigation.

Under the settlement, both parties elected to resolve the litigation and settle any and all claims made within the litigation. Neither party admitted to any of the allegations contained within the ABMC v. Bailey litigation (including any allegations made by Bailey in his counterclaim). Both parties also agreed to dismiss all claims made against each other.

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common shares are currently trading on the OTC Markets Group under their OTC Pink® Open Market under the symbol "ABMC".

The following table sets forth the high and low closing bid prices of our securities as reported by the OTC Pink Open Market in Fiscal 2019 and Fiscal 2018. The prices quoted reflect inter-dealer prices, without retail mark-up, markdown, or commission and may not necessarily represent actual transactions.

Year ended December 31, 2019	High	Low
Quarter ended December 31, 2019	\$ 0.09	\$ 0.06
Quarter ended September 30, 2019	\$ 0.08	\$ 0.06
Quarter ended June 30, 2019	\$ 0.10	\$ 0.04
Quarter ended March 31, 2019	\$ 0.10	\$ 0.07

Year ended December 31, 2018	High	Low
Quarter ended December 31, 2018	\$ 0.12	\$ 0.07
Quarter ended September 30, 2018	\$ 0.12	\$ 0.06
Quarter ended June 30, 2018	\$ 0.12	\$ 0.09
Quarter ended March 31, 2018	\$ 0.20	\$ 0.10

Holders

Based upon the number of record holders and individual participants in security position listings, as of June 26, 2020 there were approximately 1,800 holders of our securities. As of June 26, 2020, there were 35,847,093 common shares outstanding.

Dividends

We have not declared any dividends on our common shares and do not expect to do so in the foreseeable future. Future earnings, if any, will be retained for use in our business.

Securities authorized for issuance under equity compensation plans previously approved by security holders

We currently have 2 Non-statutory Stock Option Plans (the 2001 Plan and the 2013 Plan, collectively the "Plans") that have been adopted by our Board of Directors and subsequently approved by our shareholders. The Plans provide for the granting of options to employees, directors, and consultants (see Part I, Item 1A, Risk Factor titled, "Potential issuance and exercise...").

Securities authorized for issuance under equity compensation plans not previously approved by security holders

None.

The following table summarizes information as of December 31, 2019, with respect to compensation plans (including individual compensation arrangements) under which our common stock is authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans approved by security holders	2,252,000	\$ 0.13	5,565,000
Equity Compensation Plans not approved by security holders*	2,000,000	\$ 0.18	NA

*All securities are related to individual compensation arrangements.

Performance Graph

As a smaller reporting company, we are not required to provide the information required under this item.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities, Purchases of equity securities by the issuer and affiliated purchasers

7,751 restricted common shares were issued on April 8, 2020 as compensation to three (3) board members; for a total of 23,253 common shares for their attendance at a telephonic meeting of the Board of Directors held on March 31, 2020. These stock issuances were in accordance with the director compensation structure approved by the Company's Board of Directors on March 22, 2018 (as indicated our Proxy Statement filed with the SEC on April 18, 2018).

ITEM 6. SELECTED FINANCIAL DATA

As a smaller reporting company, we are not required to provide the information required under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis provides information, which we believe is relevant to an assessment and understanding of our financial condition and results of operations. The discussion should be read in conjunction with the financial statements and the notes to the financial statement contained within this Annual Report on Form 10-K. Certain statements contained in this Annual Report on Form 10-K, including, without limitation, statements containing the words "believes", "anticipates", "estimates", "expects", "intends", "projects", and words of similar import, are forward-looking as that term is defined by the Private Securities Litigation Reform Act of 1995 ("1995 Act"), and in releases issued by the United States Securities and Exchange Commission ("SEC"). These statements are being made pursuant to the provisions of the 1995 Act and with the intention of obtaining the benefits of the "Safe Harbor" provisions of the 1995 Act. We caution that any forward-looking statements made within this Annual Report on Form 10-K are not guarantees of future performance and in fact, actual results may differ materially from those results discussed in such forward-looking statements. This material difference can be a result of various factors, including, but not limited to, any risks detailed herein, including the "Risk Factors" section contained in Part I, Item 1A of this Form 10-K, or detailed in our most recent reports on Form 10-Q and Form 8-K and from time to time in our other filings with the SEC and amendments thereto. Any forward-looking statement speaks only as of the date on which such statement is made, and we are not undertaking any obligation to publicly update any forward-looking statements. Readers should not place undue reliance on these forward-looking statements.

Overview and Plan of Operations

Sales in Fiscal 2019 continued to be negatively impacted by the price competitive nature of the markets in which we sell our drug testing products. Products manufactured outside the United States continue to dominate our core markets; especially in the Government market where a tremendous amount of value is put on the lowest price.

We have brought on new products and service offerings to diversify our revenue stream through third party relationships; one of which is a lower-cost alternative for onsite drug testing. And in late 2018, we began distributing point of care products for certain infectious diseases. With the exception of the lower-cost drug test alternative, these new offerings have yet to materially positively impact sales.

We have expanded our contract manufacturing operations with two (2) new customers. One of these customers started generating sales in the three months ended March 31, 2019 while the other customer started generating sales in the fourth quarter ended December 31, 2019.

Starting in May 2019, we can sell oral fluid drug tests in the employment and insurance markets under a limited exemption set forth by the FDA. Prior to this point, we could only sell our oral fluid drug tests in the forensic market in the United States and to markets outside the United States. We are hopeful that gaining access to this market again will enable us to see revenue growth for our oral fluid drug tests in the future, although revenue in Fiscal 2019 was negligible.

We are focusing our efforts on 1) further penetration of markets with new products, including, but not limited to, the infectious disease products we are now offering, 2) marketing oral fluid drug tests in the employment market in the United States and sales of oral fluid drug tests outside the United States, and 3) further expanding our contract manufacturing business.

Operating expenses continued to decline when comparing Fiscal 2019 with Fiscal 2018. This is a result of our continued efforts to ensure that expenses are in line with revenue. We consolidated job responsibilities in certain areas of the Company as a result of employee retirement and other departures and this has enabled us to implement personnel reductions. We also continued to maintain a salary deferral program for our sole executive officer throughout Fiscal 2019 and another member of senior management until his retirement in November 2019. The program consists of a 10% salary deferral for our Chief Executive Officer/Principal Financial Officer Melissa Waterhouse and the other member of senior management until his retirement. As of December 31, 2019, we had total deferred compensation owed to these two individuals in the amount of \$191,000. As cash flow from operations allows, we intend to repay portions of the deferred compensation. We did not make any payments on deferred compensation to Melissa Waterhouse in Fiscal 2019 or Fiscal 2018. After the member of senior management retired in November 2019, we agreed to make payments for the deferred comp owed to this individual. In Fiscal 2019, we made payments totaling \$4,000 to this individual and no payments in Fiscal 2018.

Our continued existence is dependent upon several factors, including our ability to: 1) raise revenue levels even though we have lost significant accounts and the market continues to be infiltrated by product manufactured outside of the United States, 2) control operational costs to generate positive cash flows, 3) maintain our current credit facilities or refinance our current credit facilities if necessary, and 4) if needed, our ability to obtain working capital by selling additional shares of our common stock.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or "U.S. GAAP". Part IV, Item 15, Note A to our financial statements describes the significant accounting policies and methods used in the preparation of our financial statements. The accounting policies that we believe are most critical to aid in fully understanding and evaluating the financial statements include the following:

Inventory and Allowance for Slow Moving and Obsolete Inventory: We maintain an allowance for slow moving and obsolete inventory. If necessary, actual write-downs to inventory are made for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the net realizable value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory allowances or write-downs may be required.

Valuation of Receivables: We estimate an allowance for doubtful accounts based on facts, circumstances and judgments regarding each receivable. Customer payment history and patterns, length of relationship with the customer, historical losses, economic and political conditions, trends and individual circumstances are among the items considered when evaluating the collectability of the receivables. Accounts are reviewed regularly for collectability and those deemed uncollectible are written off. If our customers' economic condition changes, we may need to increase our allowance for doubtful accounts.

Estimates of the fair value of stock options and warrants at date of grant: The fair value of stock options issued to employees, members of our Board of Directors, and consultants and of warrants issued in connection with debt financings is estimated (on the date of grant) based on the Black-Scholes options-pricing model utilizing certain assumptions for a risk free interest rate; volatility; and expected remaining lives of the awards. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. If factors change and we use different assumptions, our equity-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. In estimating our forfeiture rate, we analyzed our historical forfeiture rate, the remaining lives of unvested options, and the amount of vested options as a percentage of total options outstanding. If our actual forfeiture rate is materially different from its estimate, or if we reevaluate the forfeiture rate in the future, the equity-based compensation expense could be significantly different from what we have recorded in the current period.

Use of Estimates: We make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

RESULTS OF OPERATIONS FOR FISCAL 2019 COMPARED TO FISCAL 2018

Net Sales: Net sales decreased 5.6%, or \$217,000, in Fiscal 2019 when compared to Fiscal 2018. A certain amount of this decline was still related to the loss of a government account in 2018. Fiscal 2018 included \$83,000 in sales to this government account while Fiscal 2019 did not include any. Sales in our core markets in the United States declined; this includes sales in the clinical market (some of which is due to timing of the shipment of orders). Offsetting these declines were improvements in other government sales in the United States and a slight increase in international sales (specifically related to sales in Latin and South America) along with increased contract manufacturing sales (due to the two new customers).

Gross profit: Gross profit decreased to 32.4% of net sales in Fiscal 2019 from 33.3% of net sales in Fiscal 2018. In both Fiscal 2019 and Fiscal 2018, we experienced manufacturing inefficiencies. Manufacturing inefficiencies typically occur when revenues decline because certain overhead costs are fixed and cannot be reduced; if fewer testing strips are produced and fewer products are assembled this results in higher costs being expensed through cost of goods. Lower product pricing to customers can also negatively impact gross profit. When comparing Fiscal 2019 to Fiscal 2018, revenues declined further however, the product sales mix offset the inefficiencies resulting from the revenue decline. More specifically, in Fiscal 2019 we increased our contract manufacturing sales and these sales are at higher profit margins than our drug testing sales. We are continually taking actions to adjust our production schedules to try to mitigate future inefficiencies and we closely examine our gross profit margins on our manufactured products and the products we distribute.

Operating Expenses: Operating expenses for Fiscal 2019 decreased 13.3%, or \$273,000, when compared to operating expenses in Fiscal 2018. Expenses in all operations areas of the Company decreased. More specifically:

Research and development ("R&D")

R&D expenses for Fiscal 2019 decreased 11.8%, or \$11,000, when compared to R&D expenses incurred in Fiscal 2018. The primary reason for the decline is decreased FDA compliance costs (due to timing of payments made for our FDA facility registrations). This decrease was partially offset by increased repairs and maintenance costs in our NJ facility. All other expenses remained relatively consistent year over year. Throughout Fiscal 2019, our R&D department primarily focused their efforts on the enhancement of our current products and the evaluation of potential contract manufacturing opportunities as well as final product development with one of our new contract manufacturing customers.

Selling and marketing

Selling and marketing expenses for Fiscal 2019 decreased by 15.8%, or \$86,000, when compared to selling and marketing expense in Fiscal 2018. Decreased sales salaries, benefits and travel expense (due to a decreased number of employees), auto expense (due to decreased allowances), commissions (due to lower sales and restructured commission plan), and trade show costs were nominally offset by increased marketing supplies (primarily related to literature) and postage/shipping costs.

In the Fiscal 2019, we continued selling and marketing efforts of our own drug tests and we continued to take actions to secure new contract manufacturing customers. In addition, we promoted lower cost alternatives for onsite drug testing and point of care products for infectious disease (through relationships with third parties). The addition of these offerings did not result in increased selling and marketing expenses. We will continue to take all steps necessary to ensure selling and marketing expenditures are in line with sales.

General and administrative (“G&A”)

G&A expenses for Fiscal 2019 decreased 12.5%, or \$176,000, when compared to G&A expenses in Fiscal 2018. Decreased costs for quality assurance salaries (due reclassification and consolidation of functions), consultant fees, insurance, patents and licenses, office travel and outside service fees (due to 2018 being a recertification year for our ISO certification), were partially offset by increased investor relations expense (due to timing of filing and meeting costs), warehouse salaries (due to transfer of an employee), and legal fees (related to timing of actions in the ABMC v. Bailey litigation). Share based payment expense also decreased to \$5,000 in Fiscal 2019 from \$10,000 in Fiscal 2018. This decline is due to decreased stock option amortization in Fiscal 2019).

We settled the ABMC v. Bailey litigation in August 2019; therefore, we expect legal fees related to litigation to decline in the year ending December 31, 2020. We continuously examine all G&A expenses to look for lower cost alternatives to current services/products being used. This examination has resulted in decreased G&A expenses throughout most of the expense areas of the Company.

Other income and expense:

Other expense of \$93,000 in Fiscal 2019 consisted of interest expense associated with our credit facilities, offset by other income from proceeds for an insurance claim related to our New Jersey facility (a claim that resulted from actions of a service vendor) and a gain on an accrual for a contingent liability. Other expense of \$264,000 in Fiscal 2018 consisted of interest expense associated with our credit facilities, offset by other income related to gains on certain liabilities and a small amount of interest income.

LIQUIDITY AND CAPITAL RESOURCES AS OF DECEMBER 31, 2019

Our cash requirements depend on numerous factors, including but not limited to manufacturing costs (such as raw materials, equipment, etc.), selling and marketing initiatives, product development activities, regulatory costs, legal costs, and effective management of inventory levels and production levels in response to sales history and forecasts. We expect to devote capital resources related to selling and marketing initiatives. We are examining other growth opportunities including strategic alliances. Given our current and historical cash position, such activities would need to be funded from the issuance of additional equity or additional credit borrowings, subject to market and other conditions.

In order to increase cash flow available for running our business, on December 20, 2018 we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with Chaim Davis (the Chairman of our Board of Directors) and certain other accredited investors (altogether the “Investors”), under which we issued and sold to the Investors in a private placement (the “Private Placement”) 2,000,000 units (the “Units”). We closed on the Private Placement on December 24, 2018. Each Unit consisted of one (1) share of the Company’s common stock, par value \$0.01 per share (“Common Share”), at a price per Unit of \$0.10 (the “Purchase Price”) for net proceeds of \$200,000 as there were no expenses related to the Private Placement. We did not utilize a placement agent for the Private Placement. The net proceeds were used for working capital and general corporate purposes in the early part of Fiscal 2019. (See Note J – Subsequent Event for information related to an additional Private Placement completed in February 2020).

Our financial statements for Fiscal 2019 have been prepared assuming we will continue as a going concern, which assumes the realization of assets and the satisfaction of liabilities in the normal course of business. For Fiscal 2019, we had a net loss of \$681,000 and net cash provided by operating activities of \$58,000. While this is an improvement over a loss of \$1,028,000 and net cash used in operating activities of \$171,000 in Fiscal 2018; our cash position decreased by \$109,000 in Fiscal 2019 and increased by \$77,000 in Fiscal 2018. This increase in cash in Fiscal 2018 was in large part due to the private placement we closed in December 2018. We had a working capital deficit of \$463,000 at December 31, 2019 compared to a working capital deficit of \$212,000 at December 31, 2018. This increase in working capital deficit is primarily due to decreased sales.

Our current cash balances, together with cash generated from future operations and amounts available under our credit facilities may not be sufficient to fund operations through June 2021. At December 31, 2019, we have negative Stockholders' Equity of \$790,000.

Our loan and security agreement and 2019 Term Note with Cherokee for \$900,000 and \$200,000, respectively, expired on February 15, 2020. As of December 31, 2019, all amounts due to Cherokee are included in our short-term debt given the facilities expire in less than 12 months. (See Note J – Subsequent Event for information regarding the extension of our facility with Cherokee).

Through December 31, 2019, our line of credit with Crestmark had a maximum availability of \$1,500,000; however, the amount available under our line of credit was much lower as it is based upon the balance of our accounts receivable and a limited amount of inventory. Lower sales levels result in reduced availability on our line of credit, and starting in July 2018, the Inventory Sub-Cap Limit on the line of credit (which determines our availability from the inventory) is being reduced by \$10,000 per month until the Inventory Sub-Cap Limit is \$0 (making the line of credit an accounts-receivable based line only). This means that as of December 31, 2019, the Inventory Sub-Cap Limit is only \$70,000 and that our availability related to inventory is significantly reduced. As of December 31, 2019, based on our availability calculation, there were no additional amounts available under our line of credit because we draw any balance available on a daily basis. If sales levels continue to decline, we will have reduced availability on our line of credit due to decreased accounts receivable balances. Our line of credit with Crestmark expired on June 22, 2020. (See Note J – Subsequent Event for information regarding the Crestmark LOC extension.

If availability under our line of credit is not sufficient to satisfy our working capital and capital expenditure requirements, we will be required to obtain additional credit facilities or sell additional equity securities, or delay capital expenditures which could have a material adverse effect on our business. There is no assurance that such financing will be available or that we will be able to complete financing on satisfactory terms, if at all.

In March 2020, the World Health Organization declared COVID-19 to be a pandemic. COVID-19 has spread throughout the globe, including in the State of New York where our headquarters are located, and in the State of New Jersey where our strip manufacturing facility is located. In response to the outbreak, the Company has followed the guidelines of the U.S. Centers for Disease Control and Prevention ("CDC") and applicable state government authorities to protect the health and safety of the Company's employees, families, suppliers, customers and communities. While these existing measures and, COVID-19 generally, have not materially disrupted our business to date, any future actions necessitated by the COVID-19 pandemic may result in disruption to our business.

While the COVID-19 pandemic continues to rapidly evolve, we continue to assess the impact of the COVID-19 pandemic to best mitigate risk and continue the operations of our business. The extent to which the outbreak impacts our business, liquidity, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including new information that may emerge concerning the severity of the COVID-19 pandemic and the actions to contain it or treat its impact, among others. If we, our customers or suppliers experience prolonged shutdowns or other business disruptions, our business, liquidity, results of operations and financial condition are likely to be materially adversely affected, and our ability to access the capital markets may be limited.

As of December 31, 2019, we had the following debt/credit facilities:

Facility	Debtor	Balance as of December 31, 2019	Due Date
Loan and Security Agreement	Cherokee Financial, LLC	\$ 900,000	February 15, 2020
Revolving Line of Credit	Crestmark Bank	\$ 337,000	June 22, 2020
Equipment Loan	Crestmark Bank	\$ 7,000	June 22, 2020
Term Loan	Cherokee Financial, LLC	\$ 200,000	February 15, 2019
Term Loan	Individuals	\$ 10,000	Not applicable
Term Loan	Individual	\$ 25,000	March 31, 2020
Total Debt		\$ 1,479,000	

Working Capital Deficit

At the end of Fiscal 2019, we were operating at a working capital deficit of \$463,000. This compares to a working capital deficit of \$212,000 at the end of Fiscal 2018. This increase in our working capital deficit was primarily a result of decreased sales. We have historically satisfied working capital requirements through cash from operations and bank debt.

Dividends

We have never paid any dividends on our common shares and we anticipate that all future earnings, if any, will be retained for use in our business.

Cash Flow, Outlook/Risk

We will continue to take steps to ensure that operating expenses and manufacturing costs remain in line with sales levels, however, we have been incurring increased costs related to litigation (although our ongoing litigation was settled on August 5, 2019 so we expect our legal costs to decline significantly going forward). We have consolidated job responsibilities in certain areas of the Company and this enabled us to implement personnel reductions.

Sales declines result in lower cash balances and lower availability on our line of credit at times. Fiscal 2019 and Fiscal 2018 revenues are negatively impacted by the loss of two large government accounts (which together totaled \$1,000,000 in annual revenue). We have not yet replaced these lost accounts with new revenue. We are promoting new products and service offerings to diversify our revenue stream. These new products and services (through relationships with third parties) include lower-cost alternatives for onsite drug testing and point of care products for infectious disease. We also secured the business of two (2) new contract manufacturing customers, both of which generated sales in Fiscal 2019.

In other efforts to reduce cash requirements, we have issued shares of restricted stock in lieu of cash. More specifically, we issued (1) 150,000 restricted shares of common stock to Cherokee in connection with a February 2018 debt financing, (2) 277,778 restricted shares of common stock to Landmark Pegasus, Inc. in connection with an extension of our Financial Advisory Agreement in June 2018, (3) 68,820 restricted shares of common stock to our Chairman of the Board for his attendance at two meetings of our Board of Directors in Fiscal 2018, (4) 200,000 restricted shares of common stock to Cherokee Financial, LLC in connection with our 2019 Term Loan and (5) 201,616 restricted shares of common stock issued to board members in connection with their attendance at three meetings of our Board of Directors in Fiscal 2019.

In addition, in December 2018, we closed on a private placement of 2,000,000 shares of our common stock resulting in net proceeds of \$200,000. We expect to issue additional restricted shares of common stock for attendance at meetings of the Board of Directors if a director (or directors) choose(s) payment in shares in lieu of cash as their form of payment. (See Note J - Subsequent Event for information related to the private placement completed in February 2020).

Our ability to be in compliance with our obligations under our current credit facilities will depend on our ability to replace lost sales and further increase sales. Our ability to repay our current debt may also be affected by general economic, financial, competitive, regulatory, legal, business and other factors beyond our control, including those discussed herein. If we are unable to meet our credit facility obligations, we would be required to raise money through new equity and/or debt financing(s) and, there is no assurance that we would be able to find new financing, or that any new financing would be at favorable terms.

On June 22, 2020, we extended the Crestmark LOC until June 22, 2021. All terms and conditions of the Crestmark LOC remain unchanged under the extension period with the exception of the following, 1) the maximum availability under the Crestmark LOC was reduced from \$1,500,000 to \$1,000,000, 2) availability under the Crestmark LOC is based on receivables only (under the same terms), 3) the requirement for field audits of the Company was removed, and 4) the Tangible Net Worth (TNW) covenant was removed.

Prior to the extension of the Crestmark LOC, we were not in compliance with the TNW covenant under our Crestmark LOC as of December 31, 2019. As of the date of this report, the Company is in the process of obtaining another waiver from Crestmark related to the TNW non-compliance for the three months ended December 31, 2019. Due to internal requirements within Crestmark, the waiver could not be obtained prior to the date of this report. The Company expects to be charged a fee of \$5,000 for this waiver when it is received. A failure to comply with the TNW covenant under our Crestmark LOC for the quarter ended December 31, 2019 or the quarter ended March 31, 2020; if we are not compliant at March 31, 2020, (a failure that is not waived by Crestmark) could result in an event of default, which, if not cured, could result in the Company being required to pay much higher costs associated with the indebtedness.

If we are forced to refinance our debt on less favorable terms, our results of operations and financial condition could be adversely affected by increased costs and rates. There is also no assurance that we could obtain alternative debt facilities. We may also be forced to pursue one or more alternative strategies, such as restructuring, selling assets, reducing or delaying capital expenditures or seeking additional equity capital. There can be no assurances that any of these strategies could be implemented on satisfactory terms, if at all.

Our credit facilities with Cherokee total \$1,100,000 at December 31, 2019 and expired in February 2020. (See Note J–Subsequent Event for information regarding the extension of our facilities with Cherokee).

If events and circumstances occur such that 1) we do not meet our current operating plans to increase sales, 2) we are unable to raise sufficient additional equity or debt financing, 3), we are unable to utilize equity as a form of payment in lieu of cash, or 4) our credit facilities are insufficient or not available, we may be required to further reduce expenses or take other steps which could have a material adverse effect on our future performance.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our Financial Statements are set forth beginning on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management has reviewed the effectiveness of our “disclosure controls and procedures” (as defined in the Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report and have concluded that the disclosure controls and procedures are effective to ensure that material information relating to the Company is recorded, processed, summarized, and reported in a timely manner.

Management’s Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorization of Management; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or the degree of compliance may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organization of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on that assessment, Management has concluded that our internal control over financial reporting was effective as of December 31, 2018.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the last quarterly period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Independent Registered Public Accounting Firm

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that exempt smaller reporting companies from this requirement.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item is contained in our definitive Proxy Statement with respect to our Annual Meeting of Shareholders for Fiscal 2019, under the captions “Discussion of Proposal Recommended by Board”, “Directors that are not Nominees”, “Additional Executive Officers and Senior Management”, “Section 16(a) Beneficial Ownership Reporting Compliance”, “Code of Ethics”, “Nominating Committee”, “Audit Committee” and “Audit Committee Financial Expert” and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is contained in our definitive Proxy Statement with respect to our Annual Meeting of Shareholders for Fiscal 2019, under the captions “Executive Compensation”, “Compensation of Directors”, “Compensation Committee Interlocks and Insider Participation”, and “Compensation Committee Report”, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is contained within Part II, Item 5. Market for Registrant’s Common Equity, Related Stockholders Matters and Issuer Purchases of Equity Securities earlier in this Annual Report on Form 10-K and in our definitive Proxy Statement with respect to the Annual Meeting of Shareholders for Fiscal 2019, under the caption “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is contained in our definitive Proxy Statement with respect to the Annual Meeting of Shareholders for Fiscal 2019, under the captions “Certain Relationships and Related Transactions” and “Independent Directors”, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is contained in our definitive Proxy Statement with respect to the Annual Meeting of Shareholders for Fiscal 2019, under the caption “Independent Public Accountants”, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Our financial statements

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Statements of Operations	F-4
Statements of Changes in Stockholders' Deficit	F-5
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(2) Financial Statement Schedule

As a smaller reporting company, we are only required to provide financial statements required by Article 8 of Regulation S-X in lieu of financial statements that may be required under Part II, Item 8 of this Annual Report on Form 10-K, and these financial statements are noted under Item 15(a)(1).

(3) See Item 15(b) of this Annual Report on Form 10-K.

ITEM 16. FORM 10-K SUMMARY

We are not required to provide this information.

(b) Exhibits

Number	Description of Exhibits
3.5	Amended and Restated Bylaws ⁽¹⁾
3.51	Amended and Restated Bylaws ⁽²⁾
3.7	Sixth amendment to the Certificate of Incorporation ⁽¹⁾
4.17	Fiscal 2001 Nonstatutory Stock Option Plan (filed as part of the Company's Proxy Statement for its Fiscal 2002 Annual Meeting and incorporated herein by reference) ^(a)
4.25	2013 Equity Compensation Plan (filed as Appendix A to the Company's Proxy Statement for its fiscal year ended December 31, 2012 and incorporated herein by reference) ^(a)
4.26	Securities Purchase Agreement ⁽⁶⁾
10.8	Lease dated August 1, 1999/New Jersey facility ⁽³⁾
10.40	Employment Contract between the Company and Melissa A. Waterhouse ⁽⁴⁾
10.43	Amendment No. 11 to New Jersey facility lease, dated November 20, 2017 ⁽⁵⁾
10.44	Amendment No. 12 to New Jersey facility lease, dated December 24, 2019 ⁽⁷⁾
31.1 & 31.2	Rule 13a-14(a)/15d-14(a) Certification of the Chief Executive Officer/Chief Financial Officer
32.1 & 32.2	Section 1350 Certification of the Chief Executive Officer/Chief Financial Officer
101	The following materials from our Annual Report on Form 10-K for the year ended December 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheet, (ii) Statements of Income (iii) Statements of Cash Flows, (iv) Statements of Changes in Stockholders' Equity and (v) Notes to Financial Statements.

- (a) Indicates an employee benefits plan, management contract or compensatory plan or arrangement in which a named executive officer participates.
- (1) Filed as the exhibit number listed to the Company's Form 10-KSB filed on April 15, 2002 and incorporated herein by reference.
- (2) Filed as the exhibit number listed to the Company's Current Report on Form 8-K filed on October 18, 2007 and incorporated herein by reference.
- (3) Filed as the exhibit number listed to the Company's Form 10-KSB filed on August 11, 2000 and incorporated herein by reference.
- (4) Filed as the exhibit number listed to the Company's Current Report on Form 8-K filed with the Commission on June 24, 2014.
- (5) Filed as the exhibit number listed to the Company's Form 10-K filed on April 12, 2018 and incorporated herein by reference.
- (6) Filed as the exhibit number listed to the Company's Current Report on Form 8-K filed on December 26, 2018 and incorporated herein by reference.
- (7) Filed as the exhibit number listed to this Annual Report on Form 10-K.
- (c) Not applicable.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AMERICAN BIO MEDICA CORPORATION

By: /s/ Melissa A. Waterhouse

Melissa A. Waterhouse
Chief Executive Officer (Principal Executive Officer)
Principal Financial Officer
Principal Accounting Officer

Date: June 26, 2020

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on June 26, 2020:

<u>/s/ Melissa A. Waterhouse</u>	Chief Executive Officer (Principal Executive Officer)
Melissa A. Waterhouse	Principal Financial Officer
	Principal Accounting Officer

<u>/s/ Chaim Davis</u>	Chairman of the Board
Chaim Davis	

<u>/s/ Peter Jerome</u>	Director
Peter Jerome	

<u>/s/ Jean Neff</u>	Director and Corporate Secretary
Jean Neff	

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of American Bio Medica Corporation

Opinion on the Financial Statements

We have audited the accompanying balance sheets of American Bio Medica Corporation (the Company) as of December 31, 2019 and 2018, and the related statements of operations, changes in stockholders' (deficit)/equity, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that American Bio Medica Corporation will continue as a going concern. As discussed in Note A to the financial statements, the Company has incurred recurring operating losses and its current cash position and lack of access to capital raise substantial doubt about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding those matters also are described in Note A. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to that matter.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ UHY LLP

We have served as the Company's auditor since 2015.

Albany, New York

June 26, 2020

AMERICAN BIO MEDICA CORPORATION
Balance Sheets

	December 31, 2019	December 31, 2018
<u>ASSETS</u>		
Current assets		
Cash and cash equivalents	\$ 4,000	\$ 113,000
Accounts receivable, net of allowance for doubtful accounts of \$34,000 at December 31, 2019 and \$36,000 at December 31, 2018	370,000	452,000
Inventory, net of allowance of \$291,000 at December 31, 2019 and \$268,000 at December 31, 2018	810,000	1,019,000
Prepaid expenses and other current assets	6,000	29,000
Right of use asset – operating leases	34,000	0
Total current assets	1,227,000	1,613,000
Property, plant and equipment, net	644,000	718,000
Patents, net	116,000	123,000
Right of use asset – operating leases	73,000	0
Other assets	21,000	21,000
Total assets	<u>\$ 2,078,000</u>	<u>\$ 2,475,000</u>
<u>LIABILITIES AND STOCKHOLDERS' DEFICIT</u>		
Current liabilities		
Accounts payable	\$ 652,000	\$ 359,000
Accrued expenses and other current liabilities	543,000	449,000
Right of use liability – operating leases	34,000	0
Wages payable	104,000	278,000
Line of credit	337,000	502,000
Current portion of long-term debt, net of deferred finance costs	17,000	237,000
Total current liabilities	1,687,000	1,825,000
Long-term debt/other liabilities, net of current portion and deferred financing costs	1,108,000	796,000
Right of use liability – operating leases	73,000	0
Total liabilities	2,868,000	2,621,000
COMMITMENTS AND CONTINGENCIES		
Stockholders' deficit:		
Preferred stock; par value \$.01 per share; 5,000,000 shares authorized, none issued and outstanding	0	0
Common stock; par value \$.01 per share; 50,000,000 shares authorized; 32,680,984 issued and outstanding as of December 31, 2019 and 32,279,368 issued and outstanding as of December 31, 2018	327,000	323,000
Additional paid-in capital	21,437,000	21,404,000
Accumulated deficit	(22,554,000)	(21,873,000)
Total stockholders' (deficit)	(790,000)	(146,000)
Total liabilities and stockholders' (deficit)	<u>\$ 2,078,000</u>	<u>\$ 2,475,000</u>

The accompanying notes are an integral part of the financial statements.

Statements of Operations

	Year Ended December 31,	
	2019	2018
Net sales	\$ 3,655,000	\$ 3,872,000
Cost of goods sold	<u>2,471,000</u>	<u>2,584,000</u>
Gross profit	<u>1,184,000</u>	<u>1,288,000</u>
Operating expenses:		
Research and development	82,000	93,000
Selling and marketing	459,000	545,000
General and administrative	<u>1,236,000</u>	<u>1,412,000</u>
	<u>1,777,000</u>	<u>2,050,000</u>
Operating loss	<u>(593,000)</u>	<u>(762,000)</u>
Other income / (expense):		
Interest income	0	1,000
Interest expense	(265,000)	(284,000)
Other income, net	<u>172,000</u>	<u>19,000</u>
	<u>(93,000)</u>	<u>(264,000)</u>
Net loss before tax	<u>(686,000)</u>	<u>(1,026,000)</u>
Income tax benefit / (expense)	<u>5,000</u>	<u>(2,000)</u>
Net loss	<u>\$ (681,000)</u>	<u>\$ (1,028,000)</u>
Basic and diluted loss per common share	<u>\$ (0.02)</u>	<u>\$ (0.03)</u>
Weighted average number of shares outstanding – basic and diluted	<u>32,526,669</u>	<u>30,115,063</u>

The accompanying notes are an integral part of the financial statements.

Statements of Changes in Stockholders' Deficit

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-in	Deficit	Total
			Capital		
Balance – January 1, 2018	<u>29,782,770</u>	<u>\$ 298,000</u>	<u>\$21,170,000</u>	<u>\$20,845,000</u>	<u>\$ 623,000</u>
Shares issued in connection with Landmark consulting agreement extensions	277,778	3,000	22,000		25,000
Shares issued to Cherokee in connection with loan	150,000	1,000	16,000		17,000
Shares issued for board meeting attendance in lieu of cash	68,820	1,000	6,000		7,000
Shares issued under December 2018 Private Placement	2,000,000	20,000	180,000		200,000
Share based payment expense			10,000		10,000
Net loss				(1,028,000)	(1,028,000)
Balance – December 31, 2018	<u>32,279,368</u>	<u>\$ 323,000</u>	<u>\$21,404,000</u>	<u>\$21,873,000</u>	<u>\$ (146,000)</u>
Shares issued to Cherokee in connection with loan	200,000	2,000	12,000		14,000
Shares issued for board meeting attendance in lieu of cash	201,616	2,000	15,000		17,000
Share based payment expense			6,000		6,000
Net loss				(681,000)	(681,000)
Balance – December 31, 2019	<u>32,680,984</u>	<u>\$ 327,000</u>	<u>\$21,437,000</u>	<u>\$22,554,000</u>	<u>\$ (790,000)</u>

The accompanying notes are an integral part of the financial statements.

Statements of Cash Flows

	Year Ended December 31, 2019	Year Ended December 31, 2018
Cash flows from operating activities:		
Net loss	\$ (681,000)	\$ (1,028,000)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	81,000	81,000
Amortization of debt issuance costs	108,000	126,000
Provision for bad debts	(2,000)	(16,000)
Provision for slow moving and obsolete inventory	96,000	134,000
Share-based payment expense	6,000	10,000
Director fee paid with restricted stock	17,000	6,000
Changes in:		
Accounts receivable	84,000	(88,000)
Inventory	113,000	320,000
Prepaid expenses and other current assets	23,000	93,000
Accounts payable	293,000	(15,000)
Accrued expenses and other current liabilities	94,000	138,000
Wages payable	(174,000)	19,000
Net cash provided by / (used in) operating activities	58,000	(220,000)
Cash flows from investing activities:		
Patent application costs	0	(22,000)
Net cash used in investing activities	0	(22,000)
Cash flows from financing activities:		
Proceeds from debt financing	86,000	63,000
Payments on debt financing	(88,000)	
Proceeds from private placement	0	200,000
Proceeds from lines of credit	3,835,000	4,216,000
Payments on lines of credit	(4,000,000)	(4,160,000)
Net cash (used in) / provided by financing activities	(167,000)	319,000
Net (decrease in) / increase in cash and cash equivalents	(109,000)	77,000
Cash and cash equivalents – beginning of period	113,000	36,000
Cash and cash equivalents – end of period	\$ 4,000	\$ 113,000
Supplemental disclosures of cash flow information:		
Non-Cash transactions:		
Consulting expense paid with restricted stock	\$ 0	\$ 25,000
Debt issuance cost paid with restricted stock	\$ 14,000	\$ 19,000
Director fee paid with restricted stock	\$ 17,000	\$ 6,000
Patent application costs	0	\$ 22,000
Cash paid during the year for interest	\$ 155,000	\$ 157,000
Cash paid for taxes	0	\$ 2,000

The accompanying notes are an integral part of the financial statements.

Note A - The Company and its Significant Accounting PoliciesThe Company:

American Bio Medica Corporation (the “Company”) 1) manufactures and sells lateral flow immunoassay tests, primarily for the immediate detection of drugs in urine and oral fluid, 2) provides strip manufacturing and assembly and packaging services for unaffiliated third parties and 3) sells (via distribution) a number of other products related to the immediate detection of drugs in urine and oral fluid as well as point of care diagnostic products via distribution.

Going Concern:

The Company’s financial statements have been prepared assuming the Company will continue as a going concern, which assumes the realization of assets and the satisfaction of liabilities in the normal course of business. For the year ended December 31, 2019 (“Fiscal 2019”), the Company had a net loss of \$681,000 and net cash provided by operating activities of \$58,000, compared to a net loss of \$1,028,000 and net cash used in operating activities of \$220,000 in the year ended December 31, 2018 (“Fiscal 2018”). The Company’s cash position decreased by \$109,000 in Fiscal 2019 and increased by \$77,000 in Fiscal 2019. The Company had a working capital deficit of \$463,000 at December 31, 2019 compared to a working capital deficit of \$212,000 at December 31, 2018. This increase in working capital deficit is primarily due to decreased sales.

As of December 31, 2019, the Company had an accumulated deficit of \$22,554,000. Over the course of the last several fiscal years, the Company has implemented a number of expense and personnel cuts, implemented a salary and commission deferral program (which currently only consists of salary deferral), consolidated certain manufacturing operations of the Company, and refinanced debt.

The salary deferral program consists of a 10% salary deferral for the Company’s Chief Executive Officer/Principal Financial Officer Melissa Waterhouse. The salary of another member of senior management was also deferred 10% until his retirement in November 2019. As of December 31, 2019, the Company had total deferred compensation owed to these two individuals in the amount of \$191,000. As cash flow from operations allows, the Company intends to repay portions of the deferred compensation. The Company did not make any payments on deferred compensation to Melissa Waterhouse in Fiscal 2019 or Fiscal 2018. After the member of senior management retired in November 2019, the Company agreed to make payments for the deferred comp owed to this individual. In Fiscal 2019, the Company made payments totaling \$4,000 to this individual and no payments in Fiscal 2018. The Company expects the salary deferral program will continue for an undetermined period of time.

The Company’s current cash balances, together with cash generated from future operations and amounts available under its credit facilities may not be sufficient to fund operations through June 2021. At December 31, 2019, the Company had negative Stockholders’ Equity of \$790,000.

The Company’s loan and security agreement and 2019 Term Note with Cherokee for \$900,000 and \$200,000, respectively, expired on February 15, 2020. As of December 31, 2019, all amounts due to Cherokee are included in our short-term debt given the facilities expire in less than 12 months. The Company did extend the facilities with Cherokee as indicated in Note J – Subsequent Events.

The Crestmark line of credit has a maximum availability of \$1,500,000; however, the amount available under the line of credit is much lower as it is based upon the balance of the Company’s accounts receivable and a limited amount of inventory. Lower sales levels result in reduced availability on the line of credit, and starting in July 2018, the Inventory Sub-Cap Limit on the line of credit (which determines our availability from the inventory) is being reduced by \$10,000 per month until the Inventory Sub-Cap Limit is \$0 (making the line of credit an accounts-receivable based line only). This means that as of December 31, 2019, the Inventory Sub-Cap Limit is only \$70,000 and that the Company’s availability related to inventory is significantly reduced. As of December 31, 2019, based on an availability calculation, there were no additional amounts available under the Crestmark line of credit because the Company draws any balance available on a daily basis. If sales levels continue to decline, the Company will have reduced availability on the line of credit due to decreased accounts receivable balances. The line of credit with Crestmark expires on June 22, 2020. Based on discussions with Crestmark, the Company expects to extend the current facility or enter into a new facility with Crestmark prior to the expiration date of June 22, 2020.

AMERICAN BIO MEDICA CORPORATION

Notes to financials

If availability under the Crestmark line of credit is not sufficient to satisfy the Company's working capital and capital expenditure requirements, the Company will be required to obtain additional credit facilities or sell additional equity securities, or delay capital expenditures which could have a material adverse effect on the Company's business. There is no assurance that such financing will be available or that the Company will be able to complete financing on satisfactory terms, if at all.

The Company's ability to be in compliance with the obligations under its current credit facilities will depend on the Company's ability to replace lost sales and further increase sales. The Company's ability to repay its current debt may also be affected by general economic, financial, competitive, regulatory, legal, business and other factors beyond the Company's control, including those discussed herein. If the Company is unable to meet its credit facility obligations, the Company would be required to raise money through new equity and/or debt financing(s) and, there is no assurance that the Company would be able to find new financing, or that any new financing would be at favorable terms.

On June 22, 2020, the Company extended the Crestmark line of credit until June 22, 2021. All terms and conditions of the Crestmark line of credit remain unchanged under the extension period with the exception of the following, 1) the maximum availability under the Crestmark line of credit was reduced from \$1,500,000 to \$1,000,000, 2) availability under the Crestmark line of credit is based on receivables only (under the same terms), 3) the requirement for field audits of the Company was removed, and 4) the Tangible Net Worth (TNW) covenant was removed.

Prior to the extension, the Company was not in compliance with the TNW covenant under the Crestmark line of credit as of December 31, 2019. As of the date of this report, the Company is in the process of obtaining another waiver from Crestmark related to the TNW non-compliance for the three months ended December 31, 2019. Due to internal requirements within Crestmark, the waiver could not be obtained prior to the date of this report. The Company expects to be charged a fee of \$5,000 for this waiver when it is received. A failure to comply with the TNW covenant under the Crestmark line of credit for the quarter ended December 31, 2019 or the quarter ended March 31, 2020; if the Company is not compliant at March 31, 2020, (a failure that is not waived by Crestmark) could result in an event of default, which, if not cured, could result in the Company being required to pay much higher costs associated with the indebtedness.

The Company's history of limited cash flow and/or operating cash flow deficits, its current cash position and lack of access to capital raise doubt about its ability to continue as a going concern and its continued existence is dependent upon several factors, including its ability to raise revenue levels and control costs to generate positive cash flows, to sell additional shares of the Company's common stock to fund operations and obtain additional credit facilities. Selling additional shares of the Company's common stock and obtaining additional credit facilities may be more difficult as a result of limited access to equity markets and the tightening of credit markets.

If events and circumstances occur such that 1) the Company cannot raise revenue levels, 2) the Company is unable to control operational costs to generate positive cash flows, 3) the Company cannot maintain its current credit facilities or refinance its current credit facilities, 4) the Company is unable to utilize its common stock as a form of payment in lieu of cash and 4) the Company is unable to obtain working capital by selling additional shares of common stock, , the Company may be required to further reduce expenses or take other steps which could have a material adverse effect on the Company's future performance. The Company's financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amount of or classification of liabilities that might be necessary as a result of this uncertainty.

In March 2020, the World Health Organization declared COVID-19 to be a pandemic. COVID-19 has spread throughout the globe, including in the State of New York where the Company's headquarters are located, and in the State of New Jersey where the Company's strip manufacturing facility is located. In response to the outbreak, the Company has followed the guidelines of the U.S. Centers for Disease Control and Prevention ("CDC") and applicable state government authorities to protect the health and safety of the Company's employees, families, suppliers, customers and communities. While these existing measures and, COVID-19 generally, have not materially disrupted the Company's business to date, any future actions necessitated by the COVID-19 pandemic may result in disruption to the Company's business.

While the COVID-19 pandemic continues to rapidly evolve, the Company continues to assess the impact of the COVID-19 pandemic to best mitigate risk and continue the operations of the Company's business. The extent to which the outbreak impacts the Company's business, liquidity, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including new information that may emerge concerning the severity of the COVID-19 pandemic and the actions to contain it or treat its impact, among others. If the Company, its customers or suppliers experience prolonged shutdowns or other business disruptions, the Company's business, liquidity, results of operations and financial condition are likely to be materially adversely affected, and the Company's ability to access the capital markets may be limited.

Significant Accounting Policies:

- [1] **Cash equivalents:** The Company considers all highly liquid financial instruments purchased with a maturity of three months or less to be cash equivalents.

[2] Accounts Receivable: Accounts receivable consists of mainly trade receivables due from customers for the sale of our products. Payment terms vary on a customer-by-customer basis, and currently range from cash on delivery to net 60 days. Receivables are considered past due when they have exceeded their payment terms. Accounts receivable have been reduced by an estimated allowance for doubtful accounts. The Company estimates its allowance for doubtful accounts based on facts, circumstances and judgments regarding each receivable. Customer payment history and patterns, length of relationship with the customer, historical losses, economic and political conditions, trends and individual circumstances are among the items considered when evaluating the collectability of the receivables. Accounts are reviewed regularly for collectability and those deemed uncollectible are written off. At December 31, 2019 and December 31, 2018, the Company had an allowance for doubtful accounts of \$34,000 and \$36,000, respectively.

[3] **Inventory:** Inventory is stated at the lower of cost or net realizable value. Work in process and finished goods are comprised of labor, overhead and raw material costs. Labor and overhead costs are determined on a rolling average cost basis and raw materials are determined on an average cost basis. At December 31, 2019 and December 31, 2018, the Company established an allowance for slow moving and obsolete inventory of \$291,000 and \$268,000, respectively.

[4] **Income taxes:** The Company follows ASC 740 "Income Taxes" ("ASC 740") which prescribes the asset and liability method whereby deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted laws and tax rates that will be in effect when the differences are expected to reverse. The measurement of deferred tax assets is reduced, if necessary, by a valuation allowance for any tax benefits that are not expected to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. Under ASC 740, tax benefits are recorded only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon ultimate settlement. Unrecognized tax benefits are tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards.

On December 22, 2017, the Tax Reform Act was signed into law. Among the provisions, the Tax Reform ACT reduces the U.S. federal corporate income tax rate from a maximum of 35% to a flat 21% effective January 1, 2018, requires companies to pay a one-time transition tax on deemed repatriated earnings of certain foreign subsidiaries that were previously tax deferred, and creates new taxes on certain foreign sourced earnings. At December 31, 2019, the Company has completed its accounting for the tax effects of the enactment of the Tax Reform Act. The Company has finalized the tax effects on its existing deferred tax balances and the one-time transition tax under Staff Accounting Bulletin No. 118 ("SAB 118"). The Company has also included current year impacts of the Tax Reform Act in our tax provision. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse.

[5] **Depreciation and amortization:** Property, plant and equipment are depreciated on the straight-line method over their estimated useful lives; generally 3-5 years for equipment and 30 years for buildings. Leasehold improvements and capitalized lease assets are amortized by the straight-line method over the shorter of their estimated useful lives or the term of the lease. Intangible assets include the cost of patent applications, which are deferred and charged to operations over 19 years. The accumulated amortization of patents is \$190,000 at December 31, 2019 and \$182,000 at December 31, 2018. Annual amortization expense of such intangible assets is expected to be \$7,000 per year for the next 5 years.

[6] **Revenue recognition:** The Company adopted ASU 2014-09, "Revenue from Contracts with Customers" in the first quarter of Fiscal 2018. The Company's revenues result from the sale of goods and reflect the consideration to which the Company expects to be entitled. The Company records revenues based on a five-step model in accordance with ASU 2014-09. The Company has defined purchase orders as contracts in accordance with ASU 2014-09. For its customer contracts, the Company's performance obligations are identified; which is delivering goods at a determined transaction price, allocation of the contract transaction price with performance obligations (when applicable), and recognition of revenue when (or as) the performance obligation is transferred to the customer. Goods are transferred when the customer obtains control of the goods (which is upon shipment to the customer). The Company's revenues are recorded at a point in time from the sale of tangible products. Revenues are recognized when products are shipped.

In Fiscal 2018, the Company elected the Modified Retrospective Method (the "Cumulate Effect Method") to comply with ASU 2014-09. The Cumulative Effect Method does not affect the amounts for the prior periods, but requires that the current period be reported in accordance with ASU 2014-09. ASU 2014-09 was adopted on January 1, 2018 which was the first day of the Company's 2018 fiscal year. There was no material impact on the Company's financial position or results of operations.

Product returns, discounts and allowances are variable consideration and are recorded as a reduction of revenue in the same period that the related sale is recorded. The Company has reviewed the overall sales transactions for variable consideration and has determined that these costs are not significant. The Company has not experienced any impairment losses, has no future performance obligations and does not capitalize costs to obtain or fulfill contracts.

- [7] **Shipping and handling:** Shipping and handling fees charged to customers are included in net sales, and shipping and handling costs incurred by the Company, to the extent of those costs charged to customers, are included in cost of sales.
- [8] **Research and development:** Research and development (“R&D”) costs are charged to operations when incurred. These costs include salaries, benefits, travel, costs associated with regulatory applications, supplies, depreciation of R&D equipment and other miscellaneous expenses.
- [9] **Net loss per common share:** Basic loss per common share is calculated by dividing net loss by the weighted average number of outstanding common shares during the period.

Potential common shares outstanding as of December 31, 2019 and 2018:

	December 31, 2019	December 31, 2018
Warrants	2,000,000	2,000,000
Options	2,252,000	2,222,000
Total	<u>4,252,000</u>	<u>4,222,000</u>

For Fiscal 2019 and Fiscal 2018, the number of securities not included in the diluted loss per share was 4,252,000 and 4,222,000, respectively, as their effect was anti-dilutive due to a net loss in each year.

- [10] **Use of estimates:** The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Our management believes the major estimates and assumptions impacting our financial statements are the following:
- estimates of the fair value of stock options and warrants at date of grant; and
 - estimates of accounts receivable reserves; and
 - estimates of the inventory reserves; and
 - estimates of accruals and liabilities; and
 - deferred tax valuation.

The fair value of stock options issued to employees, members of our Board of Directors, and consultants and of warrants issued in connection with debt financings is estimated on the date of grant based on the Black-Scholes options-pricing model utilizing certain assumptions for a risk free interest rate; volatility; and expected remaining lives of the awards. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment.

As a result, if factors change and the Company uses different assumptions, the Company's equity-based compensation expense could be materially different in the future. In addition, the Company is required to estimate the expected forfeiture rate and only recognize expense for those shares expected to vest. In estimating the Company's forfeiture rate, the Company analyzed its historical forfeiture rate, the remaining lives of unvested options, and the amount of vested options as a percentage of total options outstanding.

If the Company's actual forfeiture rate is materially different from its estimate, or if the Company reevaluates the forfeiture rate in the future, the equity-based compensation expense could be significantly different from what we have recorded in the current period.

Actual results may differ from estimates and assumptions of future events.

[11] Impairment of long-lived assets: The Company records impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amounts of those assets. The Company has performed an analysis of the undiscounted cash flows expected to be generated from the Company's fixed assets and intangibles. Based on the Company's analysis, the Company believes the carrying value of these assets are recoverable and an impairment does not exist.

[12] Financial Instruments: The carrying amounts of cash, accounts receivable, accounts payable, accrued expenses, and other assets/liabilities approximate their fair value based on the short term nature of those items.

Estimated fair value of financial instruments is determined using available market information. In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts.

Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange.

ASC Topic 820, "Fair Value Measurements and Disclosures" ("ASC Topic 820") establishes a hierarchy for ranking the quality and reliability of the information used to determine fair values. ASC Topic 820 requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1: Unadjusted quoted market prices in active markets for identical assets or liabilities.

Level 2: Unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices are observable for the asset or liability.

Level 3: Unobservable inputs for the asset or liability.

The Company endeavors to utilize the best available information in measuring fair value. Financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The following methods and assumptions were used by the Company in estimating its fair value disclosures for financial instruments:

Cash —The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value due to the short-term maturity of these instruments.

Line of Credit and Long-Term Debt—The carrying amounts of the Company's borrowings under its line of credit agreement and other long-term debt approximates fair value, based upon current interest rates, some of which are variable interest rates.

Other Asset/liabilities – The carrying amounts reported in the balance sheet for other current assets and liabilities approximates their fair value, based on the nature of the assets and liabilities.

In August 2018, ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement", was issued. ASU 2018-03 adds, modifies and removes several disclosure requirements relative to the three levels of inputs used to measure fair value in accordance with Topic 820, "Fair Value Measurement." ASU 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted. The Company adopted ASU 2018-03 in the quarter ended March 31, 2020 and the adoption did not have an impact on its financial position or results of operations.

[13] Accounting for share-based payments and stock warrants: In accordance with the provisions of ASC Topic 718, “Accounting for Stock Based Compensation”, the Company recognizes share-based payment expense for stock options and warrants. In June 2018, ASU 2018-07, “Compensation - Stock Compensation/Improvements to Nonemployee Share-Based Payment Accounting”, was issued. ASU 2018-07 expands the scope of ASC Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The requirements of Topic 718 must be applied to nonemployee awards except for certain exemptions specified in the amendment. ASU 2018-07 was effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. The Company adopted ASU 2018-07 in the First Quarter 2019 and the adoption did not have a material impact on its financial position or results of operations considering the limited occasions where the Company has issued share based awards to nonemployees for goods or services.

The weighted average fair value of options issued and outstanding in Fiscal 2019 and Fiscal 2018 was \$0.13 in each year. (See Note H [2] – Stockholders’ Equity)

In Fiscal 2018, the Company accounted for derivative instruments in accordance with ASC Topic 815 “Derivatives and Hedging” (“ASC Topic 815”). The guidance within ASC Topic 815 requires the Company to recognize all derivatives as either assets or liabilities on the statement of financial position unless the contract, including common stock warrants, settles in the Company’s own stock and qualifies as an equity instrument. A contract designated as an equity instrument is included in equity at its fair value, with no further fair value adjustments required; and if designated as an asset or liability is carried at fair value with any changes in fair value recorded in the results of operations. The weighted average fair value of warrants issued and outstanding was \$0.18 in both Fiscal 2019 and Fiscal 2018. (See Note H [3] – Stockholders’ Equity)

[14] Concentration of credit risk: The Company sells products primarily to United States customers and distributors. Credit is extended based on an evaluation of the customer’s financial condition.

At December 31, 2019, one customer accounted for 55.6% of the Company’s net accounts receivable and another customer accounted for 15.0%. A substantial portion of both of these balances were collected in the first quarter of the year ending December 31, 2020. Due to the long standing nature of the Company’s relationship with these customers and contractual obligations, the Company is confident it will recover these amounts.

At December 31, 2018, one customer accounted for 56.5% of the Company’s net accounts receivable. A substantial portion of this balance was collected in the first quarter of the year ended December 31, 2019. Due to the long standing nature of the Company’s relationship with this customer and contractual obligations, the Company is confident it will recover these amounts.

The Company has established an allowance for doubtful accounts of \$34,000 and \$36,000 at December 31, 2019 and December 31, 2018, respectively, based on factors surrounding the credit risk of our customers and other information.

One of the Company’s customers accounted for 44.8% of net sales in Fiscal 2019 and 44.0% of net sales in Fiscal 2018.

The Company maintains certain cash balances at financial institutions that are federally insured and at times the balances have exceeded federally insured limits.

[15] Reporting comprehensive income: The Company reports comprehensive income in accordance with the provisions of ASC Topic 220, “Reporting Comprehensive Income” (“ASC Topic 220”). The provisions of ASC Topic 220 require the Company to report the change in the Company’s equity during the period from transactions and events other than those resulting from investments by, and distributions to, the shareholders. For Fiscal 2019 and Fiscal 2018, comprehensive income was the same as net income.

[16] Reclassifications: Certain items have been reclassified from the prior years to conform to the current year presentation.

[17] New accounting pronouncements:

In the year ended December 31, 2019, we adopted the following accounting standards set forth by the Financial Accounting Standards Board ("FASB"):

ASU 2016-02, "Leases", issued in February 2016, requires a lessee to recognize a lease liability and a right-of-use asset on its balance sheet for all leases, including operating leases, with a term greater than 12 months. Lease classification will determine whether a lease is reported as a financing transaction in the income statement and statement of cash flows. ASU 2016-02 does not substantially change lessor accounting, but it does make certain changes related to leases for which collectability of the lease payments is uncertain or there are significant variable payments. Additionally, ASU 2016-02 makes several other targeted amendments including a) revising the definition of lease payments to include fixed payments by the lessee to cover lessor costs related to ownership of the underlying asset such as for property taxes or insurance; b) narrowing the definition of initial direct costs which an entity is permitted to capitalize to include only those incremental costs of a lease that would not have been incurred if the lease had not been obtained; c) requiring seller-lessees in a sale-leaseback transaction to recognize the entire gain from the sale of the underlying asset at the time of sale rather than over the leaseback term; and d) expanding disclosures to provide quantitative and qualitative information about lease transactions. ASU 2016-02 was effective for all annual and interim periods beginning January 1, 2019, and was required to be applied retrospectively to the earliest period presented at the date of initial application, with early adoption permitted.

ASU 2018-11, "Leases (Topic 842); Targeted Improvements", issued in July 2018, provides a transition election to not restate comparative periods for the effects of applying the new standard. This transition election permits entities to change the date of initial application to the beginning of the year of adoption and to recognize the effects of applying the new standard as a cumulative-effect adjustment to the opening balance of retained earnings. The Company adopted the standards using the transition election and the cumulative effect adjustment to the opening balance of retained earnings did not have a material impact on the Company's financial conditions or its results of operations.

ASU 2018-20, "Leases (Topic 842)", issued in December 2018, clarifies that lessor costs paid directly to a third-party by a lessee on behalf of the lessor, are no longer required to be recognized in the lessor's financial statements.

ASU 2019-01, Leases (Topic 842)", issued in March 2019 includes amendments that are of a similar nature to the items typically addressed in the Codification improvements project. However, FASB decided to issue a separate update for the improvements related to Update 2016-02 to increase stakeholders' awareness of the amendments and to expedite the improvements.

The Company adopted ASU 2016-02, ASU 2018-11, ASU 2018-20 and ASU 2019-01 in the first quarter of Fiscal 2019. In reviewing the Company's current leases, there were two operating leases that fell within the scope of the standard, as amended, one for a copier in the Company's New York facility and another lease related to the Company's New Jersey facility. Starting in the first quarter of Fiscal 2019, the Company is recognizing a lease liability and a right-of-use asset on its balance sheet related to both of these leases.

ASU 2017-11, "Earnings Per Share, Distinguishing Liabilities from Equity, Derivatives and Hedging", issued in July 2017, changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature will no longer preclude equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) would not be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt—Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). ASU 2017-11 was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company adopted ASU 2017-11 in the first quarter of Fiscal 2019 and the adoption did not have an impact on its financial position or results of operations.

ASU 2018-07, “Compensation - Stock Compensation/Improvements to Nonemployee Share-Based Payment Accounting”, issued in June 2018, expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The requirements of Topic 718 must be applied to nonemployee awards except for certain exemptions specified in the amendment. ASU 2018-07 was effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. The Company adopted ASU 2018-07 in the first quarter of Fiscal 2019 and the adoption did not have a material impact on its financial position or results of operations considering the limited occasions where the Company has issued share based awards to nonemployees for goods or services.

The following accounting standards have been issued prior to the end of Fiscal 2019 but, did not require adoption as in Fiscal 2019:

ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement”, issued in August 2018, adds, modifies and removes several disclosure requirements relative to the three levels of inputs used to measure fair value in accordance with Topic 820, “Fair Value Measurement.” ASU 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted. The Company is evaluating the impact of ASU 2018-13.

ASU 2019-08, Compensation – Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606)”, issued in November 2019, clarifies that an entity must measure and classify share-based payment awards granted to a customer by applying the guidance in Topic 718. ASU 2019-08 is effective for fiscal years beginning after December 15, 2019, including interim reporting periods within those fiscal years. The Company does not believe ASU 2019-08 will have a material effect on its financial statements.

ASU 2019-12, “Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes”, issued in December 2019 reduces the complexity by removing exemptions and simplifying the accounting for franchise taxes, deferred taxes and taxes related to employee’s stock ownership plan. The requirements in ASU 2019-12 will be effective for public companies for fiscal years beginning after December 15, 2020, including interim periods. The Company is evaluating the impact of ASU 2019-12.

Any other new accounting pronouncements recently issued, but not yet effective, have been reviewed and determined to be not applicable or were related to technical amendments or codification. As a result, the adoption of such new accounting pronouncements, when effective, is not expected to have a material effect on the Company’s financial position or results of operations.

NOTE B - INVENTORY

Inventory is comprised of the following:

	December 31, 2019	December 31, 2018
Raw Materials	\$ 670,000	\$ 778,000
Work In Process	141,000	184,000
Finished Goods	290,000	325,000
Allowance for slow moving and obsolete inventory	(291,000)	(268,000)
	<u>\$ 810,000</u>	<u>\$ 1,019,000</u>

NOTE C – PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment, at cost, are as follows:

	December 31, 2019	December 31, 2018
Land	\$ 102,000	\$ 102,000
Buildings and improvements	1,352,000	1,352,000
Manufacturing and warehouse equipment	2,108,000	2,108,000
Office equipment (incl. furniture and fixtures)	412,000	412,000
	<u>3,974,000</u>	<u>3,974,000</u>
Less accumulated depreciation	(3,330,000)	(3,256,000)
	<u><u>\$ 644,000</u></u>	<u><u>\$ 718,000</u></u>

Depreciation expense was \$74,000 in both Fiscal 2019 and Fiscal 2018.

NOTE D – ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following:

	December 31, 2019	December 31, 2018
Accounting fees	\$ 77,000	\$ 75,000
Interest payable	15,000	13,000
Accounts receivable credit balances	55,000	34,000
Sales tax payable	142,000	115,000
Deferred compensation	191,000	167,000
Customer Deposits	10,000	25,000
Other current liabilities	52,000	20,000
	<u>\$ 542,000</u>	<u>\$ 449,000</u>

NOTE E – DEBT AND LINE OF CREDIT

The Company's Line of Credit and Debt consisted of the following as of December 31, 2019 and December 31, 2018:

	December 31, 2019	December 31, 2018
Loan and Security Agreement with Cherokee Financial, LLC: 5 year note at a fixed annual interest rate of 8% plus a 1% annual oversight fee, interest only and oversight fee paid quarterly with first payment being made on May 15, 2015, annual principal reduction payment of \$75,000 due each year beginning on February 15, 2016, with a final balloon payment being due on February 15, 2020. Loan is collateralized by a first security interest in building, land and property.	\$ 900,000	\$ 975,000
Crestmark Line of Credit: 3 year line of credit maturing on June 22, 2020 with interest payable at a variable rate based on WSJ Prime plus 3% with a floor or 5.25%; loan fee of 0.5% annually & monthly maintenance fee of 0.3% on actual loan balance from prior month. Early termination fee of 2% if terminated prior to natural expiration. Loan is collateralized by first security interest in receivables and inventory and the all-in interest rate as of the date of this report is 12.32%.	337,000	502,000
Crestmark Equipment Term Loan: 38 month equipment loan related to the purchase of manufacturing equipment, at an interest rate of WSJ Prime Rate plus 3%; or 6.25% as of the date of this report.	7,000	19,000
2018 Term Loan with Cherokee Financial LLC: 1 year note at an annual fixed interest rate of 12% paid quarterly in arrears with first interest payment being made on May 15, 2018 and a balloon payment being due on February 15, 2019. Loan was refinanced in February 2019.	0	150,000
2019 Term Loan with Cherokee Financial, LLC: 1 year note at an annual fixed interest rate of 18% paid quarterly in arrears with first interest payment being made on May 15, 2019 and a balloon payment being due on February 15, 2020.	200,000	0
July 2019 Term Loan with Chaim Davis, et al: Notes at an annual fixed interest rate of 7.5% paid monthly in arrears with the first payment being made on September 1, 2019 and the final payment being made on October 1, 2020.	10,000	0
December 2019 Convertible Note: Convertible note with a conversion date of 120 days or upon the closing of a 2020 funding transaction (whichever is sooner).	25,000	0
	<u>\$ 1,479,000</u>	<u>\$ 1,646,000</u>
Less debt discount & issuance costs (Cherokee Financial, LLC loans)	(17,000)	(111,000)
Total debt, net	<u>\$ 1,462,000</u>	<u>\$ 1,535,000</u>
Current portion	\$ 354,000	\$ 739,000
Long-term portion, net of current portion	<u>\$ 1,125,000</u>	<u>\$ 796,000</u>

At December 31, 2019, the following are the debt maturities for each of the next five years:

2020	\$ 369,000
2021	1,110,000
2022	0
2023	0
2024	0
	<u>\$ 1,479,000</u>

LOAN AND SECURITY AGREEMENT WITH CHEROKEE FINANCIAL, LLC. (“CHEROKEE”)

On March 26, 2015, the Company entered into a LSA with Cherokee (the “Cherokee LSA”). The debt with Cherokee is collateralized by a first security interest in real estate and machinery and equipment. Under the Cherokee LSA, the Company was provided the sum of \$1,200,000 in the form of a 5-year Note at a fixed annual interest rate of 8%. The Company received net proceeds of \$80,000 after \$1,015,000 of debt payments, and \$105,000 in other expenses and fees. The expenses and fees (with the exception of the interest expense) are being deducted from the balance on the Cherokee LSA and are being amortized over the term of the debt (in accordance with ASU No. 2015-03). The Company is making interest only payments quarterly on the Cherokee LSA, with the first interest payment paid on May 15, 2015. The Company is also required to make an annual principal reduction payment of \$75,000 on each anniversary of the date of the closing; with the first principal reduction payment being made on February 15, 2016 and the most recent principal reduction payment being made on February 15, 2019; partially with proceeds received from a new, larger term loan with Cherokee (See 2019 Term Loan with Cherokee within this Note E). In addition to the 8% interest, the Company pays Cherokee a 1% annual fee for oversight and administration of the loan. This oversight fee is paid in cash and is paid contemporaneously with the quarterly interest payments. The Company can pay off the Cherokee loan at any time with no penalty; except that a 1% administration fee would be required to be paid to Cherokee to close out all participations.

The Company recognized \$166,000 in interest expense related to the Cherokee LSA in Fiscal 2019 (of which \$94,000 is debt issuance cost amortization recorded as interest expense and \$173,000 in interest expense related to the Cherokee LSA in Fiscal 2018 (of which \$94,000 is debt issuance cost amortization recorded as interest expense).

The Company had \$15,000 in accrued interest expense at December 31, 2019 and \$13,000 in accrued interest expense at December 31, 2018.

As of December 31, 2019, the balance on the Cherokee LSA was \$900,000; however, the discounted balance was \$884,000. As of December 31, 2018, the balance on the Cherokee LSA was \$975,000; however the discounted balance was \$866,000.

A final balloon payment was due on February 15, 2020. See Note J – Subsequent Events for information regarding the extension of the Cherokee LSA.

LINE OF CREDIT WITH CRESTMARK BANK (“CRESTMARK”)

On June 29, 2015 (the “Closing Date”), the Company entered into a Loan and Security Agreement (“LSA”) with Crestmark related to a revolving line of credit (the “Crestmark LOC”). The Crestmark LOC is used for working capital and general corporate purposes and expired on June 22, 2020. (See Note J- Subsequent Event for information related to the extension of the Crestmark LOC).

The Crestmark LOC provided the Company with a revolving line of credit up to \$1,500,000 (“Maximum Amount”) with a minimum loan balance requirement of \$500,000. At December 30, 2019, the Company did not meet this minimum loan balance requirement as our balance was \$337,000. Under the LSA, Crestmark has the right to calculate interest on the minimum balance requirement rather than the actual balance on the Crestmark LOC. The Crestmark LOC is secured by a first security interest in the Company’s inventory, and receivables and security interest in all other assets of the Company (in accordance with permitted prior encumbrances).

The Maximum Amount is subject to an Advance Formula comprised of: 1) 90% of Eligible Accounts Receivables (excluding, receivables remaining unpaid for more than 90 days from the date of invoice and sales made to entities outside of the United States), and 2) up to 40% of eligible inventory plus up to 10% of Eligible Generic Packaging Components not to exceed the lesser of \$350,000, or 100% of Eligible Accounts Receivable. However, as a result of an amendment executed on June 25, 2018, the amount available under the inventory component of the line of credit was changed to 40% of eligible inventory plus up to 10% of Eligible Generic Packaging Components not to exceed the lesser of \$250,000 ("Inventory Sub-Cap Limit") or 100% of Eligible Accounts Receivable. In addition, the Inventory Sub-Cap Limit is being permanently reduced by \$10,000 per month as of July 1, 2018 and thereafter on the first day of the month until the Inventory Sub-Cap Limit is reduced to \$0, (making the Crestmark LOC an accounts-receivable based line only). This means that as of December 31, 2019, the Inventory Sub-Cap Limit is only \$70,000 and that our availability related to inventory is significantly reduced.

So long as any obligations are due to Crestmark (and until the extension executed on June 22, 2020, the Company had to comply with a minimum Tangible Net Worth ("TNW") Covenant. As a result of an amendment executed in June 2019, the TNW covenant was reduced from \$150,000 to \$(600,000) effective with the quarter ended June 30, 2019. TNW is still defined as: Total Assets less Total Liabilities less the sum of (i) the aggregate amount of non-trade accounts receivables, including accounts receivables from affiliated or related persons, (ii) prepaid expenses, (iii) deposits, (iv) net lease hold improvements, (v) goodwill and (vi) any other asset that would be treated as an intangible asset under GAAP; plus Subordinated Debt. Subordinated Debt means any and all indebtedness presently or in the future incurred by the Company to any creditor of the Company entering into a written subordination agreement with Crestmark. The Company was not in compliance with the TNW covenant at December 30, 2019 and with the exception of the quarter ended June 30, 2019; the Company has not been in compliance with prior TNW covenants since December 31, 2017.

On June 22, 2020, we extended the Crestmark LOC and as a result of this extension, the TNW covenant was removed effective with the quarter ending June 30, 2020. We were not in compliance with the TNW covenant at December 31, 2019 and with the exception of the quarter ended June 30, 2019; we have not been in compliance with prior TNW covenants since December 31, 2017. We are in the process of obtaining a waiver from Crestmark Bank in connection with the non-compliance with the TNW covenant at December 31, 2019. If we are not compliant with the TNW covenant for the quarter ending March 31, 2020, we also expect to receive a waiver from Crestmark Bank. We have received a waiver from Crestmark related to our non-compliance with the TNW covenant. The Company expects to be charged a fee of \$5,000 for the receipt of this latest waiver (as this has been the fee charged for all prior waivers) and the March 31, 2020 waiver (if needed).

In the event of a default of the LSA, which includes but is not limited to, failure of the Company to make any payment when due and non-compliance with the TNW covenant (that is not waived by Crestmark and until the extension was executed on June 22, 2020), Crestmark is permitted to charge an Extra Rate. The Extra Rate is the Company's then current interest rate plus 12.75% per annum.

Interest on the Crestmark LOC is at a variable rate based on the Prime Rate plus 3% with a floor of 5.25%. As of December 31, 2019, the interest only rate on the Crestmark LOC was 7.75%; however, as of the date of this report, the interest only rate on the Crestmark LOC was 6.25% due to a decrease in the Prime Rate effective March 15, 2020. As of the date of this report, with all fees considered (the interest rate + an Annual Loan Fee of \$7,500 + a monthly maintenance fee of 0.30% of the actual average monthly balance from the prior month), the interest rate on the Crestmark LOC was 12.32%.

The Company recognized \$46,000 in interest expense related to the Crestmark LOC in Fiscal 2019 (\$0 of which is debt issuance cost amortization recorded as interest expense) and \$76,000 in interest expense related to the Crestmark LOC in Fiscal 2018 (of which \$15,000 is debt issuance cost amortization recorded as interest expense).

Given the nature of the administration of the Crestmark LOC, at December 31, 2019, the Company had \$0 in accrued interest expense related to the Crestmark LOC, and there is \$0 in additional availability under the Crestmark LOC.

As of December 31, 2019, the balance on the Crestmark LOC was \$337,000, and as of December 31, 2018, the balance on the Crestmark LOC was \$502,000.

EQUIPMENT LOAN WITH CRESTMARK

On May 1, 2017, the Company entered into term loan with Crestmark in the amount of \$38,000 related to the purchase of manufacturing equipment. The equipment loan is collateralized by a first security interest in a specific piece of manufacturing equipment. The Company executed an amendment to its LSA and Promissory Note with Crestmark. The amendments addressed the inclusion of the term loan into the LSA and an extension of the Crestmark LOC. No terms of the Crestmark LOC were changed in the amendment. The interest rate on the term loan is the WSJ Prime Rate plus 3%; or 6.25% as of the date of this report.

The Company incurred \$1,000 in interest expense in Fiscal 2019 and \$2,000 in interest expense in Fiscal 2018 related to the Equipment Loan. The balance on the Equipment Loan is \$7,000 at December 31, 2019 and \$19,000 at December 31, 2018.

2018 TERM LOAN WITH CHEROKEE

On March 2, 2018, the Company entered into a one-year Loan Agreement made as of February 15, 2018 (the "Closing Date") with Cherokee under which Cherokee provided the Company with \$150,000 (the "2018 Cherokee Term Loan"). The proceeds from the 2018 Cherokee Term Loan were used by the Company to pay a \$75,000 principal reduction payment to Cherokee that was due on February 15, 2018 and \$1,000 in legal fees incurred by Cherokee. Net proceeds (to be used for working capital and general business purposes) were \$74,000.

The annual interest rate for the 2018 Cherokee Term Loan was 12% to be paid quarterly in arrears with the first interest payment being made on May 15, 2018. The 2018 Cherokee Term Loan was required to be paid in full on February 15, 2019. In connection with the 2018 Cherokee Term Loan, the Company issued 150,000 restricted shares of common stock to Cherokee on March 8, 2018.

The Company recognized \$3,000 in interest expense related to the 2018 Cherokee Term Loan in Fiscal 2019, (of which \$2,000 was debt issuance cost amortization recorded as interest expense), and \$33,000 in interest expense related to the Cherokee Term Loan in Fiscal 2018 (of which \$19,000 was debt issuance costs recorded as interest expense). At December 31, 2019, the balance on the 2018 Cherokee Term Loan was \$0 (as it was refinanced in February 2019), and at December 31, 2018, the balance on the 2018 Cherokee Term Loan was \$150,000.

2019 TERM LOAN WITH CHEROKEE

On February 25, 2019 (the "Closing Date"), the Company entered into an agreement dated (and effective) February 13, 2019 (the "Agreement") with Cherokee under which Cherokee provided the Company with a loan in the amount of \$200,000 (the "2019 Cherokee Term Loan"). Gross proceeds of the 2019 Cherokee Term Loan were \$200,000; \$150,000 of which was used to satisfy the 2018 Cherokee Term Loan, \$48,000 (which was used to pay a portion of the \$75,000 principal reduction payment; with the remaining \$27,000 being paid with cash on hand) and \$2,000 which was used to pay Cherokee's legal fees in connection with the financing.

The annual interest rate under the 2019 Cherokee Term Loan is 18% (fixed) paid quarterly in arrears with the first interest payment being made on May 15, 2019 and the latest interest payment being made in November 2019. The loan was required to be paid in full on February 15, 2020. In connection with the 2019 Cherokee Term Loan, the Company issued 200,000 restricted shares of common stock to Cherokee in the three months ended March 31, 2019.

In the event of default, this includes, but is not limited to, the Company's inability to make any payments due under the Agreement, Cherokee has the right to increase the interest rate on the financing to 20%, automatically add a delinquent payment penalty of \$20,000 to the outstanding principal and the Company would be required to issue an additional 200,000 shares of restricted common stock.

The Company recognized \$48,000 in interest expense related to the 2019 Cherokee Term Loan in Fiscal 2019, (of which \$15,000 is debt issuance cost amortization recorded as interest expense), and \$0 in interest expense in Fiscal 2018 (as the 2019 Cherokee Term Loan was not yet in place).

The Company had \$9,000 in accrued interest related to the 2019 Cherokee Term Loan at December 31, 2019 and \$0 in accrued interest expense at December 31, 2018 (as the 2019 Cherokee Term Loan was not yet in place).

The balance on the 2019 Term Loan is \$200,000 at December 31, 2019 (however, the discounted balance is \$199,000), and \$0 at December 31, 2018 (as the facility was not in place at December 31, 2018). See Note J – Subsequent Event for information regarding the extension of the 2019 Term Loan.

JULY 2019 TERM LOAN WITH CHAIM DAVIS, ET AL

On July 31, 2019, the Company entered into loan agreements with two (2) individuals, under which each individual provided the Company the sum of \$7,000 (for a total of \$14,000) to be used in connection with certain fees and/or expenses related legal matters of the Company (the “July 2019 Term Loan”). One of the individuals was our Chairman of the Board Chaim Davis. There were no expenses related to the July 2019 Term Loan. The first payment of principal and interest was due on September 1, 2019 and the last payment of principal and interest is due on October 1, 2020. The annual interest rate of the July 2019 Term Loan is fixed at 7.5% (which represented the WSJ Prime Rate +2.0%). The Company incurred less than \$1,000 in interest expense in Fiscal 2019 and \$0 in interest expense in Fiscal 2018 (as the facility was not in place until July 2019). The balance on the July 2019 Term Loan was \$10,000 at December 31, 2019, and \$0 at December 31, 2018 (as the facility was not in place at December 31, 2018).

DECEMBER 2019 CONVERTIBLE NOTE

On December 31, 2019, the Company entered into a Convertible Note with one individual in the amount of \$25,000 (“2019 Convertible Note”). Under the terms of the 2019 Convertible Note, the principal amount would convert into equity within 120 days of the origination of the note or upon the close of a contemplated private placement in early 2020, whichever was sooner. The 2019 Convertible Note did not bear any interest and was ultimately converted into equity as part of a private placement closed in February 2020. The balance on the 2019 Convertible Note was \$25,000 at December 31, 2019 and \$0 at December 31, 2018 (as the convertible note was not in place at December 31, 2018).

NOTE F – INCOME TAXES

The Company follows ASC 740 “Income Taxes” (“ASC 740”) which prescribes the asset and liability method whereby deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities, and are measured using the enacted laws and tax rates that will be in effect when the differences are expected to reverse. The measurement of deferred tax assets is reduced, if necessary, by a valuation allowance for any tax benefits that are not expected to be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. Under ASC 740, tax benefits are recorded only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely to be realized upon ultimate settlement. Unrecognized tax benefits are tax benefits claimed in the Company’s tax returns that do not meet these recognition and measurement standards.

On December 22, 2017, the Tax Reform Act was signed into law. Among the provisions, the Tax Reform ACT reduces the U.S. federal corporate income tax rate from a maximum of 35% to a flat 21% effective January 1, 2018, requires companies to pay a one-time transition tax on deemed repatriated earnings of certain foreign subsidiaries that were previously tax deferred, and creates new taxes on certain foreign sourced earnings. At December 31, 2019, the Company has completed its accounting for the tax effects of the enactment of the Tax Reform Act. The Company has finalized the tax effects on its existing deferred tax balances and the one-time transition tax under Staff Accounting Bulletin No. 118 (“SAB 118”). The Company has also included current year impacts of the Tax Reform Act in our tax provision. Deferred income tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in tax years 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. The CARES Act also contains modifications on the limitation of business interest for tax years beginning in 2019 and 2020. The modifications to Section 163(j) increase the allowable interest expense deduction. Any tax benefit as a result of the CARES Act is primarily due to the carryback of net operating losses to prior years and increased interest expense deductions.

A reconciliation of the U.S. Federal statutory income tax rate to the effective income tax rate is as follows:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Tax expense at federal statutory rate	(21%)	(21%)
State tax expense, net of federal tax effect	0%	0%
Expired NOL	46%	0%
Deferred income tax asset valuation allowance	(26%)	21%
Effective income tax rate	(1%)	0%

Significant components of the Company's deferred income tax assets are as follows:

	December 31, 2019	December 31, 2018
Inventory capitalization	\$ 8,000	\$ 9,000
Inventory allowance	76,000	70,000
Allowance for doubtful accounts	9,000	9,000
Accrued compensation	18,000	22,000
Stock based compensation	168,000	168,000
Deferred wages payable	50,000	43,000
Depreciation – Property, Plant & Equipment	(1,000)	(6,000)
Net operating loss carry-forward	3,339,000	3,569,000
Total gross deferred income tax assets	3,667,000	3,884,000
Less deferred income tax assets valuation allowance	(3,667,000)	(3,884,000)
Net deferred income tax assets	\$ 0	\$ 0

The valuation allowance for deferred income tax assets as of December 31, 2019 and December 31, 2018 was \$3,667,000 and \$3,884,000, respectively. The net change in the deferred income tax assets valuation allowance was \$217,000 for Fiscal 2019 and \$265,000 for Fiscal 2018. The Company believes that it is more likely than not that the deferred tax assets will not be realized.

As of December 31, 2019, the prior three years remain open for examination by the federal or state regulatory agencies for purposes of an audit for tax purposes.

At December 31, 2019, the Company had Federal net operating loss carry-forwards for income tax purposes of approximately \$3,339,000. The Company's net operating loss carry-forwards began to expire in 2019 and continue to expire through 2035. In assessing the realizability of deferred income tax assets, management considers whether or not it is more likely than not that some portion or all deferred income tax assets will be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the projected future taxable income and tax planning strategies in making this assessment.

The Company's ability to utilize the operating loss carry-forwards may be subject to an annual limitation in future periods pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, if future changes in ownership occur.

The Company recognizes potential interest and penalties related to income tax positions as a component of the provision for income taxes on operations. The Company does not anticipate that total unrecognized tax benefits will materially change in the next twelve months.

NOTE G – OTHER INCOME / EXPENSE

Other expense in Fiscal 2019 consisted of interest expense associated with our credit facilities, offset by other income from proceeds for an insurance claim related to our New Jersey facility (a claim that resulted from actions of a service vendor) and a gain on an accrual for a contingent liability. Other expense in Fiscal 2018 consisted of interest expense associated with our credit facilities, offset by other income related to gains on certain liabilities and a small amount of interest income.

NOTE H – STOCKHOLDERS' EQUITY

[1] Stock option plans: The Company currently has two non-statutory stock option plans, the Fiscal 2001 Non-statutory Stock Option Plan (the “2001 Plan”) and the 2013 Equity Compensation Plan (the “2013 Plan”). Both plans have been adopted by our Board of Directors and approved by our shareholders. Both the 2001 Plan and the 2013 Plan have options available for future issuance. Any common shares issued as a result of the exercise of stock options would be new common shares issued from our authorized issued shares.

[2] Stock options: During Fiscal 2019, the Company issued four stock option grants to non-employee members of our board of directors (under the Fiscal 2001 Plan) to purchase 20,000 shares of common stock (each); for a total of 80,000 common shares. During Fiscal 2018, the Company issued four stock option grants to non-employee members of our board of directors to purchase 20,000 shares of common stock (each); for a total of 80,000 common shares.

As of December 31, 2019, there were 2,252,000 options issued and outstanding under the 2001 Plan. There were no options issued under the 2013 Plan, making the total issued and outstanding options 2,252,000 as of December 31, 2019. Of the total options issued and outstanding, 2,172,000 were fully vested as of December 31, 2019. As of December 31, 2019, there were 1,465,000 options available for issuance under the 2001 Plan and 4,000,000 options available under the 2013 Plan.

Stock option activity for Fiscal 2019 and Fiscal 2018 is summarized as follows: (the figures contained within the tables below have been rounded to the nearest thousand)

	Year Ended December 31, 2019			Year Ended December 31, 2018		
	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value as of December 31, 2019	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value as of December 31, 2018
Options outstanding at beginning of year	2,222,000	\$ 0.13	\$ 3,000	2,147,000	\$ 0.13	
Granted	80,000	\$ 0.07		80,000	\$ 0.10	
Exercised	0	NA		0	NA	
Cancelled/expired	(50,000)	\$ 0.20		(5,000)	\$ 0.26	
Options outstanding at end of year	<u>2,252,000</u>	<u>\$ 0.14</u>	<u>\$ 1,000</u>	<u>2,222,000</u>	<u>\$ 0.13</u>	<u>\$ 3,000</u>
Options exercisable at end of year	<u>2,172,000</u>	<u>\$ 0.13</u>		<u>2,142,000</u>	<u>\$ 0.13</u>	

The following table presents information relating to stock options outstanding as of December 31, 2019:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Shares	Weighted Average Exercise Price
\$0.07 - \$0.10	365,000	\$ 0.09	4.43	285,000	\$ 0.09
\$0.11 - \$0.14	1,485,000	\$ 0.12	5.35	1,485,000	\$ 0.12
\$0.15 - \$0.26	402,000	\$ 0.18	3.47	402,000	\$ 0.18
TOTAL	2,252,000	\$ 0.14	4.87	2,172,000	\$ 0.13

The following table summarizes weighted-average assumptions using the Black-Scholes option-pricing model used on the date of the grants issued during Fiscal 2019 and Fiscal 2018:

	Year Ended December 31	
	2019	2018
Volatility	85%	79%
Expected term (years)	10 years	10 years
Risk-free interest rate	2.01%	2.90%
Dividend yield	0%	0%

The Company recognized \$6,000 in share based payment expense related to stock options in Fiscal 2019, and \$10,000 in share based payment expense related to stock options in Fiscal 2018. As of December 31, 2019, there was approximately \$2,000 of total unrecognized share based payment expense related to stock options. This cost is expected to be recognized over 5 months.

[3] Warrants:

Warrant activity for Fiscal 2018 and Fiscal 2017 is summarized as follows. Any common shares issued as a result of the exercise of warrants would be new common shares issued from our authorized issued shares.

	Year Ended December 31, 2019			Year Ended December 31, 2018		
	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value as of December 31, 2019	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value as of December 31, 2018
Warrants outstanding at beginning of year	2,000,000	\$ 0.18	None	2,060,000	\$ 0.18	
Granted	0	NA		0	NA	
Exercised	0	NA		0	NA	
Cancelled/expired	(0)	NA		60,000	\$ 0.18	
Warrants outstanding at end of year	2,000,000	\$ 0.18	None	2,000,000	\$ 0.18	None
Warrants exercisable at end of year	2,000,000	\$ 0.18		2,000,000	\$ 0.18	

The Company recognized \$0 in debt issuance and deferred finance costs related to the issuance of these warrants outstanding in Fiscal 2019 and Fiscal 2018. As of December 31, 2019, there was \$0 of total unrecognized debt issuance costs associated with the issuance of the above warrants outstanding.

NOTE I – COMMITMENTS, CONTINGENCIES AND OTHER MATTERS

- [1] **Operating leases:** The Company leases office and R&D/production facilities in New Jersey under a, non-cancellable operating lease through December 31, 2019. In December 2019, the Company extended the lease for the New Jersey facility through December 31, 2022. The Company also leases office support equipment through July 2022 and December 2025. At December 31, 2019, the future minimum rental payments under these operating leases are as follows:

2020	\$ 37,000
2022	37,000
2022	36,000
2023	1,000
2024	1,000
Thereafter	1,000
	<u>\$ 113,000</u>

Rent Expense was \$46,000 and \$43,000 in Fiscal 2019 and Fiscal 2018, respectively.

- [2] **Employment agreements:** The Company has an employment agreement in place with its Chief Executive Officer/Principal Financial Officer, Melissa Waterhouse. The employment agreement with Ms. Waterhouse provides for a \$160,000 annual salary (although the salary of Ms. Waterhouse is still deferred by 10% through the date of this report; resulting in deferred compensation due to Waterhouse in the amount of \$99,000 through December 31, 2019). It automatically renews unless either party gives advance notice of 60 days. The employment agreement contains severance provisions; in the event the Company terminates Ms. Waterhouse's employment for any reason other than cause (which is defined under the employment agreement), Ms. Waterhouse would receive severance pay equal to 12 months of her base salary at the time of termination, with continuation of all medical benefits during the twelve-month period at the Company's expense. In addition, Ms. Waterhouse may tender her resignation and elect to exercise the severance provision if she is required to relocate more than 50 miles from the Company's New York facility as a continued condition of employment, if there is a substantial change in the responsibilities normally assumed by her position, or if she is asked to commit or conceal an illegal act by an officer or member of the board of directors of the Company. In the case of a change in control of the Company, Ms. Waterhouse would be entitled to severance pay equal to two times her base salary under certain circumstances.

- [3] **Legal:**

ABMC v. Todd Bailey

On August 5, 2019, we settled litigation with Todd Bailey; a former Vice President, Sales & Marketing and sales consultant of the Company until December 23, 2016; hereinafter referred to as "Bailey"). The litigation was filed by the Company in the Northern District of New York in February 2017. Our complaint sought damages related to profits and revenues that resulted from actions taken by Bailey related to our customers. The settlement also addressed a counter-claim filed by Bailey in October 2017 (filed originally in Minnesota but, transferred to the Northern District of New York in January 2019). Bailey was seeking deferred commissions in the amount of \$164,000 that he alleged were owed to him by the Company. These amounts were originally deferred under a deferred compensation program initiated in 2013; a program in which Bailey was one of the participants. We believed the amount sought was not due to Bailey given the actions indicated in our litigation.

Under the settlement, both parties elected to resolve the litigation and settle any and all claims made within the litigation. Neither party admitted to any of the allegations contained within the ABMC v. Bailey litigation (including any allegations made by Bailey in his counterclaim). Both parties also agreed to dismiss all claims made against each other.

NOTE J – SUBSEQUENT EVENTS

PRIVATE PLACEMENT

On February 20, 2020, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with Chaim Davis (the Chairman of our Board of Directors) and certain other accredited investors (the “Investors”), pursuant to which the Company agreed to issue and sell to the Investors in a private placement (the “Private Placement”), 2,842,857 Units (the “Units”).

Each Unit consists of one (1) share of the Company’s common stock, par value \$0.01 per share (“Common Share”), at a price per Unit of \$0.07 (the “Purchase Price”) for aggregate gross proceeds of approximately \$199,000. The Company received net proceeds of \$199,000 from the Private Placement as expenses related to the Private Placement were minimal. The Company did not utilize a placement agent for the Private Placement. The Company used the net proceeds for working capital and general corporate purposes.

The Company does not intend to register the Units issued under the Private Placement; rather the Units issued will be subject to the holding period requirements and other conditions of Rule 144.

CHEROKEE FINANCIAL LLC LOAN EXTENSIONS

On February 24, 2020 (the “Closing Date”), the Company completed a transaction related to a one-year Extension Agreement dated February 14, 2020 (the “Extension Agreement”) with Cherokee under which Cherokee extended the due date of the Company’s credit facilities (a \$900,000 (mortgage) Term Note and a \$200,000 2019 Term Loan) to February 15, 2021. No terms of either facility were changed under the Extension Agreement. For consideration of the Extension Agreement, the Company issued 1.5% of the \$200,000 principal, or \$3,000, in 42,857 restricted shares of the Company’s common stock to Cherokee and, 2% of the \$900,000 principal, or \$18,000, in 257,143 restricted shares of the Company’s common stock to Cherokee on behalf of their investors.

The Company also paid Cherokee’s legal fees in the amount of \$1,000.

SBA PAYCHECK PROTECTION LOAN (PPP LOAN)

On April 22, 2020, the Company entered into a Promissory Note (“PPP Note”) for \$332,000 with Crestmark Bank, pursuant to the U.S. Small Business Administration Paycheck Protection Program under Title I of the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act passed by Congress and signed into law on March 27, 2020. The PPP Note is unsecured, bears interest at 1.00% per annum, with principal and interest payments deferred for the first six months, and matures in two years. The principal is payable in equal monthly installments, with interest, beginning on the first business day after the end of the deferment period. The PPP Note may be forgiven subject to the terms of the Paycheck Protection Program.

Additionally, certain acts of the Company, including but not limited to: (i) the failure to pay any taxes when due, (ii) becoming the subject of a proceeding under any bankruptcy or insolvency law, (iii) making an assignment for the benefit of creditors, or (iv) reorganizing, merging, consolidating or otherwise changing ownership or business structure without PPP Lender’s prior written consent, are considered events of default which grant Lender the right to seek immediate payment of all amounts owing under the PPP Note.

COVID-19

On March 11, 2020, the World Health Organization declared a pandemic related to the rapidly spreading COVID-19 outbreak, which has led to a global health emergency. The extent of the public-health impact of the outbreak is currently unknown and rapidly evolving, and the related health crisis could adversely affect the global economy, resulting in an economic downturn. Any disruption of the Company’s facilities or those of our suppliers could likely adversely impact the Company’s operations. Currently, there is significant uncertainty relating to the potential effect of the novel coronavirus on our business.

DISTRIBUTION OF COVID-19 RAPID TEST

On March 23, 2020, the Company announced in a press releases that it began marketing (on March 17, 2020), via a distribution partnership, a Rapid Test to detect Covid-19 antibodies in whole blood, serum or plasma.. The test is not available for consumer use and is being marketed in full compliance with the March 16, 2020 Emergency Use Authorization (“EUA”) policy set forth by the FDA. An EUA was issued by FDA on May 29, 2020. While The Company does expect the marketing of the Covid-19 test to positively impact its revenues in Fiscal 2021, the Company does not yet know the full extent of the positive impact of COVID-19 test sales on its business, its financial condition and results of operations. The extent to which sales of the COVID-19 test may impact the Company’s business, operating results, financial condition, or liquidity in the future will depend on future developments which are evolving and highly uncertain including the duration of the outbreak and the need for antibody testing in the future.

EXTENSION OF THE CRESTMARK LINE OF CREDIT

On June 22, 2020, the Company extended its line of credit with Crestmark Bank extending the line of credit until June 22, 2021. All terms and conditions of the line of credit remain unchanged under the extension period with the exception of the following,

1) the maximum availability under the line of credit was reduced from \$1,500,000 to \$1,000,000, 2) availability under the line of credit is based on receivables only (under the same terms), 3) the requirement for field audits of the Company was removed, and 4) the Tangible Net Worth (TNW) covenant was removed.

NOTE L- SEGMENT AND GEOGRAPHIC INFORMATION

The Company operates in one reportable segment. All of the Company's long-lived assets are located within the United States.

Information concerning net sales by principal geographic location is as follows:

	Year Ended December 31, 2019	Year Ended December 31, 2018
United States	\$ 3,189,000	\$ 3,411,000
North America (not domestic)	11,000	56,000
Europe	108,000	133,000
Asia/Pacific Rim	13,000	25,000
South America	344,000	246,000
Africa	0	1,000
	<u>\$ 3,655,000</u>	<u>\$ 3,872,000</u>