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

FORM 10-K

(Mark One)
[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 from _____ to_____

Commission file number: 001-36268

Akers Biosciences, Inc.
(Exact name of registrant as specified in its charter)

New Jersey	22-2983783
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
201 Grove Road Thorofare, NJ	**08086**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (856) 848-8698

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

Title of Each Class:	Trading Symbol(s)	Name of Each Exchange on Which Registered:
Shares of common stock, no par value	**AKER**	**The NASDAQ Stock Market LLC**

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 [X]

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

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 [X] 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 and post such files). Yes [X] No [ ]

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

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
Emerging growth company	[ ]		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 28, 2019, based on a closing price of $10.80 was $5,835,000. As of March 24, 2020, the registrant had 2,700,240 shares of its common stock, no par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE
None.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Report and the documents we have filed with the Securities and Exchange Commission (which we refer to herein as the SEC) that are incorporated by reference herein contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve significant risks and uncertainties. Any statements contained, or incorporated by reference, in this Report that are not statements of historical fact may be forward-looking statements. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements.

Examples of forward-looking statements in this Annual Report and the our other SEC filings include, but are not limited to, our expectations regarding our business strategy, business prospects, operating results, operating expenses, working capital, liquidity and capital expenditure requirements. Important assumptions relating to the forward-looking statements include, among others, assumptions regarding demand for our products and services, the cost, terms and availability of components, pricing levels, the timing and cost of capital expenditures, competitive conditions and general economic conditions. These statements are based on our management's expectations, beliefs and assumptions concerning future events affecting us, which in turn are based on currently available information. These assumptions could prove inaccurate. Although we believe that the estimates and projections reflected in the forward-looking statements are reasonable, our expectations may prove to be incorrect.

Important factors that could cause actual results to differ materially from the results and events anticipated or implied by such forward-looking statements include, but are not limited to:

- changes in the market acceptance of our products and services;
- challenges we may face in identifying, acquiring and operating new business opportunities;
- the outcome of litigation or other proceedings to which we are subject as described in the "Legal Proceedings" section of this Annual Report or which we may become subject to in the future;
- increased levels of competition;
- changes in political, economic or regulatory conditions generally and in the markets in which we operate;
- our relationships with our key customers;
- adverse conditions in the industries in which our customers operate;
- our ability to retain and attract senior management and other key employees;
- our ability to quickly and effectively respond to new technological developments;
- delisting of our common stock from the NASDAQ capital market;
- our ability to protect our trade secrets or other proprietary rights, operate without infringing upon the proprietary rights of others and prevent others from infringing on our proprietary rights;
- our ability to achieve the expected benefits and costs of the transactions related to the acquisition of Cystron Biotech, LLC, including;
- the timing of, and our ability to, obtain and maintain regulatory approvals for clinical trials of our vaccine product candidate;
- the timing and results of our planned clinical trials for our vaccine product candidate;
- the amount of funds we require for our vaccine product candidate;
- our ability to maintain our existing license with Premas Biotech PVT Ltd;
- other risks, including those described in the "Risk Factors" section of this Annual Report.

We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all of those risks, nor can we assess the impact of all of those risks on our business or the extent to which any factor may cause actual results to differ materially from those contained in any forward-looking statement. The forward-looking statements in this Annual Report and our other filings with the SEC are based on assumptions management believes are reasonable. However, due to the uncertainties associated with forward-looking statements, you should not place undue reliance on any forward-looking statements. Further, forward-looking statements speak only as of the date they are made, and unless required by law, we expressly disclaim any obligation or undertaking to publicly update any of them in light of new information, future events, or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Annual Report and the documents we have filed with the SEC.

PART I

Unless the context provides otherwise, all references in this Annual Report to "Akers", "ABI", "Akers Bio", the "Company", "we", "our" and "us" refer to Akers Biosciences, Inc.

Item 1. Business.

We were incorporated in 1989 in the state of New Jersey. Our principal executive offices are located at 201 Grove Road, Thorofare, New Jersey USA 08086 and our telephone number is (856) 848-8698. Our corporate website address is www.akersbio.com.

On March 23, 2020, we entered into a Membership Interest Purchase Agreement (the "MIPA") with the members of Cystron Biotech, LLC (individually, each a "Seller," and collectively, the "Sellers"), pursuant to which the Company will acquire 100% of the membership interests (the "Membership Interests") of Cystron Biotech, LLC ("Cystron"). Cystron is a party to license agreement with Premas Biotech PVT Ltd ("Premas) whereby Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other corona virus infections.

We also develop, manufacture, and supply rapid, point-of-care screening and testing products designed to bring health-related information directly to the patient or clinician in a timely and cost-efficient manner. We believe that we have advanced the science of diagnostics through the development of several proprietary platform technologies. Our current product offerings focus on delivering diagnostic assistance in a variety of healthcare fields/specialties, including diagnostic rapid manual point-of-care tests for the detection of allergic reactions to Heparin and for on- and off-the-job alcohol safety initiatives.

While we continue to sell our rapid, point-of-care screening and testing products, as of December 31, 2019, we eliminated our sales force and we are also experiencing a production backlog for some our diagnostic products as further described below. We are exploring ways to revitalize our screening and testing products business, but, for the time being, we also intend to focus our efforts on the business of Cystron and our exploration of strategic alternatives in the cannabinoid space announced in November 2019 and as further described below.

Recent Developments

Acquisition of Cystron

On March 23, 2020, we acquired Cystron pursuant to the MIPA.

As consideration for the Membership Interests, we will deliver to the Sellers: (1) that number of newly issued shares of our common stock equal to 19.9% of the issued and outstanding shares of our common stock and pre-funded warrants as of the date of the MIPA, but, to the extent that the issuance of the our common stock would result in any Seller owning in excess of 4.9% of our outstanding common stock, then, at such Seller's election, such Seller may receive "common stock equivalent" preferred shares with a customary 4.9% blocker (with such common stock and preferred stock collectively referred to as "Common Stock Consideration"), and (2) $1,000,000 in cash.

Additionally, we shall (A) make an initial payment to the Sellers of up to $1,000,000 upon our receipt of cumulative gross proceeds from the consummation of an initial equity offering after the date of the MIPA of $8,000,000, and (B) pay to Sellers an amount in cash equal to 10% of the gross proceeds in excess of $8,000,000 raised from future equity offerings after the date of the MIPA until the Sellers have received an aggregate additional cash consideration equal to $10,000,000. Upon the achievement of certain milestones, including the completion of a Phase 2 study for a COVID-19 vaccine that meets its primary endpoints, Sellers will be entitled to receive an additional 750,000 shares of our common stock or, in the event we are unable to obtain stockholder approval for the issuance of such shares, 750,000 shares of non-voting preferred stock that are valued following the achievement of such milestones and shall bear a 10% annual dividend (the "Milestone Shares"). Sellers will also be entitled to contingent payments from us of up to $20,750,000 upon the achievement of certain milestones, including the approval of a new drug application by the U.S. Food and Drug Administration ("FDA").

We shall also make quarterly royalty payments to Sellers equal to 5% of the net sales of a COVID-19 vaccine or combination product by the Company (the "COVID-19 Vaccine") for a period of five (5) years following the first commercial sale of the COVID-19 Vaccine; provided, that such payment shall be reduced to 3% for any net sales of the COVID-19 Vaccine above $500 million.

In addition, Sellers shall be entitled to receive 12.5% of the transaction value, as defined in the MIPA, of any change of control transaction, as defined in the MIPA, that occurs prior to the fifth (5th) anniversary of the closing date of the MIPA, provided that the Company is still developing the COVID-19 Vaccine at that time. Following the consummation of any change of control transaction, the Sellers shall not be entitled to any payments as described above under the MIPA.

Support Agreement

On March 23, 2020, as an inducement to enter into the MIPA, and as one of the conditions to the consummation of the transactions contemplated by the MIPA, the Sellers entered into a shareholder voting agreement with the Company (the "Support Agreement"), pursuant to which each Seller agreed to vote their shares of our common stock or preferred stock in favor of each matter proposed and recommended for approval by our management at every meeting of the stockholders and on any action or approval by written consent of the stockholders.

Registration Rights Agreement

To induce the Sellers to enter into the MIPA, on March 23, 2020, we entered into a registration rights agreement (the "Registration Rights Agreement") with the Sellers, pursuant to which we shall by the 30th day following the closing of the transactions contemplated by the MIPA, file with the United States Securities and Exchange Commission (the "SEC") an initial Registration Statement on Form S-3 (if such form is available for use by the Company at such time) or, otherwise, on Form S-1, covering all of the shares of our common stock issued, or underlying the preferred stock issued, at closing under the MIPA and to subsequently register the common stock issued or underlying the preferred stock issued at Milestone Shares.

License Agreement

Cystron is a party to a License and Development Agreement (the "Initial License Agreement") with Premas Biotech PVT Ltd. ("Premas"). As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other corona virus infections.

Upon the achievement of certain developmental milestones by Cystron, Cystron shall pay to Premas a total of up to $2,000,000.

Series D Convertible Preferred Stock

On March 24, 2020, we filed the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of New Jersey. Pursuant to the Certificate of Designation, in the event of the Company's liquidation or winding up of its affairs, the holders of our Series D Convertible Preferred Stock (the "Preferred Stock") will be entitled to receive the same amount that a holder of our common stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations set forth in the Certificate of Designation) to common stock which amounts shall be paid pari passu with all holders of the Company's common stock. Each share of Preferred Stock has a stated value equal to $0.01 (the "Stated Value"), subject to increase as set forth in Section 7 of the Certificate of Designation.

A holder of Preferred Stock is entitled at any time to convert any whole or partial number of shares of Preferred Stock into shares of our common stock determined by dividing the Stated Value of the Preferred Stock being converted by the conversion price of $0.01 per share.

A holder of Preferred Stock will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding (with such ownership restriction referred to as the "Beneficial Ownership Limitation"). However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

Subject to the Beneficial Ownership Limitation, on any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of a meeting), each holder of Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of our common stock into which the shares of Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of our certificate of incorporation, the holders of Preferred Stock will vote together with the holders of our common stock and any other class or series of stock entitled to vote thereon as a single class.

A holder of Preferred Stock shall be entitled to receive dividends as and when paid to the holders of our common stock on an as-converted basis.

Production Backlog of PIFA® Heparin/PF4 and PIFA® Pluss/PF4

We are currently experiencing a production backlog of our PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays. While we believe that we will be able to remedy the production backlog, we cannot be certain what impact this backlog will have on our business and it may have an adverse effect on our 2020 revenues and results of operation.

Exploration of Strategic Alternatives

On November 7, 2018, we announced that our board of directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. The Company will continue its strategic alternatives review and has identified the hemp and minor cannabinoid sectors as potential opportunities that could benefit from our core competencies. The Company continues to explore how to leverage its 30 years of operational history in its medical device business, where its current products have FDA clearance, its current operations practice Good Manufacturing Processes (cGMP), its medical device facility is certified under ISO 13485 – 2016 and the facility carries an Analytical Lab Certification for Schedules 2, 3, 4 and 5 controlled substances issued by the U.S. Drug Enforcement Administration (DEA) and the State of New Jersey. The Company intends to pursue opportunities in the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry, including pathways to consumer products with a focus on minor cannabinoids.

Our Current Products

We are commercialing our Particle Immuno-Filtration Assay (PIFA®) Technology platform. PIFA® technology is a patented immunoassay method which rapidly and accurately detects target antigens or antibodies. It is the technology platform utilized in the Company's core commercialized products, the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays, which test for an allergic reaction to Heparin. These products account for the significant majority of the Company's current revenues.

Our portfolio also includes the manufacture and sale of BreathScan Alcohol Detectors (based on the Company's Micro Particle Catalyzed (MPC) Biosensor technology platform). In September 2019, we determined that it was no longer economically appropriate to offer our Tri- Cholesterol products (which was based on the Company's Rapid Enzymatic Assay (REA™) technology platform). Furthermore, we determined that it was not economically appropriate to further develop or pursue approval of the PIFA PLUSS Chlamydia Rapid Assay device. As of December 31, 2019, the Company's marketed products consist of its PIFA® Heparin/PF4, PIFA PLUSS® PF4 and BreathScan Alcohol Detector families of products.

All of Akers' rapid, single-use tests are performed in vitro (outside the body) and are designed to enhance patient well-being and reduce the cost of healthcare. Our current product offerings focus on delivering diagnostic assistance in a variety of healthcare fields/specialties, including diagnostic rapid manual point-of-care tests for the detection of allergic reactions to Heparin and for on- and off-the-job alcohol safety initiatives.

Akers believes that low-cost, single-use testing not only saves time and money, but allows for more frequent, near-patient testing which may save lives. We believe that our FDA-cleared rapid diagnostic tests help facilitate targeted diagnoses and real-time treatment. We also believe that our rapid diagnostic tests surpass most other current diagnostic products with their flexibility, speed, ease-of-use, readability, low cost and accuracy. In minutes, detection of a medical condition can be performed on single-patient specimens without sacrificing accuracy.

We believe the use of rapid tests, which can be performed at the point-of-care when and where the patient is being consulted, can result in immediate diagnostic decisions and subsequent treatment regimens and is an important development in the practice of medicine. Point-of-care testing addresses today's challenges in the healthcare industry, such as:

- cost pressures/efficiency of healthcare delivery; and
- need for easy to use, accurate at-home tests for individuals to monitor their personal health and wellness

Strategy

Akers' strategy for the medical device business is to leverage where possible our distributor relationships, while exploring strategies for further reducing our costs.

Akers has developed and currently maintains strategic relationships with established companies in the clinical laboratory market.

Current Testing Platform Technologies

Particle ImmunoFiltration Assay (PIFA®) Technology

PIFA ® technology is an accurate, rapid, immunoassay (*a procedure for detecting or measuring specific proteins or other substances through their properties as antigens or antibodies*) method based on the selective filtration of dyed microparticles coated with antigen or antibody. The microparticles are combined with a test sample (whole blood or serum) within a self-contained device. If a patient tests positive for the antibody or antigen, a binding event will occur and the dyed microparticles will be trapped by a filter within the device. As a result, the test window will be void of any color. Conversely, if the patient tests negative, the dyed microparticles will flow freely into the test window. Specific to the PIFA Heparin tests, we have two international patents and one US patent granted in force.

MPC Biosensor Technology

MicroParticle Catalyzed Biosensor ("MPC Biosensor") Technology permits the rapid identification of medical conditions through biomarkers in exhaled breath. MPC Biosensor-based products contain microparticles that change color to indicate a positive test result. The microparticles are coated with agents that both decrease the time to result and exhibit a more defined color change when appropriate. MPC Biosensor-based products are packaged in small, disposable cartridges through which test subjects can easily blow for several seconds.

Current Sample Preparation Technology

Rapid Blood Cell Separation Technology

Akers' Rapid Blood Cell Separation ("Separator") Technology, labeled under the brand name seraSTAT ®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment. The disposable Separator device requires only a small-volume blood sample obtained through a venous blood draw. Akers has obtained the appropriate US FDA regulatory clearances for seraSTAT ® as a stand-alone device and the technology is currently integrated into PIFA PLUSS PF4 devices. The seraSTAT ® Rapid Blood Cell Separation Technology is currently protected by two U.S. patents and three international patents.

Current Product Portfolio

Akers is positioned as a provider of rapid diagnostic solutions.

At present, Akers' commercialized product portfolio incorporates the three aforementioned proprietary platform testing and sample preparation technologies: PIFA ®, MPC Biosensor and Rapid Blood Cell Separation Technology.

The following table sets forth our marketed products, identifies the appropriate "prescription use" or "OTC" designation and the required clearance that has been obtained.

Our marketed products include:

Product	Platform	Marketed/Pipeline	FDA Clearance Required Prescription Use/OTC	FDA Clearance Status Obtained/Needed	Description
BreathScan ™	MPC	Marketed	OTC	Obtained	Disposable breath alcohol detector
PIFA ® Heparin/PF4 & PIFA PLUSS ® PF4	PIFA	Marketed	Prescription Use	Obtained	Rapid tests for Heparin/PF4 antibodies to detect an allergy to the widely used blood thinner, Heparin
seraSTAT ®	seraSTAT	Marketed	Prescription Use	Obtained	Rapid Blood Cell Separator, marketed under the brand name seraSTAT ®, further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically.

PIFA ® Technology

The core products marketed under the PIFA ® platform are the PIFA ® Heparin/PF4 Rapid Assay, and the PIFA PLUSS ® PF4.

PIFA ® Heparin/PF4 Rapid Assay and PIFA PLUSS ® PF4 remain the only FDA-cleared rapid manual assays that quickly determine if a patient being treated with the blood thinner Heparin may be developing a drug allergy. This clinical syndrome, referred to as Heparin-Induced Thrombocytopenia ("HIT"), reverses the Heparin's intended therapeutic effect and transforms it into a clotting agent. Patients with HIT are at risk of developing limb- and life-threatening complications, so the timely test result provided by Akers' Heparin/PF4 devices is paramount to effective clinical decision making. The largest at-risk populations are patients undergoing major cardiac or orthopedic surgical procedures. It is estimated that up to 50% of cardiac surgery patients develop HIT-antibodies. Given the size of the aging baby boomer market segment and the prevalence of cardiac disease, surgeries within this category is expected to increase, as would the potential demand for our convenient, rapid tests.

The PIFA ® Heparin/PF4 Rapid Assay improves the standard of care in HIT-testing with its result delivered in less than five minutes after the patient sample has been prepared. Traditional methods required the use of expensive equipment, specialized laboratory personnel and hours of technician time to complete the 20+ assay test procedure in-house. Clinicians were subjected to a 24-to-72 hour turnaround time if the HIT-antibody determination was outsourced to a reference laboratory. Especially in the latter scenario, the patient information obtained is retrospective in nature as the HIT-antibody result cannot be factored into time-sensitive diagnostic and treatment decisions.

We have also introduced PIFA PLUSS ® PF4 to U.S. hospitals to further improve the rate at which healthcare professionals can obtain a HIT-antibody result. This PIFA ® line extension merges the ease-of-use of the PIFA testing platform with Akers' recently patented Rapid Blood Cell Separation Technology, marketed under the brand name seraSTAT ®. The marriage of these two technologies condenses the sample preparation and analysis procedures as the precise micro-volume of a seraSTAT® -prepared patient specimen is delivered directly into the PIFA ® cassette for immediate testing. This eliminates an additional one-hour of sample processing time and the need for healthcare personnel to have access to a centrifuge to separate the liquid fraction of blood from the cellular fraction. As a result, HIT-testing can be initiated and completed at or near the point-of-care, especially in emergency and critical care departments where time-efficient diagnostic results can drastically improve patient outcomes.

Since the appropriate regulatory clearances have been obtained in the United States for these products, we do not anticipate needing to fund additional clinical trials to facilitate product marketing domestically. In addition, the current technical file that has been assembled for seraSTAT ® and PIFA PLUSS PF4 ® will also be used to support Akers' CE-marking self-certification process for potential sales in the EU; the PIFA Heparin/PF4 Rapid Assay is already CE-marked.

MPC Biosensor Technology

Breath Alcohol Products

BreathScan ® originated the disposable breath alcohol detector category and was the first single-use breathalyzer to obtain the FDA 510(k) clearance in 2006 for Over-the-Counter use required to facilitate sales to U.S. consumers; CE certification is not required to market the product in the EU because BreathScan ® results are not used to diagnose any medical conditions. Our breath alcohol detector technology was granted an Australian Standard certification trademark, which cleared the commercial pathway for product sales in Australia, New Zealand, and South Africa.

Our disposable breath alcohol detectors are available in versions designed to detect .02%, .04%, .05% and .08% blood alcohol concentrations ("BACs") and provide users with a test result in two minutes. If the crystals in the interior of the device change from yellow to aqua, the user has tested positive for the specific alcohol level. Should the crystals remain yellow, the result is negative.

Sample Preparation Technology

Rapid Blood Cell Separation Technology

In addition to our testing platforms, Akers' patented Rapid Blood Cell Separation ("Separator") Technology, marketed under the brand name seraSTAT ®, which further accelerates the rate at which a test result is obtained as the often-required sample preparation step is abbreviated drastically. Conventional methods of blood cell separation are labor-intensive and time-consuming, typically involving blood collection and laboratory personnel, as well as electrically-powered centrifuges and other specialized equipment.

The required micro-volume specimen of serum or plasma is immediately extracted and introduced into a rapid assay device for real-time analysis. The savings afforded by the Separator device can be measured in time and cost given its quick turn-around-time and straightforward, easy-to-master procedure.

Currently, seraSTAT ® is integrated into PIFA PLUSS PF4 devices. We have modified one of our prescription use, 510(k)-cleared devices, specifically the PIFA Heparin/PF4 Rapid Assay to include our seraSTAT device. However, we determined that, in our view, based on FDA guidance as to when to submit a 510(k) notification for changes to a cleared device, new 510(k) clearances or PMA approvals were not required. We cannot assure you that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA approval. The seraSTAT ® Rapid Blood Cell Separation Technologies is currently protected by two United States patents (7,896,167; 8,097,171) and one international patent (JP 4,885,134).

Competition

Competitors of Akers include other companies developing and marketing rapid, point-of-care diagnostic devices and companies with dedicated laboratory instruments and/or automated test systems. We face intense competition from companies with dominant market positions within the *in vitro* diagnostic testing market such as Abbott, ACON Laboratories, Inc., Immucor, Inc., OraSure Technologies, Inc., and Quidel Corporation.

We believe the primary criteria for determining competitiveness within the rapid point-of-care sector are cost, ease-of-use, speed, readability, accuracy and flexibility.

That said, our competitors have significantly greater financial, technical, marketing and other resources than we have and may be better able to:

- respond to new technologies or technical standards;
- devote resources to the development, production, promotion, support and sale of products;
- acquire other companies to gain new technologies or products that may displace our product lines;
- react to changing customer requirements and expectations;
- manufacture, market and sell products; and
- deliver a broad range of competitive products at lower prices.

Our principal competitors are able to leverage their broader product portfolios and dominant market positions in some segments by, for example, bundling their products into specially priced packages that create strong financial incentives for their customers to purchase their products. These practices may negate savings customers would gain from buying select products from Akers and may deter such customers from buying Akers' products. We expect competition in the markets in which we participate to continue to increase as existing competitors improve or expand their product offerings.

How We Generate Revenue

Our revenue comes from selling rapid, screening and testing products, largely through our distributor networks. Most of our assays are used in the clinical laboratory to ultimately help healthcare professionals to diagnose a medical condition or complication that may require treatment. Other products can be sold over-the-counter, to the general public, to help assess an individual's status as it relates to his/her blood alcohol level.

Our Current Markets

Regarding our test for the heparin drug allergy, the testing market largely resides within the clinical hospital laboratories of medical facilities.

The markets for alcohol breathalyzers are reached through a network of large and small distributors. These markets include industrial safety, education, social responsibility and retail.

COVID-19

Many pharmaceutical and biotechnology companies are seeking to develop vaccines and other treatments for COVID-19. Several of them are large, multi-national pharmaceutical companies with significantly more resources than us.

Manufacturing and Suppliers

We are a vertically integrated manufacturer, producing substantially all of our devices in-house. The vast majority of our products start out as high quality, medical grade polymers and exit our facilities as fully manufactured and packaged medical devices. As a result, we have a short supply line between our raw materials and finished goods which gives us greater control over our product quality. The downside of our in-house manufacturing is the requirements for facilities, personnel, and equipment. This approach also requires mid-to-long-term planning and the ability to predict future needs. Many of our processes are unique to us, but our flexible manufacturing capabilities and unused current capacity generally translate into relatively short production timelines.

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements. U.S. medical device manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products are known as current good manufacturing practices (“cGMP’s”). cGMP requirements for devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. From time to time, we are required to source and requalify raw materials from new suppliers, when an existing supplier discontinues a product. We have from time to time we have experienced short-term difficulties in locating and obtaining the materials necessary to fulfill our production requirements.

Effective February 2, 2018, our quality management system was certified as compliant with the International Standards Organization’s (“ISO”) 13485:2016 requirements for the design, manufacture and distribution of medical devices including in vitro diagnostic products.

Distribution

We distribute our products through direct and indirect channels of distribution. We have indirect distribution channels in the U.S. with, among others, Cardinal Health 200, Inc. (“Cardinal Health”) and Fisher Healthcare, a Division of Thermo Fisher Scientific Inc. (“Fisher Healthcare”) for our PIFA Heparin/PF4 assays. The relationships with Cardinal Health and Fisher Healthcare provide us with access to most U.S. hospitals.

Our PIFA Heparin/PF4 assays are also sold direct to certain hospitals and buying groups.

With respect to our breath alcohol product, Akers has focused its commercial attention within the on-the-job safety/human resources sector. Access was and currently is largely achieved through designated BreathScan ® distributors and limited arrangements in which we serve in an OEM capacity.

Intellectual Property

We rely on a combination of patent, trademark and trade secret laws in the U.S. and other jurisdictions to protect our proprietary platform technologies and our brands. We also rely on confidentiality procedures and agreements with key employees and distribution/business partners where appropriate, and contractual provisions to achieve the same. We do not pursue patent protection where the possibility for meaningful enforcement is limited.

The Akers logo is a registered trademark in the U.S. Other registered trademarks/service marks include: BreathScan®, PIFA ®, PIFA PLUSS ®, seraSTAT ®.

The following table summarizes the U.S. and international utility patents that currently protect Akers intellectual property for actually marketed products:

Description	Jurisdiction	Utility Patent No.	Type of Protection	Expiration Date	Product(s) To Which They Relate
blood separator	US	7,896,167	Manufacture	9/7/2026	seraSTAT ®; PIFA PLUSS ® PF4; PIFA PLUSS ® Rapid Assays
method of separating fluid fraction from whole blood	US	8,097,171	Process	8/5/2025	seraSTAT ®; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Rapid Assays
blood separator and method of separating fluid fraction from whole blood	Japan	4,885,134	Manufacture	8/5/2025	seraSTAT ®; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Rapid Assays
blood separator	European Union	1793906	Manufacture	8/5/2025	seraSTAT ®; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Rapid Assays
blood separator	Hong Kong	1104006	Manufacture	8/5/2025	seraSTAT ®; rapid blood cell separator also integrated into PIFA PLUSS ® PF4 and PIFA PLUSS ® Infectious Diseases Rapid Assays
methods for detecting heparin platelet factor 4 antibodies	US	9,383,368	Process	10/4/2024	PIFA ® Heparin/PF4 Rapid Assay; PIFA PLUSS ® PF4
methods and kits for detecting heparin/platelet factor 4 antibodies	Japan	4,931,821	Manufacture	10/4/2025	PIFA ® Heparin/PF4 Rapid Assay; PIFA PLUSS ® PF4
Methods and kits for detecting heparin platelet factor 4 antibodies	Japan	5775790	Manufacture	10/4/2025	PIFA ® Heparin/PF4 Rapid Assay; PIFA PLUSS ® PF4

Circumstances outside our control could pose a threat to our intellectual property. For example, effective intellectual property protection may not be available in every country in which our products are distributed. Also, the efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights is costly and time consuming. Any increase in unauthorized use of our intellectual property could make it more expensive to do business and harm our operating results.

Akers' PIFA Heparin/PF4 Rapid Assay is CE-marked for sale in the EU for professional use. The CE-mark must be affixed to a product that is intended, by the manufacturer, to be used for a medical purpose.

Foreign Regulation

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Companies are now required to obtain a CE Mark, which shows conformance with the requirements of applicable European Conformity directives, prior to sale of some medical devices within the European Union. Some of our current products that require CE Markings have them and it is anticipated that additional and future products may require them as well. As of the date of this filing, the Company has received CE marks for its commercialized products/product components: PIFA Heparin/PF4 Rapid Assay and Heparin/PF4 Serum Panels.

Other U.S. Regulation

We must also comply with numerous federal, state and local laws relating to matters such as healthcare fraud and abuse, anti-kickback, false claims, HIPAA, environmental protection, safe working conditions, manufacturing practices, fire hazard control and, among other things, the generation, handling, transportation and disposal of hazardous substances.

Third-Party Reimbursement

Health care providers, including hospitals, that purchase our products generally rely on third-party payors, including the Medicare and Medicaid programs, and private payors, such as indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of the products and the procedures in which they are used. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payors.

CMS, the federal agency responsible for administering the Medicare program, along with its contractors establishes coverage and reimbursement policies for the Medicare program. In addition, private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

In general, Medicare will cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage. For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets. There can be no assurance that reimbursement for our products, will be obtained or that such reimbursement will be adequate.

Available information

Our website address is *www.akersbio.com*. We do not intend our website address to be an active link or to otherwise incorporate by reference the contents of the website into this Annual Report on Form 10-K. The SEC maintains an Internet website (*http://www.sec.gov*) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Employees

We currently employ 12 full-time equivalent employees, contractors or consultants, which include five in general and administrative, three in regulatory compliance and four in direct and indirect manufacturing. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We believe that we have good relations with our employees.

Item 1A. Risk Factors

An investment in our securities is speculative involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks described below, together with other information in this Annual Report and the other information and documents we file with the SEC. The occurrence of any of the following risks could have a material and adverse effect on our business, reputation, financial condition, results of operations and future growth prospects, as well as our ability to accomplish our strategic objectives. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.

Risks Related to Our Acquisition

We may fail to realize the anticipated benefits of our acquisition of Cystron and those benefits may take longer to realize than expected.

On March 23, 2020, we entered into the MIPA with the Sellers, pursuant to which we will acquire the Membership Interests of Cystron. Cystron is a party to the Initial License Agreement with Premas. As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a COVID-19 vaccine or combination product by the Company (the "COVID-19 Vaccine"). Our ability to realize the anticipated benefits of the acquisition will depend, to a large extent, on our ability to produce a vaccine that successfully treats coronavirus ("COVID-19"). The development of the COVID-19 Vaccine is in very early stages and there is no assurance that we will be able to produce an effective vaccine. The failure to produce the COVID-19 Vaccine could adversely affect our business, financial condition and results of operations. In addition, we expect to incur significant expenses related to the acquisition. These expenses include, but are not limited to, the Common Stock Consideration, a cash consideration of $1.0 million, related contingent fees, legal fees and other related fees and expenses. Many of these expenses will be payable by us regardless of our ability to successfully develop the COVID-19 Vaccine, and we will not be able to recover these expenses in the event that we fail to develop the COVID-19 Vaccine.

Our acquisition of Cystron could result in additional costs, integration or operating difficulties, dilution and other adverse consequences.

In connection with the acquisition of the Cystron and in pursuit of developing the COVID-19 Vaccine, we may:

- issue equity securities that may substantially dilute our stockholders' percentage of ownership;
- be obligated to make milestone, royalty or other contingent or non-contingent payments; and
- incur debt or non-recurring and other charges, or assume liabilities.

In addition, the process of integrating Cystron may create operating difficulties and expenditures and pose numerous additional risks to our operations, including:

- failure to develop, manufacture or supply the COVID-19 Vaccine economically or successfully commercialize or achieve market acceptance of the COVID-19 Vaccine;
- exposure to liabilities of Cystron, including known or unknown risks relating to the validity or enforceability of exclusivity rights and generic competition;

- adverse effects on our operating results or financial condition, including due to expenditures or acquisition-related costs, costs of commercialization or amortization or impairment costs for acquired goodwill and other intangible assets;
- impairment of relationships with key suppliers and manufacturers due to changes in management and ownership and difficulty in maintaining existing agreements, licenses and other arrangements or rights on substantially similar terms as existed prior to the acquisition;
- regulatory changes and market dynamics after the acquisition; and
- potential loss of key employees, particularly those of the acquired entity.

If any of the above events (or more) occur, or if we cannot effectively manage or respond to such events following the acquisition, they may have material adverse effect on our business, results of operations and financial condition.

Cystron is dependent on technologies that is has licensed, and Cystron may need to license in the future, and if Cystron fails to obtain licenses it needs, or fails to comply with its payment obligations in the agreements under which Cystron in-license intellectual property and other rights from third parties, Cystron could lose its ability to develop a COVID-19.

Cystron currently is dependent on a license from Premas for its key technologies. Any failure to make the payments required by the license agreement may permit Premas to terminate the license. If Cystron were to lose or otherwise be unable to maintain the license for any reason, it would halt Cystron's ability to develop a COVID-19 vaccine. The foregoing could result in a material adverse effect on our business or results of operations.

In addition, Cystron does not own the patents or patent applications that it licenses, and as such, Cystron may need to rely upon Premas to properly prosecute and maintain those patent applications and prevent infringement of those patents. If Premas is unable to adequately protect their proprietary intellectual property Cystron licenses from legal challenges, or Cystron is unable to enforce such licensed intellectual property against infringement or alternative technologies, we will not be able to compete effectively in the drug discovery and development business.

Cystron will face intense competition.

We believe that many other pharmaceutical and biotechnologies are working on vaccines and treatments for COVID—19. Some of them are large, multi-national pharmaceutical companies with significantly greater resources than Cystron. If one of these other companies develops an effective vaccine or treatment for COVID-19 before Cystron, then even if Cystron successfully develops a vaccine it may never gain market acceptance.

Risks Related to Our Business

We have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability.

We have recorded a net loss attributable to common stockholders in most reporting periods since our inception. Our net losses for the years ended December 31, 2019 and 2018 were $3,888,249 and $10,849,034, respectively. Our accumulated deficit at December 31, 2019 was $119,583,130. Our strategy for the medical device business is to leverage where possible our distributor relationships, while exploring strategies for further reducing our costs. Overall, we are working to reduce our cash burn in order to have sufficient cash funds available to execute on a transaction which would result from our pursuit of strategic alternatives. There can be no assurance of success in reducing our loss, becoming profitable, or having sufficient cash to complete a strategic alternative transaction.

Our pursuit of the COVID-19 Vaccine is at an early stage. We have not previously tested our rapid response capability and may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all.

In response to the global outbreak of COVID-19, we are pursuing the rapid development of the COVID-19 Vaccine. Our development of the vaccine is in early stages, and we may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all. Additionally, our ability to develop an effective vaccine depends on the success of our rapid response capability, which we have not previously tested and which will need to be funded by third parties in order to enable us to have sufficient capacity to respond to a global health challenge. If the outbreak is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture the COVID-19 Vaccine, we may be unable to successfully generate revenue from the manufacturing of the COVID-19 Vaccine. We are also committing financial resources and personnel to the development of the COVID-19 Vaccine which may cause delays in or otherwise negatively impact our other business operations, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective.

Furthermore, the biotechnology market is highly competitive, is subject to rapid technological change and is significantly affected by existing rival drugs and medical procedures, new product introductions and the market activities of other participants. Pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations may pursue the research and development of a vaccine to treat COVID-19. Our competitors may develop products more rapidly or more effectively than us. If our competitors are more successful in commercializing their products than us, their success could adversely affect our competitive position and harm our business prospects and may also lead to the diversion of funding away from us and toward other companies.

If we are successful in producing the COVID-19 Vaccine, we may need to devote significant resources to its scale-up and development including for use by the U.S. government.

In the event that the preclinical and clinical trials for the COVID-19 Vaccine are perceived to be successful, we may need to work toward the large scale technical development, manufacturing scale-up and larger scale deployment of this potential vaccine through a variety of U.S. government mechanisms such as an Expanded Access Program or an Emergency Use Authorization program. In this case we may need to divert significant resources to this program, which would require diversion of resources from our other businesses. In addition, since the path to licensure of any vaccine against COVID-19 is unclear, if use of the vaccine is mandated by the U.S. government, we may have a widely used vaccine in circulation in the United States or another country prior to our full validation of the overall long term safety and efficacy profile of our vaccine platform and technology. Unexpected safety issues in these circumstances could lead to significant reputational damage for the Company going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

We may be unable to advance the COVID-19 Vaccine successfully through the preclinical and clinical development process.

Our ability to develop, obtain regulatory approval for, and ultimately commercialize, the COVID-19 Vaccine effectively will depend on many factors, including the following:

- successful completion of preclinical studies and clinical trials;

  successful achievement of the objectives of planned preclinical studies and clinical trials;

- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States;

- establishing efficient and effective commercial manufacturing, supply and distribution arrangements;

- establishing sufficient market share and promoting acceptance of the product by patients, the medical community and third-party payors;

- successfully executing an effective pricing and reimbursement strategy;

- maintaining a continued acceptable safety and adverse event profile following regulatory approval; and

- qualifying for, identifying, registering, maintaining, enforcing and defending intellectual property rights and claims.

The COVID-19 Vaccine will require additional non-clinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can be in a position to generate any revenue from product sales. We are not permitted to market or promote any vaccine before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. If we are unable to develop or receive marketing approval in a timely manner or at all, we could experience significant delays or an inability to commercialize the COVID-19 vaccine, which would materially and adversely affect our business, financial condition and results of operations.

Due to our dependence on a limited number of customers and the loss of any such customer would have a material adverse effect on our operating results and prospects.

As of December 31, 2019, we had two principal U.S. customers: Cardinal Health, Inc. ("Cardinal Health") and Fisher Healthcare ("Fisher"). Each has the non-exclusive right to distribute PIFA Heparin/PF4 Rapid Assays within the U.S. For the year ended December 31, 2019, Cardinal Health and Fisher accounted for approximately 79% of our product revenue.

Because of our dependence on a limited number of key customers, the loss of a major customer (or loss of a key program with a major customer), or any significant reduction in orders by a major customer or termination of any of their distribution agreements would materially affect our business, our results of operations and our financial condition. We expect that sales to relatively few customers will continue to account for a significant percentage of our net sales for the foreseeable future, however there can be no assurance that any of these customers or any of our other customers will continue to utilize our products or our services at current levels.

Due to our dependence on a limited number of customers, we are subject to a concentration of credit risk.

As of December 31, 2019, five customers accounted for 83% of trade receivables net of customer credits and allowance for doubtful accounts, as compared to December 31, 2018, where two customers accounted for 99% of such trade receivables. In the case of insolvency by one of our significant customers, a trade receivable with respect to that customer might not be collectible, might not be fully collectible, or might be collectible over longer than normal terms, each of which could adversely affect our financial position.

Our business would suffer if we were unable to acquire adequate sources of supply.

We use a diverse and broad range of raw materials in the manufacturing of our products. We purchase all of our raw materials and select items, such as packaging, from external suppliers. In addition, we purchase some supplies from single sources for reasons of proprietary know-how, quality assurance, sole source availability, or due to regulatory qualification requirements and disruption of these sources could have, at a minimum, a temporary adverse effect on shipments and the financial results of our company. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. Any prolonged inability to obtain certain materials or components could have an adverse effect on our financial condition or results of operations and could result in damage to our relationships with our customers and, accordingly, adversely affect our business.

We expect to require additional capital in the future in order to pursue strategic alternative transactions. If we do not obtain any such additional financing, it may be difficult to effectively realize our long-term strategic goals and objectives.

To execute our long-term business strategy, we expect to require additional financing and in connection therewith to issue additional equity securities in public or private offerings. If we cannot secure this additional funding when such funds are required, we may be forced to forego certain strategic opportunities.

Any additional capital raised through the sale of equity or equity-backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

Because we may not be able to maintain or obtain necessary regulatory clearances for some of our products, we may not generate revenue in the amounts we expect, or in the amounts necessary to continue our business.

All of our existing products are subject to regulation in the U.S. by the FDA and/or other domestic and international governmental, public health agencies, regulatory bodies or non-governmental organizations. In particular, we are subject to strict governmental controls on the development, manufacture, labeling, distribution and marketing of our products and may not be able to maintain the necessary regulatory clearances for some of our products.

The process of obtaining required approvals or clearances for a potential new product varies according to the nature of and uses for a specific product. These processes can involve lengthy and detailed laboratory testing, human clinical trials, sampling activities, and other costly, time-consuming procedures. The submission of an application to a regulatory authority does not guarantee that the authority will grant an approval or clearance for the product. Each authority may impose its own requirements and can delay or refuse to grant approval or clearance, even though a product has been approved in another country.

The time taken to obtain approval or clearance varies depending on the nature of the application and may result in the passage of a significant period of time from the date of submission of the application. Delays in the approval or clearance processes increase the risk that we will not succeed in introducing or selling the subject products, and we may be required to abandon a proposed product after devoting substantial time and resources to its development.

Changes in domestic and foreign government regulations could increase our costs and could require us to undergo additional trials or procedures, or could make it impractical or impossible for us to market our products for certain uses, in certain markets, or at all.

Changes in government regulations may adversely affect our financial condition and results of operations because we may have to incur additional expenses if we are required to change or implement new testing, manufacturing and control procedures. If we are required to devote resources to develop such new procedures, we may not have sufficient resources to devote to research and development, marketing, or other activities that are critical to our business.

We are subject to ongoing regulation by various government agencies, and, if we are unable to comply with such regulations, our products could be subject to restrictions or withdrawal from the market and/or we could be subject to a wide-range of enforcement actions, any of which would materially affect our business.

In the United States, medical devices, including *in vitro* diagnostics, are subject to extensive regulation by FDA under the Federal Food, Drug, and Cosmetic ("FD&C") Act and its implementing regulations, along with other federal and state statutes and regulations. To be lawfully marketed in the United States, medical devices must generally receive 510(k) clearance or premarket approval ("PMA") from the FDA. All of our currently commercial devices have received 510(k) clearance.

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include: compliance with the Quality System Regulation ("QSR"), which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; the reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk of health posed by the device or to remedy a violation of the FD&C Act; and the Medical Device Reporting ("MDR") regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur. Manufacturers are also required to register and list their devices with the FDA, based on which the FDA will conduct inspections to ensure continued compliance with applicable regulatory requirements.

The FDA has broad post-market and regulatory and enforcement powers. Failure to comply with the applicable U.S. medical device regulatory requirements could result in, among other things, warning letters; fines; injunctions; consent decrees; civil penalties; repairs, replacements or refunds; recalls, corrections or seizures of products; total or partial suspension of production; the FDA's refusal to grant future premarket clearances or approvals; withdrawals or suspensions of current product applications; and criminal prosecution. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some people with brain related disorders from using our products and adversely affect our reputation and the perceived accuracy and safety of our products. If any of these events were to occur, they could have a material adverse effect on our business, financial condition and results of operations.

Additionally, as a U.S. medical device manufacturer, we must operate our production facility in accordance with the QSR requirements established by the FDA under the FD&C Act. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and recordkeeping. As such, we have implemented a quality system that is intended to comply with applicable regulations. Our manufacturing plant is subject to periodic inspections by the FDA, and at last inspection, the facility was found to be in substantial compliance with current good manufacturing practice ("cGMP") requirements. cGMP requirements could change and negatively impact our ability to manufacture our products without modifications to our operating procedures or changes to our equipment or human resource allocations which may materially affect our business. If the FDA believes that our manufacturing practices are not compliant with applicable QSR requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

If we fail to obtain regulatory approval in foreign jurisdictions, then we cannot market our products in those jurisdictions.

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. Companies are now required to obtain a CE Mark, which shows conformance with the requirements of applicable European Conformity directives, prior to the sale of some medical devices within the European Union. Some of our current products that require CE Markings have them. We may be required to conduct additional testing or to provide additional information, resulting in additional expenses, to obtain necessary approvals. If we fail to obtain approval in such foreign jurisdictions, we would not be able to sell our products in such jurisdictions, thereby reducing the potential revenue from the sale of our products.

We may be unable to market our products outside the United States if our products cannot meet certain requirements of the Federal Food, Drug and Cosmetic Act requirements for exporting medical devices.

Any medical device that is legally marketed in the U.S. may be exported anywhere in the world without prior FDA notification or approval. Medical devices that are not FDA-cleared for marketing legally in the U.S. may be exported under section 801(e)(1) of the FD&C Act, provided that they are intended for export only, they are class I or class II devices, and they are:

- In accordance with the specifications of the foreign purchaser;
- Not in conflict with the laws of the country to which they are intended for export;
- Labeled on the outside of the shipping package that they are intended for export; and
- Not sold or distributed in the U.S.

We cannot guarantee that certain current and future products will meet all of the aforementioned specifications for export which could adversely impact our ability to market our products outside the U.S.

Modifications to our devices may require additional FDA clearance or approval, which could force us to cease marketing and/or recall the modified device until we obtain new approvals.

After a device receives a 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a Premarket approval ("PMA"). The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA also can require the manufacturer to cease marketing and/or recall the modified devices until 510(k) clearance or PMA approval is obtained, among other enforcement actions. We have modified one of our prescription use, 510(k)-cleared devices, specifically the PIFA Heparin/PF4 Rapid Assay, to include our seraSTAT device. However, we determined that, in our view, based on FDA guidance as to when to submit a 510(k) notification for changes to a cleared device, a new 510(k) clearance was not required. We cannot assure you that the FDA would agree with any of our decisions not to seek 510(k) clearance or PMA approval. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval, which could harm our operating results and require us to redesign the product.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions which may materially affect our business operations.

We are subject to inspection and market surveillance by the FDA to determine compliance with regulatory requirements. If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

- fines, injunctions and civil penalties;
- recall, detention or seizure of our products;
- the issuance of public notices or warnings;
- operating restrictions, partial suspension or total shutdown of production;

- refusing our requests for a 510(k) clearance of new products;
- withdrawing a 510(k) clearance already granted; and
- criminal prosecution.

The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

Our marketed products may be used by physicians for indications that are not cleared by the FDA. If the FDA finds that we promoted one or more of our products for off-label use(s), we may be subject to civil or criminal penalties.

Under the FD&C Act and other laws, we are prohibited from promoting our products for "off-label" uses. This means that we may not make claims about the use of any of our marketed medical device products outside of their cleared indications, and that our website, advertising promotional materials and training methods may not promote or encourage any unapproved uses. Therefore, we may not provide information to physicians or patients that promote off-label uses, except in limited circumstances. Should the FDA determine that we have engaged in the promotion of any of our device products for off-label uses, the FDA could bring a wide range of enforcement actions against us and/or our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve or clear products, the withdrawal of an approved product from the market, product recalls, fines, disgorgement of profits, operating restrictions, injunctions or criminal prosecutions. Any of these adverse regulatory actions could result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business.

In addition to potential FDA enforcement, the Department of Justice, as well as state attorneys general, may work with the FDA or on their own to bring enforcement action against us and/or our executives in connection with any off-label promotion of our products. Such action may include civil and criminal penalties, including significant fines, among other serious consequences. Even if we are successful in resolving such matters without incurring penalties, responding to investigations or prosecutions will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition, and ability to finance our operations. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

We may not have the resources to conduct clinical protocols sufficient to yield data suitable for publication in peer-reviewed journals and our inability to do so in the future could have an adverse effect on marketing our products effectively.

In order for our products targeted for use by hospital laboratory professionals and healthcare providers to be widely adopted, we would have to conduct clinical protocols that are designed to yield data suitable for publication in peer-reviewed journals. These studies are often time-consuming, labor-intensive and expensive to execute. We have not had the resources to effectively implement such clinical programs within our clinical development activities and may not be able to do so in the future. In addition, if a protocol is initiated, the results of which may ultimately not support the anticipated positioning and benefit proposition for the product. Either of these scenarios could hinder our ability to market our products and revenue may decline.

If we fail to establish, maintain and expand relationships with distributors, sales of our products would decline.

We do not control the efforts of our distributors and our distributors are not prohibited from selling competing products. Our ability to sell our products depends largely on our relationships with such distributors. Accordingly, we are subject to the risk that they may not commit the financial and other resources to market and sell our products to our level of expectation, they may experience financial hardship or they may otherwise terminate our relationship on short notice. In the U.S. clinical laboratory marketplace, many of our existing and potential customers purchase our products through our two national distributors, Cardinal Health and Fisher Health. In addition, we rely on our distribution network to negotiate pricing arrangements and contracts with Group Purchasing Organizations and their affiliated hospitals and other members. For the year ended December 31, 2019, two customers generated 48 % and 31 %, or 79 % in the aggregate, of our revenue. For the year ended December 31, 2018, two customers generated 57%, and 14%, or 71% in the aggregate, of our revenue. In the future, if we are unable to maintain existing relationships, our competitive position would likely suffer and our business would be harmed.

Our business is vulnerable to the availability of raw materials, our ability to forecast customer demand and our ability to manage production capacity.

Our ability to meet customer demand depends, in part, on our production capacity and on obtaining supplies, a number of which can only be obtained from a single supplier or a limited number of suppliers. A reduction or disruption in our production capacity or our supplies could delay products and fulfillment of orders and otherwise negatively impact our business.

We must accurately predict both the demand for our products and the lead times required to obtain the necessary components and materials. If we overestimate demand, we may experience underutilized capacity and excess inventory levels. If we underestimate demand, we may miss delivery deadlines and sales opportunities and incur additional costs for labor overtime, equipment overuse and logistical complexities. Additionally, our production capacity could be affected by manufacturing problems. Difficulties in the production process could reduce yields or interrupt production, and, as a result, we may not be able to deliver products on time or in a cost-effective, competitive manner. Our failure to adequately manage our capacity could have a material adverse effect on our business, financial condition and results of operations.

Our ability to meet customer demand also depends on our ability to obtain timely and adequate delivery of materials, parts and components from our suppliers. We generally do not maintain contracts with any of our key suppliers. From time to time, suppliers may extend lead times, limit the amounts supplied to us or increase prices due to capacity constraints or other factors. Supply disruptions may also occur due to shortages in critical materials. In addition, a number of our raw materials are obtained from a single supplier. Many of our suppliers must undertake a time-consuming qualification process before we can incorporate their raw materials into our production process. If we are unable to obtain materials from a qualified supplier, it can take up to a year to qualify a new supplier, assuming an alternative source of supply is available. A reduction or interruption in supplies or a significant increase in the price of one or more supplies could have a material adverse effect on our business, financial condition and results of operations.

Some of our finished goods, including our PIFA products and control materials related to PIFA Heparin/PF4 assays, are temperature-sensitive.

Proper packaging and time in transit are critical to the stability of some of our clinical laboratory products when they are en route to our distributors or end users. If certain specialized packaging materials cannot be obtained, and/or if our contracted common carriers, or those of our distributors, cannot meet product-specific delivery requirements, our products may not perform as intended and may lead to requests for product replacement. If such issues become widespread, it could hurt our reputation and we could potentially lose customers which would adversely affect our business.

Also, given the issue of temperature sensitivity, time in transit may limit our ability to service potential markets outside of the U.S. for those products, especially those with geographies that do not allow for shipment and customs clearance within four business days. This could adversely affect our potential to generate revenue for some products on an international level.

Demands of third-party payors, cost reduction pressures among our customers and restrictive reimbursement practices may adversely affect our revenue.

Our ability to negotiate favorable contracts with non-governmental payors, including managed-care plans or Group Purchasing Organizations ("GPOs"), even if facilitated by our distributors, may significantly affect revenue and operating results. Our customers continue to face cost reduction pressures that may cause them to curtail their use of, or reimbursement for some of our products, to negotiate reduced prices or other concessions or to delay payment. Furthermore, the increasing leverage of organized buying groups among non-governmental payors may reduce market prices for our products and services, thereby reducing our profitability. Reductions in price increases or the amounts received from current customers or lower pricing for our products to new customers could have a material adverse effect on the financial position, cash flows and results of operations.

Failure to obtain medical reimbursement for our products, as well as a changing regulatory and reimbursement environment, may impact our business.

The U.S. healthcare regulatory environment may change in a way that restricts our ability to market our products due to medical coverage or reimbursement limits. Sales of our diagnostic tests will depend in part on the extent to which the costs of such tests are covered by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health payor administration authorities, private health coverage insurers and other third-party payors. These healthcare payors are increasingly challenging the prices charged for medical products and services. The containment of healthcare costs has become a priority of federal and state governments. Accordingly, our products may not be considered to be cost effective, and reimbursement may not be available or sufficient to allow us to sell our products on a competitive basis. Legislation and regulations affecting reimbursement for our products may change at any time and in ways that are difficult to predict and these changes may have an adverse effect to us.

CMS, the federal agency responsible for administering the Medicare program, along with its contractors establishes coverage and reimbursement policies for the Medicare program. In addition, private payors often follow the coverage and reimbursement policies of Medicare. We cannot assure you that government or private third-party payors will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate.

For some of our products, our success in non-U.S. markets may depend upon the availability of coverage and reimbursement from the third-party payors through which health care providers are paid in those markets. Health care payment systems in non-U.S. markets vary significantly by country, and include single-payor, government managed systems as well as systems in which private payors and government-managed systems exist, side-by-side. For some of our products, our ability to achieve market acceptance or significant sales volume in international markets may be dependent on the availability of reimbursement for our products under health care payment systems in such markets. There can be no assurance that reimbursement for our products will be obtained or that such reimbursement will be adequate.

We may experience delays in any phase of the preclinical or clinical development of a product, including during its research and development.

The completion of any of these studies may be delayed or halted for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical study protocol or place a clinical study on hold;
- patients do not enroll in a clinical study or results from patients are not received at the expected rate;
- patients discontinue participation in a clinical study prior to the scheduled endpoint at a higher than expected rate;
- patients experience adverse events from a product we develop;
- third-party clinical investigators do not perform the studies in accordance with the anticipated schedule or consistent with the study protocol and good clinical practices or other third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- third-party clinical investigators engage in activities that, even if not directly associated with our studies, result in their debarment, loss of licensure, or other legal or regulatory sanction;
- regulatory inspections of manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend the preclinical or clinical studies;
- changes in governmental regulations or administrative actions;
- the interim results of the preclinical or clinical study, if any, are inconclusive or negative; and
- the study design, although approved and completed, is inadequate to demonstrate effectiveness and safety.

If the preclinical and clinical studies that we are required to conduct to gain regulatory approval are delayed or unsuccessful, we may not be able to market any product that we develop in the future. Preclinical studies and clinical trials are expensive and difficult to design and implement and any delays or prolongment in our preclinical and clinical studies will require additional capital. There is no assurance that we will be able to acquire additional capital to support our studies. The failure to obtain additional capital would have a material adverse effect on the Company.

We anticipate that we will rely completely on third parties to manufacture certain preclinical and all clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in the conduct of our clinical studies, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. In order to develop products, apply for regulatory approvals and commercialize our products, we will need to develop, contract for, or otherwise arrange for access to the necessary manufacturing capabilities. We anticipate that we will rely on CMOs, or contract manufacturing organizations, and other third party contractors, some of whom may have limited cGMP experience, to manufacture formulations and produce larger scale amounts of drug substance and the drug product required for any clinical trials that we initiate.

The manufacturing process for any vaccine candidate is subject to the FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. In addition, if we receive the necessary regulatory approval for any product candidate, we also expect to rely on third parties to produce materials required for commercial supply. We may experience difficulty in obtaining adequate manufacturing capacity for our needs. Furthermore, it is our responsibility to ensure that all of our third-party contractors meet cGMP laws, regulations and guidance. Due to their failure to comply with applicable regulatory requirements, we may face fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. These actions could have a material impact on the availability of products. If we are unable to obtain or maintain contract manufacturing for these product candidates, or to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize our products.

To the extent that we enter into manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner and consistent with regulatory requirements, including those related to quality control and quality assurance. The failure of a third-party manufacturer to perform its obligations as expected could adversely affect our business in a number of ways, including:

- we may not be able to initiate or continue preclinical and clinical trials of products that are under development;
- we may need to repeat pivotal clinical trials;
- we may be delayed in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- we may lose the cooperation of our collaborators;
- our products could be the subject of inspections by regulatory authorities;
- we may be required to cease distribution or recall some or all batches of our products; and
- ultimately, we may not be able to meet commercial demands for our products.

If a third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to seek out one or more other third-party manufacturers to manufacture our preclinical and/or clinical trial materials, which could cause delays in the FDA approval process. Further, should our vaccine candidate be approved for marketing by the FDA, a change in a third-party manufacturer could cause significant delays to meeting the demand of patients. In some cases, the technical skills required to manufacture our product may be unique to the original manufacturer and we may have difficulty transferring such skills to a back-up or alternate manufacturer, or we may be unable to transfer such skills at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also be required to demonstrate that the newly manufactured material is the same or similar to the previously manufactured material, or we may need to repeat clinical trials with the newly manufactured material. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently, which would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our products.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

We plan to rely upon third-party contract research organizations, or CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our licensed ongoing preclinical and clinical programs. We expect to continue to rely on these parties for execution of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, current Good Clinical Practices or cGCP, and current Good Laboratory Practices, or cGLP, which are a collection of laws and regulations enforced by the FDA or comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of manufacturing facilities, preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products manufactured consistently with cGMP regulations. Failure by us or our third party CRO to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

If any of our relationships with these third-party CROs, medical institutions, clinical investigators or contract laboratories terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties, or comply with cGCP laws, regulations and guidance, or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

The COVID-19 Vaccine that we develop in the future will be subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization.

Rigorous preclinical studies, clinical trials and extensive regulatory approval processes are required to be successfully completed in the United States and in many foreign jurisdictions before a new product may be offered and sold in any of these countries or regions. Satisfaction of these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays.

In the United States, the products that we intend to develop and market are regulated by the FDA under its drug development and review process. The time required to obtain FDA and other approvals for any product that we develop in the future is inherently unpredictable. Before such products can be marketed, we must obtain clearance from the FDA first through submission of an investigational new drug ("IND"), then through successful completion of human testing under three phases of clinical trials and finally through submission of a new drug application ("NDA"). Even after successful completion of clinical testing, there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our NDA submission.

There can be no assurance that the FDA will grant a license for any NDA that we may submit. It is possible that none of the products that we develop in the future will obtain the appropriate regulatory approvals necessary for us to commence the offer and sale of such products. Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from a particular prospective product.

If we decide to market any drug that we develop in jurisdictions in addition to the United States, we may incur the same costs or more in satisfying foreign regulatory requirements governing the conduct of preclinical and clinical trials, manufacturing and marketing and commercialization of any product that we develop in the future. Approval by the FDA by itself does not assure approval by regulatory authorities outside the United States. Each of these foreign regulatory approval processes includes all of the risks associated with the FDA approval process, as well as risks attributable to having to satisfy local regulations within each of these foreign jurisdictions. Our inability to obtain regulatory approval outside the United States may adversely compromise our business prospects

We may fail to retain qualified personnel.

We have substantially reduced the number of our employees in order to reduce our costs. Accordingly, retaining our remaining personnel in the future will be critical to our success. If we fail to retain and motivate these highly skilled personnel, we may be unable to continue our operating activities, and this could have a material adverse effect on our business, financial condition, results of operations and future prospects.

We rely on the key executive officer of the management team.

We are dependent on our management team to execute against our business plan. Failure could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

Expenses incurred with respect to monitoring, protecting, and defending our intellectual property rights could adversely affect our business.

Competitors and others may infringe on our intellectual property rights, or may allege that we have infringed on theirs. Monitoring infringement and misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect infringement or misappropriation of our proprietary rights.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

Some or all of our patent applications may not result in the issue of patents, or the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors, if any, may be challenged and subsequently narrowed, invalidated, found unenforceable or circumvented. Patent litigation is widespread in the biotechnology industry and could harm our business. Litigation might be necessary to protect our patent position. Patentability, invalidity, freedom-to-operate or other opinions may be required to determine the scope and validity of third-party proprietary rights. If we choose to go to court to stop a third party from using the inventions protected by our patent, that third party would have the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and we may not have the required resources to pursue such litigation or to protect our patent rights. In addition, there is a risk that the court will decide that our patents are not valid or that we cannot stop the other party from using their inventions. There is also the risk that, even if the validity of these patents is upheld, the court will find that the third party's activities do not infringe our rights in these patents.

Furthermore, a third party may claim that we are infringing the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products or product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party's treble damages or attorneys' fees for having violated the other party's patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the claims of the relevant patent and/or that the third-party patent claims are invalid, and we may not be able to do this. Proving invalidity in the United Sates is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

In addition, changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have no knowledge of any claims against us, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. To date, none of our employees have been subject to such claims.

We may be at risk that our former employees may wrongfully use or disclose our trade secrets.

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee, former employee, consultant, former consultant or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

The marketing, sale, and use of our PIFA products and any other devices we currently manufacture or may manufacture in the future could result in serious injuries, product liability claims, regulatory enforcement action, and/or recalls or market withdrawals, any of which would likely subject us to substantial costs and reputational harm and have a material adverse effect on our business.

Our success depends on the market's confidence that we can continue to provide reliable, high-quality diagnostic tests. We believe that our customers are likely to be particularly sensitive to test defects and errors, as the conditions that the PIFA products are designed to identify may cause limb- and life-threatening complications if not accurately diagnosed in a timely manner. As a result, the failure of our tests or services to perform as expected could impair our reputation and the public image of our tests and services, and we may be subject to legal claims arising from any defects or errors.

The marketing, sale, and use of our PIFA products and our other products could lead to product liability (and other similar) claims against us if someone were to allege that one of our tests failed to perform as it was designed or as claimed in our promotional materials, was performed pursuant to incorrect or inadequate laboratory procedures, if we delivered incorrect or incomplete test results, or if someone were to misinterpret test results. In addition, we may be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide, or for failure to provide such information, in connection with our marketing and promotional activities or as part of the results generated by our products. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

While our PIFA products are highly accurate, they are not 100% accurate and may generate erroneous results that could cause patient harm. For example, PIFA could provide a so-called "false negative" result upon which a patient or physician may rely to make a conclusion about how to proceed with the patient's treatment. If the false negative causes, or exacerbates, a patient injury or condition, the patient (and/or the patient's family) may file a lawsuit against us based on product liability. On July 25, 2019, we received a product-liability petition, alleging that multiple false-negative PIFA Heparin/PF4 Rapid Assay results caused a patient's treating hospital to delay the appropriate diagnosis by several days, which, the petition argues, was a substantial contributing factor in the ultimate amputation of the patient's left leg. We are contesting this action vigorously and believe our product liability insurance will be adequate to cover any costs incurred in connection with this matter. However, we cannot guarantee that our insurance will fully protect us from the financial impact of defending against product liability claims or any judgments, fines, or settlement costs arising out of any such claims.

Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates, cause our insurance coverage to be terminated or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could harm our reputation, result in a cessation of our services or cause our partners to terminate our agreements with them, any of which could adversely impact our results of operations.

Further, under the FDA's MDR regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. For example, once brought to our attention, we reported the injury described above in connection with alleged false-negative PIFA Heparin/PF4 Rapid Assay results. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

We currently manufacture our products at a single location. Any disruption at this facility could adversely affect our business and results of operations.

We currently manufacture all our products at our manufacturing plant. If our manufacturing plant were damaged or destroyed, or otherwise subject to disruption, it would require substantial lead-time to replace or rebuild the facility for the manufacture of our products. In such event, we would be forced to rely entirely on third-party contract manufacturers for an indefinite period of time. We do not currently have established relationships with any back-up manufacturers. Even if we are able to establish a relationship with a third-party manufacturer, there is no assurance that such manufacturer will be able to meet our needs from a technical, timing, or cost effective manner.

We are currently subject to a number of securities litigations and we may be subject to similar or other litigation in the future.

We are currently subject to a number of litigations as described in the "Legal Proceedings" section. In connection with certain of these litigations, we have entered into settlements of claims for significant monetary damages. We may also be subject to judgements or enter into additional settlements of claims for significant monetary damages for the securities litigations that we have yet to enter into settlement agreements. Defending against the current litigations is or can be time-consuming, expensive and cause diversion of our management's attention.

With respect to any litigation, our insurance may not reimburse us or may not be sufficient to reimburse us for the expenses or losses we may suffer in contesting and concluding such lawsuit. Substantial litigation costs, including the substantial self-insured retention that we are required to satisfy before any insurance applies to a claim, unreimbursed legal fees or an adverse result in any litigation may adversely impact our business, operating results or financial condition. We believe that our directors' and officers' liability insurance will cover our potential liability with respect to the securities class-action lawsuit; however, the insurer has reserved its rights to contest the applicability of the insurance to such claims and the limits of the insurance may be insufficient to cover our eventual liability.

We face substantial competition from other companies and our operating results may suffer if we fail to compete effectively.

Competition among providers of rapid, point-of-care screening and testing products is intense and subject to rapid technological change and evolving industry requirements and standards. We compete with many companies that have greater financial, product development, sales and marketing resources and experience than we do. Furthermore, new product development and technological change characterize the areas in which we compete. Our present or future products could be rendered obsolete or uneconomical as a result of technological advances by one or more of our present or future competitors. We must continue to develop and commercialize new products and technologies to remain competitive in the diagnostic testing industry. We believe that we compete primarily on the basis of our single-use testing. Customer and clinical support, and data that demonstrate both improvement in a patient's quality of life and a product's cost-effectiveness are additional aspects of competition.

We are aware of other rapid, point-of-care screening and diagnostic testing products in the U.S., Canada, and Europe. Specifically, Abbott, ACON Laboratories, Inc., Immucor, Inc., OraSure Technologies, Inc., and Quidel Corporation are companies that develop rapid, point-of-care screening and diagnostic testing products and currently maintain dominant market positions within the diagnostic testing market.

If we market products or interact with health care practitioners in a manner that violates healthcare fraud or abuse laws, we may be subject to civil or criminal penalties, including exclusion from participation in government healthcare programs.

We receive payments directly from or bill directly to Medicare, Medicaid or other national or third-party payers for our current product, U.S. federal and state healthcare laws and regulations pertaining to fraud or abuse are and will be applicable to our business. We are subject to healthcare fraud and abuse regulation by the U.S. federal government and the states in which we conduct our business.

The laws that may affect our ability to operate include the federal healthcare program anti-kickback statute, which prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, the purchase, lease or order, or arrangement for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute applies to arrangements between pharmaceutical manufacturers and prescribers, purchasers and formulary managers. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product, reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates, engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses and submitting inflated best price information to the Medicaid Drug Rebate Program.

The Health Insurance Portability and Accountability Act of 1996 also created prohibitions against healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. The false statements statute immediately noted above prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. The ACA, through the Physician Payment Sunshine Act of 2010, imposed new requirements on manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members and payments or other "transfers of value" to such physician owners and their immediate family members. Manufacturers are required to report such data to the government by the 90th calendar day of each year.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, as amended. Moreover, certain states mandate the tracking and reporting of gifts, compensation and other remuneration paid by us to physicians and other healthcare providers.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, cause reputational harm and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable U.S. federal and state laws may prove costly.

Data security breaches may disrupt our operations and adversely affect our operating results.

Our network security and data recovery measures and those of third parties with which we contract, may not be adequate to protect against computer viruses, cyber-attacks, breaches, and similar disruptions from unauthorized tampering with our computer systems. The misappropriation, theft, sabotage or any other type of security breach with respect to any of our proprietary and confidential information that is electronically stored, including patient data, could cause interruptions in our operations, could result in a material disruption of our business operations and could expose us to third-party legal claims. Furthermore, we could be required to make substantial expenditures of resources to remedy the cause of cyber-attacks or break-ins. This disruption could have a material adverse impact on our business, operating results and financial condition.

Our business processes personal medical information. The use of this information is critical to our operations and innovation. New and evolving regulations could bring increased scrutiny of our data management in the future. Any cyber-attacks or other failure to protect critical and sensitive systems and information could damage our reputation, prompt litigation or lead to regulatory sanctions, all of which could materially affect our financial condition and results of operation.

We are subject to various internal control reporting requirements under the Sarbanes-Oxley Act. We can provide no assurance that we will at all times in the future be able to report that our internal controls over financial reporting are effective.

As a public company, we are required to comply with Section 404 of the U.S.*Sarbanes-Oxley Act of 2002* ("Section 404"). In any given year, we cannot be certain as to the time of completion of our internal control evaluation, testing and remediation actions or of their impact on our operations. Upon completion of this process, we may identify control deficiencies of varying degrees of severity under applicable SEC and Public Company Accounting Oversight Board (U.S.) rules and regulations. Our management, including our chief executive officer and principal financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, as a public company, we are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal controls that, or that are reasonably likely to, materially affect internal controls over financial reporting. A "material weakness" is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual consolidated financial statements will not be prevented or detected on a timely basis. If we fail to comply with the requirements of Section 404 or if we report a material weakness, we might be subject to regulatory sanction and investors may lose confidence in our consolidated financial statements, which may be inaccurate if we fail to remedy such material weakness.

We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC and the Nasdaq Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time-consuming and costly. It is also more expensive for us to obtain director and officer liability insurance.

Our business may be materially adversely affected by the recent coronavirus (COVID-19) outbreak.

The outbreak of the COVID-19 could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. COVID-19 illness could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

Supplies could be disrupted if the manufacturers or suppliers of our products experience absenteeism due to illness of their employees or due to local quarantines. Absenteeism due to coronavirus illness could also impact companies that the suppliers use to ship products to us. We cannot presently predict the extent to which the virus may impact our operations.

The anticipated economic consequences of the COVID-19 pandemic have adversely impacted financial markets, resulting in high share price volatility, reduced market liquidity, and substantial declines in the market prices of the shares of most publicly traded companies, including Akers. Volatile or declining markets for equities could adversely affect our ability to raise capital when needed through the sale of shares of common stock or other equity securities. While these market conditions persist when we need to raise capital, and if we are able to sell shares of our common stock under then prevailing market conditions, we might have to accept lower prices for our shares and issue a larger number of shares than might have been the case under better market conditions, resulting in significant dilution of the interests of our shareholders.

Risks Related to our Pursuit of Strategic Alternatives

We may opportunistically review strategic transactions and there can be no assurance that that any such strategic transaction we may purse will result in additional value for our stockholders.

In November 2018, we announced that our Board of Directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. The Company sought to explore how to leverage its 30 years of operational history in its medical device business, where its current products have FDA clearance, its current operations practice Good Manufacturing Processes (cGMP), its medical device facility is certified under ISO 13485 – 2016 and the facility carries an Analytical Lab Certification for Schedules 2, 3, 4 and 5 controlled substances issued by the U.S. Drug Enforcement Administration (DEA) and the State of New Jersey. The Company intends to pursue opportunities in the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry, including pathways to consumer products with a focus on minor cannabinoids. To the extent we engage in other strategic transactions, the process may be time consuming and disruptive to our business operations and, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with evaluating and negotiating potential strategic alternatives. Furthermore, our ability to effectively integrate any future acquisitions will depend on, among other things, the adequacy of our implementation plans, the ability of our management to oversee and operate effectively the combined operations and our ability to achieve desired operational efficiencies. If we are unable to successfully integrate the operations of any businesses that we may acquire in the future, our business, financial position, results of operations or cash flows could be adversely affected. There can be no assurance that any potential transaction, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock.

If we are unable to make acquisitions and investments, or successfully integrate them into our business, our business could be harmed.

As part of our business strategy, we may acquire other companies or businesses. However, we may not be able to find suitable acquisition candidates, and we may not be able to complete acquisitions on favorable terms, if at all. Acquisitions involve numerous risks, any of which could harm our business and negatively affect our operating results, including:

- difficulties in integrating the technologies, operations, existing contracts and personnel of an acquired company;
- difficulties in supporting and transitioning clients and suppliers, if any, of an acquired company;
- diversion of financial and management resources from existing operations or alternative acquisition opportunities;
- failure to realize the anticipated benefits or synergies of a transaction;
- failure to identify all of the problems, liabilities or other shortcomings or challenges of an acquired company or technology, including issues related to intellectual property, regulatory compliance practices, revenue recognition or other accounting practices, or employee or client issues;
- risks of entering new markets in which we have limited or no experience;
- potential loss of key employees, clients, vendors and suppliers from either our current business or an acquired company’s business;
- inability to generate sufficient revenue to offset acquisition costs;
- additional costs or equity dilution associated with funding the acquisition; and
- possible write-offs or impairment charges relating to acquired businesses.

If we acquire a new business, or retain individuals with expertise in a new industry to pursue a strategic alternative, we will have a limited operating history in such new industry, specifically the cannabis industry, and may not succeed.

We will have a limited operating history within the cannabis industry and may not succeed. We will be subject to all risks inherent in a developing business enterprise. The likelihood of our continued viability must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with manufacturing specialty products and the competitive and regulatory environment in which we operate. For example, the cannabis industry is a new industry that, as a whole, may not succeed, particularly if the Federal government changes course and decides to prosecute those dealing in cannabis under Federal law. If that happens, there may not be an adequate market for our products. As a new industry, there are not established players on whose business models we can follow or build upon. Similarly, there is limited information about comparable companies available for potential investors to review in making a decision about whether to invest in our company. Furthermore, as the industrial hemp industry is a new market, it is ripe for technological advancements that could limit or eliminate the need for our products. Furthermore, unanticipated expenses, problems, and technical difficulties may occur and they may result in material delays in the operation of our business, in particular with respect to our new products. We may not be able to successfully address these risks and uncertainties or successfully implement our operating strategies. If we fail to do so, such failure could materially harm our business to the point of having to cease operations and could impair the value of our common stock to the point investors may lose their entire investment.

If we acquire a business in the cannabis industry or otherwise pursues a strategic alternative, we would face additional unique and evolving risks.

Further legislative development beneficial to the cannabis industry is not guaranteed

If we acquire a business in the cannabis industry or otherwise pursues a strategic alternative, the success of such business would depend on the continued development of the cannabis industry and the activity of commercial business and government regulatory agencies within the industry. The continued development of the cannabis industry is dependent upon continued legislative and regulatory authorization of cannabis at the state level and a continued laissez-faire approach by federal enforcement agencies. Any number of factors could slow or halt progress in this area. Further regulatory progress beneficial to the industry cannot be assured. While there may be ample public support for legislative action, numerous factors impact the legislative and regulatory process, including election results, scientific findings or general public events. Any one of these factors could slow or halt progressive legislation relating to cannabis and the current tolerance for the use of cannabis by consumers, which could adversely affect the business we may acquire or pursue. These changes may require us, should we acquire a business or otherwise pursues a strategic alternative in the cannabis industry, to incur substantial costs associated with legal and compliance fees and ultimately require us to alter our business plan. Furthermore, violations of these laws, or alleged violations, could disrupt our business and result in a material adverse effect on our operations. In addition, we cannot predict the nature of any future laws, regulations, interpretations or applications, and it is possible that regulations may be enacted in the future that will be directly applicable to the business we may acquire or pursue.

The cannabis industry could face strong opposition from other industries

We believe that established businesses in other industries may have a strong economic interest in opposing the development of the cannabis industry. Cannabis may be seen by companies in other industries as an attractive alternative to their products, including recreational marijuana as an alternative to alcohol, and medical marijuana as an alternative to various commercial pharmaceuticals. Many industries that could view the emerging cannabis industry as an economic threat are well established, with vast economic and federal and state lobbying resources. It is possible that companies within these industries could use their resources to attempt to slow or reverse legislation legalizing cannabis. Any inroads these companies make in halting or impeding legislative initiatives that would be beneficial to the cannabis industry could have a detrimental impact on our potential business.

The legality of marijuana could be reversed in one or more states

There is a substantial amount of change occurring in the U.S. regarding the use of medical and recreational marijuana products. While federal law prohibits the sale and distribution of cannabis products not approved or authorized by the FDA, at least 30 jurisdictions and the District of Columbia have enacted state laws to enable possession and use of marijuana in some form for medical purposes, and at least ten jurisdictions for recreational purposes. However, notwithstanding the permissive regulatory environment in some states, marijuana continues to be classified as a Schedule I controlled substance under the federal Controlled Substances Act and, thus, engaging in commercial activities involving such products violates federal law. Further, the voters or legislatures of states in which marijuana has already been legalized could potentially repeal applicable laws which permit the operation of both medical and retail marijuana businesses. These actions might force our potential business to cease operations in one or more states entirely.

Banking regulations could limit access to banking services

Since the use of marijuana is illegal under federal law, there is a compelling argument that banks cannot lawfully accept for deposit funds from businesses involved with marijuana. Consequently, businesses involved in the cannabis industry often have trouble finding a bank willing to accept their business. The inability to open bank accounts may make it difficult for our potential business to operate and our reliance on cash could result in a heightened risk of theft. Additionally, some courts have denied marijuana-related businesses bankruptcy protection, thus, making it very difficult for lenders to recoup their investments, which may limit the willingness of banks to lend to us.

Insurance risks

In the United States, many marijuana-related businesses are subject to a lack of adequate insurance coverage. In addition, many insurance companies may deny claims for any loss relating to marijuana or marijuana-related operations based on their illegality under federal law, noting that a contract for an illegal transaction is unenforceable. Thus, if we acquire a business or otherwise pursues a strategic alternative in the cannabis industry, we may have a difficult time obtaining certain insurances that are desired to operate our business, which may expose us to additional risks and financial liabilities.

Risks Related to our Common Stock and our Company Generally

The market price for our common stock may be volatile, and your investment in our common stock could decline in value.

The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours without product revenues and earnings, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval or disapproval of our product candidates or other product-related actions;
- developments involving our discovery efforts and clinical studies;
- developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;
- announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general;

- public concerns as to the safety or efficacy of our products or our competitors' products;
- changes in government regulation of the pharmaceutical or medical industry;
- changes in the reimbursement policies of third party insurance companies or government agencies;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- developments involving corporate collaborators, if any;
- changes in accounting principles; and
- the loss of any of our key scientific or management personnel.

In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

Our failure to meet the continued listing requirements of The NASDAQ Capital Market could result in a delisting of our common stock. The delisting could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is listed on NASDAQ. In order to maintain our listing, we must meet minimum financial and other requirements, including requirements for a minimum amount of capital and a minimum price per share. We cannot assure you that we will continue to meet the continued listing requirements in the future.

If NASDAQ delists our common stock from trading on its exchange, due to failure to meet its continued listing requirements, and we are not able to list our common stock on another national securities exchange, we expect our securities could be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our common stock;
- reduced liquidity for our common stock;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible or exercisable into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on the NASDAQ, the market for our shares has demonstrated varying levels of trading activity. There has been limited trading of our common stock in the U.S since we began trading on NASDAQ in January 2014. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our Board of Directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our Board of Directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales by our stockholders of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

We may issue additional series of preferred stock that rank senior or equally to the Series C Preferred Stock as to dividend payments and liquidation preference.

Neither our certificate of incorporation nor the Certificate of Designation for the Series C Preferred Stock prohibits us from issuing additional series of preferred stock that would rank senior or equally to the Series C Preferred Stock as to dividend payments and liquidation preference. Our certificate of incorporation provides that we have the authority to issue up to 50,000,000 shares of preferred stock, no shares of which are outstanding prior to this offering. The issuances of other series of preferred stock could have the effect of reducing the amounts available to the Series C Preferred Stock in the event of our liquidation, winding-up or dissolution. It may also reduce cash dividend payments on the Series C Preferred Stock if we do not have sufficient funds to pay dividends on all Series C Preferred Stock outstanding and outstanding parity preferred stock.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Property

Our corporate headquarters which houses our manufacturing, operations and support personnel, is located in Thorofare, New Jersey, in an office consisting of a total of 12,500 square feet. For the past twelve years, we have leased this facility at this location. The current lease term is effective from January 1, 2020 through December 31, 2021 with an annual rent of $132,000.

We believe our current facilities are sufficient for our current needs and will be adequate, or that suitable additional or substitute space will be available on commercially reasonable terms, for the foreseeable future.

Item 3. Legal Proceedings.

From time to time we are a party to litigation and subject to claims incident to the ordinary course of business. Future litigation may be necessary to defend ourselves and our customers by determining the scope, enforceability, and validity of third party proprietary rights or to establish our proprietary rights.

Faulkner v. Akers Biosciences, Inc., No. 2:18-cv-10521 (D.N.J.) and *Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.)*

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against our company, John J. Gormally and Gary M. Rauch ("Individual Defendants" and together with our company, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018 (the "Faulkner Action"). The complaint alleged violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleged that Defendants made false and/or misleading statements and/or failed to disclose in our first, second, and third quarter 2017 10-Qs and our 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in our internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On June 20, 2018, Plaintiff David Gleason filed a class action complaint under the caption Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.) based on the same allegations and causes of action (the "Gleason Action"). On November 21, 2018, the Faulkner and Gleason Actions were consolidated under the Faulkner Action docket. The parties conducted a mediation on January 10, 2019, and agreed to a settlement in principle disposing of the consolidated action as to all Defendants, including the Individual Defendants. On March 8, 2019, the parties signed a settlement agreement, subject to approval by the Court, whereby we agreed to pay $2,250,000 in exchange for full releases and discharge of all claims against us. On the same day, Plaintiffs Tim Faulkner and David Gleason filed a motion for preliminary approval of the settlement and to establish notice procedures. On July 3, 2019, the Court granted the motion for preliminary approval and scheduled a final settlement hearing for November 8, 2019. On or about July 24, 2019, our directors and officers' insurer sent the settlement payment of $2,250,000 to the settlement agent for the class. On September 20, 2019, the Court granted the parties' request to adjourn the final settlement hearing and scheduled a final settlement hearing for December 20, 2019, at 11:00 a.m. On October 11, 2019, Lead Plaintiffs filed motions for final approval of the proposed settlement and award of attorneys' fees, and reimbursement of expenses. On December 20, 2019, the Court granted final approval of the settlement and award of attorneys' fees, and reimbursement of expenses.

Watts v. Gormally, et al., No. 2:18-15992 (D.N.J.) *and Chan v. Gormally, et al*., No. 2:19-cv-4989 (D.N.J.)

On November 9, 2018, Cale Watts ("Watts Plaintiff") filed a verified shareholder derivative complaint alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on alleged material weaknesses in controls, management, and documentation (the "Watts Action"). On January 14, 2019, the parties reached an agreement in principle to settle the Watts Action that included corporate reforms and a payment of attorneys' fees of $200,000. The parties finalized a Stipulation of Settlement on March 4, 2019. On February 7, 2019, Tiffany Chan, Jasmine Henderson, and Don Danesh ("Chan Plaintiffs") filed a verified shareholder derivative complaint alleging violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on the same circumstances as the Watts Action (the "Chan Action"). The Chan Action further alleged that we should not have settled the Watts Action because the Watts Action plaintiffs lacked standing and the settlement would cause irreparable harm to us and our shareholders. On March 22, 2019, the Watts Plaintiff filed a motion for preliminary approval of the proposed settlement, approving the proposed form and method of providing notice of the settlement, scheduling a hearing for final approval of the settlement ("Watts Motion for Preliminary Approval"). On April 1, 2019, the Chan Plaintiffs filed an Opposition to the Motion for Preliminary Approval and a Motion to Intervene and Stay Proceedings ("Motion to Intervene and Stay"). Subsequently, the Watts Plaintiff, Chan Plaintiffs, and Defendants reached an agreement in principle to settle the Watts and Chan Actions that included corporate reforms and a payment of attorneys' fees of $325,000. On October 2, 2019, the Watts Plaintiff filed an Unopposed Motion for Preliminary Approval of the Settlement (the "Omnibus Motion for Preliminary Approval"). The Omnibus Motion for Preliminary Approval was granted on January 8, 2020. Plaintiffs must file a motion for final approval of the proposed settlement by May 7, 2020. The Final Settlement hearing is scheduled for May 28, 2020.

NovoTek Therapeutics Inc. and NovoTek Pharmaceuticals Limited v. Akers Biosciences, Inc.

On June 21, 2019, we received a complaint, filed by Novotek Therapeutics Inc., and Novotek Pharmaceuticals Limited (collectively, "Novotek"), Beijing-based entities, in the United States District Court for the District of New Jersey, alleging, among other things, breach of contract. Novotek is seeking, among other things, damages in the amount of $1,551,562, plus interest, disbursements and attorneys' fees. We vigorously dispute the allegations in the complaint and has retained counsel to defend it. On September 16, 2019, we filed a partial motion to dismiss the complaint which was submitted on November 4, 2019. We are not yet able to determine the amount of our exposure, if any.

Neelima Varma v. Akers Biosciences, Inc. and St. David's Healthcare Partnership, L.P., LLP CAUSE NO: D-1-GN-19-004262

On July 25, 2019, we were notified that on July 23, 2019, a complaint was filed by Neelima Varma, against our company and St. David's Healthcare Partnership, L.P., LLP ("St. David's"), in the district court of Travis County, Texas, alleging, among other things, negligence, gross negligence and strict product liability, breach of express warranty, breach of implied warranty and fraudulent misrepresentation and omission in connection with allegedly erroneous results generated by the PIFA Heparin/PF4 Rapid Assay. The complaint argues that the allegedly erroneous results caused St. David's to continue with a course of treatment that ultimately contributed to the loss of the plaintiff's left leg. Ms. Varma is seeking aggregate monetary relief from us and St. David's in excess of $1,000,000. On September 20, 2019, we filed the original answer to plaintiff's original petition and on October 1, 2019, we received from plaintiff their first interrogatories and request for production of documents. We carry product liability insurance. The insurance carrier has provided notice that it has reserved certain rights. We and our insurance carrier will contest this complaint vigorously. We believe that our product liability insurance coverage will be adequate to cover the potential exposure from defending against this matter and any judgments, fines, or settlement costs directly resulting from this matter.

Douglas Carrara v. Akers Biosciences, Inc., John Does 1-10, and XYZ Corp. 1-10, Docket No. ESX-L-5272-19 (N.J. Super. Ct., Essex County):

Douglas Carrara, a former executive, has sued the Company over the termination of his employment. The executive seeks contractual severance pay in the amount of $200,000. The executive asserts that the termination was without cause within the meaning of his employment agreement, which provides for severance of one year's salary in the event of termination without cause. The executive also seeks indemnification for approximately $10,000 in attorneys' fees that he contends he incurred in regard to company business. On August 29, 2019, the Company filed an answer to the second amended complaint and the parties have exchanged documents and interrogatories as part of the discovery process. No trial date or discovery cutoff has been set. With regard to both claims, the executive seeks to recover his attorneys' fees under a fee-shifting provision in his employment agreement. With respect to the matter, the Company believes that the ultimate liability from the resolution of this matter will not be material to the Company's consolidated financial statements. Discover in the case is continuing and is expected to conclude this summer. No trial date has been set.

The Company intends to establish a rigorous defense of all claims. All legal fees were expensed as and when incurred.

Item 4. Mine Safety Disclosures

Not Applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities.

(a) Market Information

Our common stock began trading on the NASDAQ Capital Market under the symbol "AKER" on January 23, 2014. Prior to that, our common stock traded on the OTCQB of the OTC Markets Group Inc. under the same symbol.

(b) Holders

As of March 20, 2020, there were approximately 698 holders of record of our common stock. This figure does not include shareholders whose certificates are held in the name of the broker-dealers of other nominees.

(c) Dividends

We have never paid any cash dividends on our common shares, and we do not anticipate that we will pay any dividends with respect to those securities in the foreseeable future. Our current business plan is to retain any future earnings to finance the expansion and development of our business.

(d) Securities Authorized for Issuance Under Equity Compensation Plans

The following table shows information with respect to this plan as of the fiscal year ended December 31, 2019.

Equity Compensation Plan Information

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	40	$ 236.16	67,959
Equity compensation plans not approved by security holders	-	$ -	-
Total	40	$ 236.16	67,959

Transfer Agent

Our transfer agent is VStock Transfer LLC, 18 Lafayette Place, Woodmere, NY 11598.

(e) **Recent Sales of Unregistered Securities**

We issued 1,667 blank shares of our Common Stock to Typenex Medical, LLC on December 3, 2019. The shares of Common Stock were issued to Typenex pursuant to an exemption from registration afford by Section 4(a)(2) of the Securities Act of 1933, as amended. Except for the foregoing, During the year ended December 31, 2019, we have not issued any securities which were not registered under the Securities Act and not previously disclosed in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

(f) **Purchases of Equity Securities by Issuer and Affiliated Purchasers**

During the year ended December 31, 2019, we and to our knowledge our affiliated purchasers have not purchased any securities which were not previously disclosed in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K.

Item 6. Selected Financial Data

Not Applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our plan of operation and results of operations should be read in conjunction with the financial statements and related notes to the financial statements included elsewhere in this Annual Report. This discussion contains forward-looking statements that relate to future events or our future financial performance. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. These risks and other factors include, among others, those listed under "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" and those included elsewhere in this Annual Report.

Overview

Akers develops, manufactures, and supplies rapid, point-of-care screening and testing products designed to bring health-related information directly to the patient or clinician in a timely and cost-efficient manner. Akers believes it has advanced the science of diagnostics through the development of several proprietary platform technologies.

All of Akers' rapid, single-use tests are performed in vitro (outside the body) and are designed to enhance patient well-being and reduce the cost of healthcare. Our current product offerings focus on delivering diagnostic assistance in a variety of healthcare fields/specialties, including diagnostic rapid manual point-of-care tests for the detection of allergic reactions to Heparin, for cholesterol screening and for on- and off-the-job alcohol safety initiatives.

Akers believes that low-cost, single-use testing not only saves time and money, but allows for more frequent, near-patient testing which may save lives. We believe that our FDA-cleared rapid diagnostic tests help facilitate targeted diagnoses and real-time treatment.

On March 23, 2020, we entered into a Membership Interest Purchase Agreement (the "MIPA") with the members of Cystron Biotech, LLC (individually, each a "Seller," and collectively, the "Sellers"), pursuant to which the Company will acquire 100% of the membership interests (the "Membership Interests") of Cystron Biotech, LLC ("Cystron"). Cystron is a party to license agreement with Premas Biotech PVT Ltd ("Premas) whereby Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other corona virus infections.

Recent Developments

Acquisition of Cystron

On March 23, 2020, we acquired Cystron pursuant to the MIPA.

As consideration for the Membership Interests, we will deliver to the Sellers: (1) that number of newly issued shares of our common stock equal to 19.9% of the issued and outstanding shares of our common stock and pre-funded warrants as of the date of the MIPA, but, to the extent that the issuance of the our common stock would result in any Seller owning in excess of 4.9% of our outstanding common stock, then, at such Seller's election, such Seller may receive "common stock equivalent" preferred shares with a customary 4.9% blocker (with such common stock and preferred stock collectively referred to as "Common Stock Consideration"), and (2) $1,000,000 in cash.

Additionally, we shall (A) make an initial payment to the Sellers of up to $1,000,000 upon our receipt of cumulative gross proceeds from the consummation of an initial equity offering after the date of the MIPA of $8,000,000, and (B) pay to Sellers an amount in cash equal to 10% of the gross proceeds in excess of $8,000,000 raised from future equity offerings after the date of the MIPA until the Sellers have received an aggregate additional cash consideration equal to $10,000,000. Upon the achievement of certain milestones, including the completion of a Phase 2 study for a COVID-19 vaccine that meets its primary endpoints, Sellers will be entitled to receive an additional 750,000 shares of our common stock or, in the event we are unable to obtain stockholder approval for the issuance of such shares, 750,000 shares of non-voting preferred stock that are valued following the achievement of such milestones and shall bear a 10% annual dividend (the "Milestone Shares"). Sellers will also be entitled to contingent payments from us of up to $20,750,000 upon the achievement of certain milestones, including the approval of a new drug application by the U.S. Food and Drug Administration ("FDA").

We shall also make quarterly royalty payments to Sellers equal to 5% of the net sales of a COVID-19 vaccine or combination product by the Company (the "COVID-19 Vaccine") for a period of five (5) years following the first commercial sale of the COVID-19 Vaccine; provided, that such payment shall be reduced to 3% for any net sales of the COVID-19 Vaccine above $500 million.

In addition, Sellers shall be entitled to receive 12.5% of the transaction value, as defined in the MIPA, of any change of control transaction, as defined in the MIPA, that occurs prior to the fifth (5th) anniversary of the closing date of the MIPA, provided that the Company is still developing the COVID-19 Vaccine at that time. Following the consummation of any change of control transaction, the Sellers shall not be entitled to any payments as described above under the MIPA.

Support Agreement

On March 23, 2020, as an inducement to enter into the MIPA, and as one of the conditions to the consummation of the transactions contemplated by the MIPA, the Sellers entered into a shareholder voting agreement with the Company (the "Support Agreement"), pursuant to which each Seller agreed to vote their shares of our common stock or preferred stock in favor of each matter proposed and recommended for approval by our management at every meeting of the stockholders and on any action or approval by written consent of the stockholders.

Registration Rights Agreement

To induce the Sellers to enter into the MIPA, on March 23, 2020, we entered into a registration rights agreement (the "Registration Rights Agreement") with the Sellers, pursuant to which we shall by the 30th day following the closing of the transactions contemplated by the MIPA, file with the United States Securities and Exchange Commission (the "SEC") an initial Registration Statement on Form S-3 (if such form is available for use by the Company at such time) or, otherwise, on Form S-1, covering all of the shares of our common stock issued, or underlying the preferred stock issued, at closing under the MIPA and to subsequently register the common stock issued or underlying the preferred stock issued at Milestone Shares.

License Agreement

Cystron is a party to a License and Development Agreement (the "Initial License Agreement") with Premas Biotech PVT Ltd. ("Premas"). As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other corona virus infections.

Upon the achievement of certain developmental milestones by Cystron, Cystron shall pay to Premas a total of up to $2,000,000.

Series D Convertible Preferred Stock

On March 24, 2020, we filed the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of New Jersey. Pursuant to the Certificate of Designation, in the event of the Company's liquidation or winding up of its affairs, the holders of our Series D Convertible Preferred Stock (the "Preferred Stock") will be entitled to receive the same amount that a holder of our common stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations set forth in the Certificate of Designation) to common stock which amounts shall be paid pari passu with all holders of the Company's common stock. Each share of Preferred Stock has a stated value equal to $0.01 (the "Stated Value"), subject to increase as set forth in Section 7 of the Certificate of Designation.

A holder of Preferred Stock is entitled at any time to convert any whole or partial number of shares of Preferred Stock into shares of our common stock determined by dividing the Stated Value of the Preferred Stock being converted by the conversion price of $0.01 per share.

A holder of Preferred Stock will be prohibited from converting Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding (with such ownership restriction referred to as the "Beneficial Ownership Limitation"). However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

Subject to the Beneficial Ownership Limitation, on any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of a meeting), each holder of Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of our common stock into which the shares of Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of our certificate of incorporation, the holders of Preferred Stock will vote together with the holders of our common stock and any other class or series of stock entitled to vote thereon as a single class.

A holder of Preferred Stock shall be entitled to receive dividends as and when paid to the holders of our common stock on an as-converted basis.

Production Backlog of PIFA® Heparin/PF4 and PIFA® Pluss/PF4

As of March 20, 2020, we are experiencing a production backlog of our PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays. As a result, one of our distributors notified us that the distributor is informing its customers that the PIFA® Heparin/PF4 and PIFA® Pluss/PF4 rapid assays are temporarily unavailable. While we believe that we will be able to remedy the production backlog in several weeks, we cannot be certain what impact this backlog will have on our business and it may have an adverse effect on our 2020 revenues and results of operation.

Key Events, Management's Plans and Basis of Presentation

Board's Evaluation of Strategic Alternatives

On November 7, 2018, we announced that our board of directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. The Company continues to explore how to leverage its 30 years of operational history in its medical device business, where its current products have FDA clearance, its current operations practice Good Manufacturing Processes (cGMP), its medical device facility is certified under ISO 13485 – 2016 and the facility carries an Analytical Lab Certification for Schedules 2, 3, 4 and 5 controlled substances issued by the U.S. Drug Enforcement Administration (DEA) and the State of New Jersey. The Company intends to pursue opportunities in the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry, including pathways to consumer products with a focus on minor cannabinoids.

Further to our pursuit of strategic alternatives, pursuant to an unsecured promissory note date July 4, 2019, on July 25, 2019 we advanced $100,000 to a company in the hemp related industry with which we had been considering a potential business transaction. Discussions with this party toward a potential transaction have been suspended. The unsecured promissory note became due on October 2, 2019 and we are pursuing collection of the obligation.

Delisting from AIM

On December 19, 2018, we announced our intent to delist from the AIM Market of the London Stock Exchange. We believed that due to the relatively low liquidity in our common stock, reaming listed on the AIM did not merit the ongoing costs and regulatory complexities associated with maintaining the AIM listing. On March 5, 2019, we held a special meeting of shareholders who then voted in favor of our delisting from the AIM Market. The delisting took effect on March 29, 2019.

Board Compensation

On March 29, 2019, the Compensation Committee of the Board of Directors approved payments to the members of the Board of Directors, which were paid as follows (i) lump sum payment of $64,000 to each of Mr. Schreiber and Mr. White and a lump sum payment of $56,000 to Mr. Silverman, (ii) each of Mr. Schreiber, Mr. White and Mr. Silverman were granted 5,201 Restricted Stock Units ("RSUs"), which vested on January 1, 2020, and (iii) beginning April 2019, each serving director who is not also holding a position as an executive officer shall be paid $8,000 per month. The lump sum payments were paid during April 2019 and the monthly payments to directors have been paid each month. There was no other compensation for directors during the year ended December 31, 2019.

Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

We filed two certificates of amendment (each a "Certificate of Amendment", collectively, the "Certificates of Amendment") to our Amended and Restated Certificate of Incorporation with the Secretary of State of the State of New Jersey, each to be effective as of November 25, 2019, to reduce our authorized common stock at a ratio of one-for-eight then effect a reverse stock split of our authorized and outstanding common stock at a ratio of one-for-twenty four. The reduction and the reverse stock split affected all stockholders uniformly and did not alter any stockholder's percentage interest in our equity, except to the extent that the reverse stock split would have resulted in a stockholder owning a fractional share. Fractional shares have not been issued as a result of the reverse stock split; instead, the Board of Directors determined to effect an issuance of shares to holders that would otherwise have been entitled to a fractional share such that any fractional shares were rounded up to the nearest whole number. The Certificates of Amendment reduced the number of outstanding shares of our common stock to 521,676 and the number of shares of common stock we are authorized to issue to 2,604,167. On December 30, 2019, our shareholders approved an increase to 100,000,000 of the number of the authorized shares of our Common Stock.

Appointment of Christopher C. Schreiber as Executive Chairman of the Board of Directors

On November 1, 2019, the Board of Directors appointed Christopher C. Schreiber, a current director of our company, as Executive Chairman of the Board of Directors of our company, effective immediately. Due to Mr. Schreiber's appointment as Executive Chairman of the Board of Directors, Mr. Schreiber is no longer "independent" within the meaning of the Nasdaq Stock Market Rules and under Rule 10A-3(b)(1)(i) of the Securities Exchange Act of 1934 and is no longer a "non-employee director" under Rule 16b-3 of the Securities Exchange Act of 1934. As such, on November 1, 2019, Mr. Schreiber resigned from our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. In order to fill the vacancy occasioned by the resignation of Mr. Schreiber as the Chairman of the Compensation Committee, Mr. Joshua Silverman, a current director and member of the Compensation Committee, was appointed as the Chairman of the Compensation Committee.

Appointment of Robert C. Schroeder as a Director

On November 1, 2019, the Board of Directors appointed Robert C. Schroeder as a director and as a member of our Audit Committee, effective immediately.

Reverse Stock Split

On November 15, 2019, the Board of Directors approved a reverse stock split of our authorized and issued and outstanding common stock at a ratio of 1-for-24, effective on Monday, November 25, 2019 at 8:00 a.m. Trading on our common stock on a post-reverse stock split basis began at market open on November 25, 2019 (the "Reverse Stock Split"). No fractional shares have been issued in the Reverse Stock Split and the remaining fractions were rounded up to the next whole share. On November 22, 2019, the Board of Directors approved an amendment to the amended and restated certificate of incorporation to reduce the number of authorized shares of common stock, prior to the Reverse Stock Split, at a ratio of 1-for-8.

In connection with the Reverse Stock Split, all shares of our common stock subject to all outstanding equity awards and the exercise price of any such award (if applicable) have been reduced by the 1-for-24 ratio. The number of shares remaining available for issuance under the 2018 Akers Biosciences, Inc. Equity Incentive Plan were not reduced by the 1-for-24 ratio.

Advisory Board

On December 4, 2019, we formed an advisory board (the "Advisory Board") with expertise in the hemp and minor cannabinoid sectors. We will continue our strategic alternatives review and have identified the hemp and minor cannabinoid sectors as potential opportunities that could benefit from our core competencies. We are exploring how to leverage its 30 years of operational history in our medical device business, where our current products have U.S. Food and Drug Administration (FDA) clearance, our current operations practice Good Manufacturing Processes (cGMP), our medical device facility is certified under ISO 13485 – 2016 and the facility carries an Analytical Lab Certification for Schedules 2, 3, 4 and 5 controlled substances issued by the U.S. Drug Enforcement Administration (DEA) and the State of New Jersey. The Advisory Board will assist the Board of Directors in its strategic review including, potentially, the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry. The Advisory Board may also explore a pathway to consumer products with a focus on minor cannabinoids.

Summary of Statements of Operations for the Fiscal Years Ended December 31, 2019 and 2018

Revenue

The Company's revenue for the year ended December 31, 2019 totaled $1,577,033, a 5% decrease from the same period in 2018. The table below summarizes our revenue by product line for the years ended December 31, 2019 and 2018, as well as the percentage of change year-over-year:

	For the Years Ended December 31,		
Product Lines	2019	2018	Percent Change
Particle ImmunoFiltration Assay ("PIFA")	$ 1,327,752	$ 1,422,361	(7)%
MicroParticle Catalyzed Biosensor ("MPC")	126,150	123,941	2%
Rapid Enzymatic Assay ("REA")	85,000	68,750	24%
Other	38,131	50,518	(25)%
Total Revenue	$ 1,577,033	$ 1,665,570	(5)%

Revenue from the Company's PIFA products decreased 7% to $1,327,752 (2018: $1,422,361) during the year ended December 31, 2019, as compared to the same period of 2018. The decrease was attributable to both a decline in shipments of the PIFA products as well as increase in customer rebates.

The Company's largest U.S. distribution partners are Cardinal Health and Thermo Fisher Scientific. Domestic net sales for the year ended December 31, 2019 for these two distributors accounted for $1,249,913 of the total PIFA related product revenue as compared to $1,104,533 for the same period of 2018.

The Company's MPC product sales increased by 2% to $126,150 (2018: $123,941) during the year ended December 31, 2019.

The Company's REA products generated $85,000 (2018: $68,750) during the year ended December 31, 2019, principally on account of a large order by a customer during the 2019 period.

Other revenue, consisting primarily of shipping and handling charges, decreased to $38,131 (2018: $50,518) during the year ended December 31, 2019 due to a decline in orders shipped.

Gross Margin

The Company's gross profit percentage improved to 30% (2018: 8%), and the gross margin improved to $478,747 (2018: $127,285) for the year ended December 31, 2019, principally due to our focus on a more narrowed and higher margin product lineup. Furthermore, improvements in gross margin were attributable to cost reductions, including reduced headcount .

Cost of sales for the year ended December 31, 2019 decreased to $1,098,286 (2018: $1,538,285) primarily as a result of decreases in manufacturing personnel costs ($286,187 (2018: $471,563)), inventory obsolescence ($336,349 (2018: $453,761)) and shipping expenses ($46,534 (2018: 93,558)).

Administrative Expenses

Administrative expenses for the year ended December 31, 2019, totaled $3,728,514 which was a 34% decrease as compared to $5,666,018 for the year ended December 31, 2018.

The table below summarizes our administrative expenses for the years ended December 31, 2019 and 2018 as well as the percentage of change year-over-year:

	For the Years Ended December 31,		
Description	2019	2018	Percent Change
Personnel Costs	$ 722,111	$ 998,605	(28)%
Professional Service Costs	911,063	2,455,933	(63)%
Stock Market & Investor Relations Costs	415,637	681,545	(39)%
Other Administrative Costs	1,679,703	1,529,935	10%
Total Administrative Expense	$ 3,728,514	$ 5,666,018	(34)%

Personnel expenses decreased by 28% for the year ended December 31, 2019 as compared to the same period of 2018 on account of a reduction bonus expense, benefits, payroll service fees and auto allowances during 2019, as compared to December 31, 2018.

Professional service costs decreased 63% for the year ended December 31, 2019 as compared to the same period of 2018, principally on account of reduced legal fees ($699,118 (2018: $1,551,798)) and accounting and audit expenses ($51,381 (2018: $657,045)). The higher costs in 2018 were principally attributable to the investigation and restatement of the financial statements, and certain litigation defense costs.

Stock market and investor fees decreased 39% for the year ended December 31, 2019. The decrease in these fees was principally associated with the costs savings generated by the withdrawal from the London Stock Exchange.

Other administrative expenses increased by 10%, principally attributable to increased Director's fees and expenses ($706,964 (2018: $409,910)), including the amortization of RSU awards, of ($362,005 (2018: $0)).

Sales and Marketing Expenses

Sales and marketing expenses for the year ended December 31, 2019 totaled $238,036 which was an 87% decrease compared to $1,782,315 for the year ended December 31, 2018.

The table below summarizes our sales and marketing expenses for the years ended December 31 and 2018 as well as the percentage of change year-over-year:

	For the Years Ended December 31,		
Description	2019	2018	Percent Change
Personnel Costs	$ 65,718	$ 1,001,781	(93)%
Professional Service Costs	71,401	258,484	(72)%
Royalties and Outside Commission Costs	71,943	296,154	(76)%
Other Sales and Marketing Costs	28,974	225,896	(87)%
Total Sales and Marketing Expenses	$ 238,036	$ 1,782,315	(87)%

During the first quarter of 2019, as part of our cost savings measures, we eliminated the personnel within the sales and marketing departments, including employees, consultants and third-party related representatives.

Personnel expenses decreased by 93% for the year ended December 31, 2019 as compared to the same period of 2018 on account of the reduction in the sales and marketing headcount to zero as of December 31, 2019, as compared to four as of December 31, 2018.

Professional service costs decreased by 72% for year ended December 31, 2019, as compared to the same period of 2018 primarily on account of reductions in marketing and sales related consultants.

Royalties and outside commission costs decreased by 76%, principally on account of ISR costs incurred for approximately two months in 2019 as compared to twelve months in the 2018 period. An evaluation of the ISR program determined it to be ineffective and, as a result, all ISR's agreements were terminated effective February 19, 2019.

Other sales and marketing costs declined to $28,974 (2018: $225,896) principally due to the reductions in travel and entertainment for the sales and marketing personnel.

Compliance, Research and Development Expenses

Compliance, research and development expenses for the year ended December 31, 2019 totaled $276,788, which was a 74% decrease as compared to $1,063,253 for the year ended December 31, 2018.

The table below summarizes our compliance, research and development expenses for the years ended December 31, 2019 and 2018 as well as the percentage of change year-over-year:

	For the Years Ended December 31,		
Description	2019	2018	Percent Change
Personnel Costs	$ 244,255	$ 670,117	(64)%
Clinical Trial Costs	-	1,845	(100)%
Professional Service Costs	20,666	207,366	(90)%
Other Compliance, Research and Development Costs	11,867	183,925	(94)%
Total Compliance, Research and Development Expenses	$ 276,788	$ 1,063,253	(74)%

Personnel expenses decreased by 64% for the year ended December 31, 2019 as compared to the same period of 2018 due to a reduction in the headcount to three as of December 31, 2019, as compared to four as of December 31, 2018. These staff reductions eliminated the research & development functions, with the remaining personnel maintaining regulatory and quality assurance (compliance) functions.

Professional service costs, principally third-party engineering costs, declined by 90% for the year ended December 31, 2019, as compared to the same period of 2018, principally on account of the elimination of research & development activities.

Other compliance, research and development costs declined by 94%, for the year ended December 31, 2019, as compared to the same period of 2018, principally on account of reduction in research and development activities, as discussed above.

Litigation Settlement Expense

Litigation settlement expenses for the year ended December 31, 2019, were $141,478 as compared to $1,505,000 for the year ended December 31, 2018.

Litigation settlement expenses for the year ended December 31, 2018 principally consisted of the settlement of the Pulse Litigation which resulted in a one-time charge of $930,000 and $500,000 in connection with the class action and derivative lawsuits.

Amortization of Non-Current Assets

Amortization of non-current assets for the year ended December 31, 2019 totaled $40,008, which was a 77% decrease as compared to $171,108 for the year ended December 31, 2018. The 2019 amount was less on account of impairment of intellectual property recorded in 2018, principally connected with the settlement of the Pulse Litigation.

Other Income and Expense

Other income, net of expense, for the year ended December 31, 2019 totaled $57,828 as compared to other expenses, net of income of $788,625 for the year ended December 31, 2018.

The table below summarizes our other income and expenses for the years ended December 31, 2019 and 2018 as well as the percentage of change year-over-year:

	For the Years Ended December 31,		
Description	2019	2018	Percent Change
Impairment of Intangible Assets	$ 32,980	$ 716,148	95%
Impairment of Other Assets	-	64,092	100%
Loss on Disposal of Property and Equipment	9,576	156,493	94%
Foreign Currency Transaction (Gain)/Loss	5,051	6,726	25%
Other Income	-	(4,172)	100%
(Gain)/Loss on Investments	(3,952)	15,178	126%
Interest and Dividend Income	(101,483)	(165,840)	(39)%
Total Other (Income)/Expense	$ (57,828)	$ 788,625	107%

Impairment of intangible assets, for the year ended December 31, 2019 totaled $32,980 as compared to $716,418 for the year ended December 31, 2018. The 2018 amount included the impairment of intellectual property principally as a result of the settlement of the Pulse Litigation.

Loss on disposal of property and equipment, for the year ended December 31, 2019 totaled $9,576 as compared to $156,493 for the year ended December 31, 2018. The 2018 amount included the write-off of computer equipment, computer software and production molds no longer in use by the Company.

Income Taxes

As of December 31, 2019, and 2018, the Company had Federal net operating loss carry forwards of approximately $79,678,000 and $80,500,000, respectively, expiring through the year ending December 31, 2039. As of December 31, 2019, and 2018, the Company had New Jersey state net operating loss carry forwards of approximately $28,855,000 and $29,700,000, respectively, expiring the year ending December 31, 2025.

Liquidity and Capital Resources

As of December 31, 2019, the Company's cash on hand was $632,538 (which included restricted cash of $115,094 and its marketable securities were $9,164,273. The Company has incurred net losses of $3,888,249 and $10,849,034 for the years ended December 31, 2019 and 2018, respectfully. As of December 31, 2019, the Company had working capital of $8,781,049 and a stockholder's deficit of $119,583,130. During the year ended December 31, 2019, cash flows used in operating activities were $3,074,283, consisting primarily of a net loss of $3,888,249, which includes non-cash stock-based compensation charges of $400,174. Since inception, the Company has met its liquidity requirements principally through the sale of its common stock in public and private placements.

On December 9, 2019, the Company raised proceeds of $6,965,635 net of offering costs of $994,227 in connection with a registered offering of its common stock.

However, our current cash resources will not be sufficient to fund the development of our COVID-19 Vaccine candidate through all of the required clinical trials to receive regulatory approval and commercialization. While we do not currently have an estimate of all of the costs that we will incur in the development of the COVID-19 Vaccine, we anticipate we will need to raise significant additional funds in order to continue the development of the our COVID-19 Vaccine candidate during the next 12-months. In addition, we could also have increased capital needs if we were to engage in a strategic transaction in the cannabinoid space.

The Company believes that its current financial resources as of the date of the issuance of these consolidated financial statements, are sufficient to fund its current twelve month operating budget, alleviating any substantial doubt raised by our historical operating results and satisfying our estimated liquidity needs for twelve months from the issuance of these consolidated financial statements.

Capital expenditures for the year ended December 31, 2019 were $0 (2018: $68,214).

Operating Activities

Our net cash consumed by operating activities totaled $3,074,283 during the year ended December 31, 2019. Cash was consumed by the loss of $3,888,249 reduced by non-cash adjustments principally consisting of $3,353 for accrued interest on marketable securities, $74,064 for depreciation and amortization of non-current assets, $32,980 for impairment of intangible assets, $9,576 for the loss on the disposal of fixed assets, $371,997 for charge for obsolescence, $105,325 for the allowance of doubtful accounts and other receivables and $400,174 for share based compensation. For the year ended December 31, 2019, within changes of assets and liabilities, cash provided consisted of a decrease in trade receivables of $128,120, a decrease in deposits and other receivables of $9,347, a decrease in inventories of $14,285, a decrease in prepaid expenses of $103,152 and a decrease in other assets of $9,280, off-set by a decrease in trade and other payables of $443,735.

Our net cash consumed by operating activities totaled $8,502,192 during the year ended December 31, 2018. Cash was consumed by the loss of $10,849,034 reduced by non-cash adjustments principally consisting of impairment of intangible assets of $716,148, reserve for obsolete inventory of $279,029, $234,486 for depreciation and amortization of non-current assets, $156,835 for the allowance of doubtful accounts, $50,647 for share based compensation less $11,011 for accrued interest and dividends on marketable securities. For the year ended December 31, 2019, within changes of assets and liabilities, cash provided consisted of a decrease in trade receivables of $631,510, a decrease in inventories of $83,316, an increase in trade and other payables of $188,462, off-set by an increase in prepaid expenses of $225,586.

Investing Activities

The Company's net cash provided by investing totaled $3,940,627, as compared to $359,685 during the years ended December 31, 2019 and 2018, respectively. Net cash provided by investing activities for the year ended December 31, 2019 consisted of proceeds from the sale of marketable securities of $2,857,960 and the sale of equipment of $6,250 offset by $6,704,837 consumed by the purchase of marketable securities and $100,000 for the issuance of a short-term note receivable. During the year ended December 31, 2018, investing activities consisted of proceeds from the sale of marketable securities of $6,313,330 offset by $6,604,801 consumed by the purchase of marketable securities and $68,214 for capital expenditures.

Financing Activities

The Company's net cash provided by financing activities in 2019 was $6,965,693 (2018: $9,105,200). Net cash provided during the 2019 period consisted of $2,147,778 of net proceeds from the issuance of common shares, $4,817,857 of net proceeds for the issuance of prepaid equity forward contracts for the purchase of common shares and $58 of net proceeds for the exercise of prepaid equity forward contracts for common shares Net cash provided during the 2018 period consisted of $1,950,000 of net proceeds for the issuance of common shares and $7,155,200 for the exercise of warrants for common shares.

Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (US GAAP) requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Future events and their effects cannot be determined with absolute certainty. Therefore, the determination of estimates requires the exercise of judgment. Actual results inevitably will differ from those estimates, and such differences may be material to the financial statements. The most significant accounting estimates inherent in the preparation of our financial statements include estimates associated with revenue recognition, impairment analysis of intangibles and stock-based compensation.

Our financial position, results of operations and cash flows are impacted by the accounting policies we have adopted. In order to get a full understanding of our financial statements, one must have a clear understanding of the accounting policies employed. A summary of our critical accounting policies is presented within the footnotes in the consolidated financial statements presented with in the Annual Report.

Quantitative and Qualitative Disclosure About Market Risk

Not required.

Off-Balance Sheet Arrangements

We have no significant known off balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not required.

Item 8. Financial Statements and Supplementary Data.

Our financial statements are contained in pages F-1 through F-44 which appear at the end of this Annual Report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

There have been no changes in or disagreements with accountants on accounting and financial disclosure.

Item 9A. Controls and Procedures.

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in paragraph (e) of Rules 13a-15 and 15d-15 under the Exchange Act) designed to ensure that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified under the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Executive Chairman, as appropriate to allow timely decisions regarding required disclosures. As required by paragraph (b) of Rules 13a-15 and 15d-15 under the Exchange Act, our Executive Chairman (our principal executive officer) and our interim Chief Financial Officer (our principal financial officer) carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2019. Based on this evaluation, our Executive Chairman and our interimChief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2019.

(b) Management's Report on Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our Board of Directors, management and other personnel, 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.

Internal control over financial reporting cannot provide absolute assurance of achieving their objectives. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgement and breakdowns resulting from human failures. Due to their inherent limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. It is possible to design safeguards to reduce, but not eliminate, this risk. Management is responsible for establishing and maintaining adequate internal control over financial reporting for our company.

Management has used the framework set forth in the report entitled Internal Control—Integrated Framework published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), known as COSO, to evaluate the effectiveness of our internal control over financial reporting.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Based on such evaluation, our Principal Executive Officer and our Principal Financial Officer have concluded that, as of December 31, 2019, our internal controls over financial reporting were effective.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements or fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, which permits us to provide only management's report in this annual report.

(c) Changes in Internal Control over Financial Reporting

During the three months ended December 31, 2019, our Board of Directors appointed Christopher C. Schreiber, an existing director, to the additional role of Executive Chairman (principal executive officer) and we implemented additional controls in connection with the accounting for inventory.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

Directors and Executive Officers

The following table sets forth the names, ages and positions of all of our directors and executive officers and the positions they hold as of the date hereof. Our directors serve until their successors are elected and shall qualify. Executive officers are elected by the Board of Directors and serve at the discretion of the directors.

Name	Age	Position
Howard R. Yeaton	65	Interim Chief Financial Officer
Christopher C. Schreiber	54	Executive Chairman of the Board of Directors and Director
Joshua Silverman	49	Lead Independent Director
Bill J. White	58	Independent Director
Robert C. Schroeder	53	Independent Director

Set forth below is a brief description of the background and business experience of each of our executive officers and directors.

Howard R. Yeaton, has been our interim Chief Financial Officer since October 5, 2018. Mr. Yeaton has been the Managing Principal of Financial Consulting Strategies, LLC since 2003, a firm serving principally early stage public companies with financial reporting support and other related strategic services. Until November 2019, Mr. Yeaton served as a director, Vice Chairman and Chairman of the audit committee for Stewardship Financial Corporation, a community bank. From 2014 to 2019, Mr. Yeaton served as Interim Chief Financial Officer of Propel Media, Inc. and from July 2014 to July 2015, Mr. Yeaton served as Interim Chief Financial Officer of Energous Corporation, a public company listed on the Nasdaq Capital Market; both clients of Financial Consulting Strategies, LLC. In addition, prior to founding Financial Consulting Strategies, LLC, Mr. Yeaton served in various financial leadership positions for Konica and Teco Energy. Mr. Yeaton began his career with Deloitte, an international accounting and auditing firm. Mr. Yeaton has a BS in accounting from Florida State University in Tallahassee, FL, and a Master's in Business Administration from the University of Connecticut in Storrs, CT.

Christopher C. Schreiber, has been a director of our company since August 8, 2017 and currently serves as our Executive Chairman. Mr. Schreiber combines over 30 years of experience in the securities industry. As the Managing Director of Capital Markets at Taglich Brothers, Inc., Mr. Schreiber builds upon his extensive background in capital markets, deal structures, and syndications. Prior to his time at Taglich Brothers, he was a member of the board of directors of Paulson Investment Company, a 40-year-old full service Investment Banking firm. In addition, Mr. Schreiber serves as a director and partner of Long Island Express North, an elite lacrosse training organization for teams and individuals. He also volunteers on the board of directors for Fox Lane Youth Lacrosse, a community youth program. Mr. Schreiber is a graduate of Johns Hopkins University, where he received a Bachelor's Degree in Political Science. Mr. Schreiber was selected to serve on the Board of Directors in part because of his significant experience in capital markets and knowledge of our company.

Joshua Silverman, has been a director of our company since September 6, 2018. Mr. Silverman currently serves as the Managing Member of Parkfield Funding LLC. Mr. Silverman was the co-founder, and a Principal and Managing Partner of Iroquois Capital Management, LLC, an investment advisory firm. Since its inception in 2003 until July 2016, Mr. Silverman served as Co-Chief Investment Officer of Iroquois. While at Iroquois, he designed and executed complex transactions, structuring and negotiating investments in both public and private companies and has often been called upon by the companies solve inefficiencies as they relate to corporate structure, cash flow, and management. From 2000 to 2003, Mr. Silverman served as Co-Chief Investment Officer of Vertical Ventures, LLC, a merchant bank. Prior to forming Iroquois, Mr. Silverman was a Director of Joele Frank, a boutique consulting firm specializing in mergers and acquisitions. Previously, Mr. Silverman served as Assistant Press Secretary to The President of the United States. Mr. Silverman currently serves as a director of DropCar, Inc., Protagenic Therapeutics, and Neurotrope, Inc., all of which are public companies. He previously served as a Director of National Holdings Corporation from July 2014 through August 2016 and as a Director of Marker Therapeutics, Inc. from August 2016 until October 2018. Mr. Silverman received his B.A. from Lehigh University in 1992.

Bill J. White, has been a director of our company since August 8, 2017. Mr. White has more than 30 years of experience in financial management, operations and business development. He currently serves as Chief Financial Officer, Treasurer and Secretary of Intellicheck Mobilisa, Inc., a technology company listed on the NYSE MKT. Prior to working at Intellicheck Mobilisa, Inc., he served 11 years as the Chief Financial Officer, Secretary and Treasurer of FocusMicro, Inc. ("FM"). As co-founder of FM, Mr. White played an integral role in growing the business from the company's inception to over $36 million in annual revenue in a five-year period. Mr. White has broad domestic and international experience including managing rapid and significant growth, import/export, implementing tough cost management initiatives, exploiting new growth opportunities, merger and acquisitions, strategic planning, resource allocation, tax compliance and organization development. Prior to co-founding FM, he served 15 years in various financial leadership positions in the government sector. Mr. White started his career in Public Accounting. Mr. White holds a Bachelor of Arts in Business Administration from Washington State University and is a Certified Fraud Examiner. Mr. White was selected to serve on the Board of Directors in part because of his significant financial and accounting experience with public companies.

Robert C. Schroeder, has been a director of our company since November 1, 2019. Mr. Schroeder is currently the Vice President of Investment Banking at Taglich Brothers, a brokerage firm, and specializes in advisory services and capital raising for small public and private companies. Prior to his time at Taglich Brothers, Mr. Schroeder served as a Senior Equity Analyst publishing sell-side research on publicly traded companies and served in various other positions in the brokerage and public accounting industry. Mr. Schroeder currently serves on the board of directors of publicly traded Intellinetics, Inc., a document solutions software development, sales and marketing company, Air Industries Group (NYSE:AIRI), a manufacturer of aerospace parts and assemblies, and Decisionpoint Systems, Inc., a leading provider and integrator of Enterprise Mobility, Wireless Applications and RFID solutions. Mr. Schroeder received a B.S. degree in accounting and economics from New York University. The Board of Directors believes Mr. Schroeder is well qualified to serve on the Board of Directors due to his leadership skills, capital markets expertise, and extensive experience as a director of the board for other public companies.

Family Relationships

There are no family relationships between any of our officers or directors.

Board Composition and Committees and Director Independence

On December 30, 2019, our shareholders reelected Christopher C. Schreiber, Joshua Silverman, and Bill J. White, and elected Robert C. Schroeder as members of the Board. Mr. Silverman, Mr. Schroeder, and Mr. White comprise the Board's Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee. Mr. White acts as Chairman of the Audit Committee, and Mr. Silverman acts as Chairman of the Compensation Committee. The directors will serve until our next annual meeting and until their successors are duly elected and qualified. We define "independent" as that term is defined in Rule 5605(a)(2) of the Nasdaq listing standards.

In making the determination of whether a member of the Board of Directors is independent, our Board of Directors consider, among other things, transactions and relationships between each director and his immediate family and us, including those reported under the caption "Related Party Transactions". The purpose of this review is to determine whether any such relationships or transactions are material and, therefore, inconsistent with a determination that the directors are independent. On the basis of such review and its understanding of such relationships and transactions, our Board of Directors affirmatively determined that Mr. Joshua Silverman, Mr. Bill J. White and Mr. Robert C. Schroeder are qualified as independent and that none of them have any material relationship with us that might interfere with his or her exercise of independent judgment.

Meetings of the Board of Directors and Shareholders

Our Board of Directors met in person and telephonically 5 times during 2019 and also acted by unanimous written consent. Each member of our Board of Directors was present at least 75% of the Board of Directors meetings held, while such individual was a member. It is our policy that all directors must attend all shareholder meetings, barring extenuating circumstances. All directors were present at the 2019 Annual Meeting of Shareholders, either in person or telephonically.

Board Committees

We have established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee met in person and telephonically 4 times, 1 time and 1 time, respectively, during 2019, and also acted by unanimous written consents. Each committee has its own charter, which is available on our website at *www.akersbio.com.* Information contained on our website is not incorporated herein by reference.

Audit Committee

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act of 1934, as amended (the "Exchange Act"). The members of our Audit Committee are Mr. White, Mr. Silverman and Mr. Schroeder. Each of these Committee members is "independent" within the meaning of Rule 10A-3 under the Exchange Act and the Nasdaq Stock Market Rules. Our Board of Directors has determined that Mr. White is an "audit committee financial expert", as such term is defined in Item 407(d)(5) of Regulation S-K. Mr. White serves as Chairman of our Audit Committee. Each member of the Audit Committee was present at 100% of the Audit Committee meetings held during such director's tenure as a member of the Audit Committee.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits and reviews of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually). As summarized below, the Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service and fees therefor to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;

- oversees all aspects of our systems of internal accounting and financial reporting control; and

- provides oversight in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the Board of Directors regarding corporate governance issues and policy decisions.

Compensation Committee

The members of our Compensation Committee are Mr. Joshua Silverman, and Mr. Bill White. Each such member is "independent" within the meaning of the Nasdaq Stock Market Rules. In addition, each member of our Compensation Committee qualifies as a "non-employee director" under Rule 16b-3 of the Exchange Act. Our Compensation Committee assists the Board of Directors in the discharge of its responsibilities relating to the compensation of the Board of Directors and our executive officers. Mr. Silverman will serve as Chairman of our Compensation Committee.

The Committee's compensation-related responsibilities include, but are not limited to:

- reviewing and approving on an annual basis the corporate goals and objectives with respect to compensation for our Chief Executive Officer;

- reviewing, approving and recommending to our Board of Directors on an annual basis the evaluation process and compensation structure for our other executive officers;

- determining the need for an the appropriateness of employment agreements and change in control agreements for each of our executive officers and any other officers recommended by the Executive Chairman or Board of Directors;

- providing oversight of management's decisions concerning the performance and compensation of other company officers, employees, consultants and advisors;

- reviewing our incentive compensation and other equity-based plans and recommending changes in such plans to our Board of Directors as needed, and exercising all the authority of our Board of Directors with respect to the administration of such plans;

- reviewing and recommending to our Board of Directors the compensation of independent directors, including incentive and equity-based compensation; and

- selecting, retaining and terminating such compensation consultants, outside counsel or other advisors as it deems necessary or appropriate.

The Compensation Committee has the authority to directly engage, at our expense, any compensation consultants or other advisers as it deems necessary to carry out its responsibilities in determining the amount and form of employee, executive and director compensation.

Nominating and Corporate Governance Committee

The members of our Nominating and Corporate Governance Committee are Mr. Josh Silverman and Mr. Bill White. Each such member is "independent" within the meaning of the Nasdaq Stock Market Rules. The purpose of the Nominating and Corporate Governance Committee is to recommend to the board nominees for election as directors and persons to be elected to fill any vacancies on the board, develop and recommend a set of corporate governance principles and oversee the performance of the board.

The Committee's responsibilities include:

- recommending to the Board of Directors nominees for election as directors at any meeting of shareholders and nominees to fill vacancies on the board;
- considering candidates proposed by shareholders in accordance with the requirements in the Committee charter;
- overseeing the administration of our Code of Ethics;
- reviewing with the entire Board of Directors, on an annual basis, the requisite skills and criteria for Board of Director candidates and the composition of the Board of Directors as a whole;
- the authority to retain search firms to assist in identifying Board of Director candidates, approve the terms of the search firm's engagement, and cause us to pay the engaged search firm's engagement fee;
- recommending to the Board of Directors on an annual basis the directors to be appointed to each committee of the Board of Directors;
- overseeing an annual self-evaluation of the Board of Directors and its committees to determine whether it and its committees are functioning effectively; and
- developing and recommending to the Board of Directors a set of corporate governance guidelines applicable to us.

The Nominating and Corporate Governance Committee may delegate any of its responsibilities to subcommittees as it deems appropriate. The Nominating and Corporate Governance Committee is authorized to retain independent legal and other advisors, and conduct or authorize investigations into any matter within the scope of its duties.

Management-Non-Executive Director Compensation

On March 29, 2019, the Compensation Committee of the Board of Directors approved payments to the members of the Board of Directors, payable as follows (i) lump sum payment of $64,000 to each of Mr. Schreiber and Mr. White and a lump sum payment of $56,000 to be paid to Mr. Silverman, (ii) each of Mr. Schreiber, Mr. White and Mr. Silverman were granted 5,201 Restricted Stock Units ("RSUs"), which vested on January 1, 2020, and (iii) beginning April 2019, each director was paid $8,000 per month. The lump sum payments were paid during April 2019 and the monthly payments to directors have been paid each month. There was no other compensation for directors during the year ended December 31, 2019.

Legal Proceedings

To the best of our knowledge, none of our directors or executive officers has, during the past ten years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;

- been found by a court of competent jurisdiction in a civil action or by the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Except as set forth in our discussion below in "Certain Relationships and Related Transactions," none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the Commission.

Compliance with Section 16(A) of the Exchange Act

Section 16(a) of the Exchange Act requires our directors, executive officers and persons who beneficially own 10% or more of a class of securities registered under Section 12 of the Exchange Act to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Directors, executive officers and greater than 10% shareholders are required by the rules and regulations of the SEC to furnish us with copies of all reports filed by them in compliance with Section 16(a).

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2019, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, with exceptions of Mr. Howard R. Yeaton, who did not timely file a Form 4 that was due on which was due on October 15, 2019 until October 16, 2019.

Shareholder Communications with Directors

Shareholders and other interested parties may send correspondence by mail to the full Board of Directors or to individual directors. Shareholders should address such correspondence to the Board of Directors or the relevant Board of Directors members in care of: Akers Biosciences, Inc., 201 Grove Road Thorofare, New Jersey USA 08086, Attention: Secretary.

All such correspondence will be compiled by our Secretary and forwarded as appropriate. In general, correspondence relating to corporate governance issues, long-term corporate strategy or similar substantive matters will be forwarded to the Board, one of the committees of the Board, or a member thereof for review. Correspondence relating to the ordinary course of business affairs, personal grievances, and matters as to which we tend to receive repetitive or duplicative communications are usually more appropriately addressed by the officers or their designees and will be forwarded to such persons accordingly.

Code of Ethics and Business of Conduct

We have adopted a Code of Business Conduct and Ethics, which applies to our Board of Directors, our executive officers and our employees, outlines the broad principles of ethical business conduct we adopted, covering subject areas such as:

- compliance with applicable laws and regulations,
- handling of books and records,
- public disclosure reporting,
- insider trading,
- discrimination and harassment,
- health and safety,
- conflicts of interest,
- competition and fair dealing, and
- protection of company assets.

A copy of our Code of Business Conduct and Ethics is available without charge, to any person desiring a copy of the Code of Business Conduct and Ethics, by written request to us at our principal offices at 201 Grove Road, Thorofare, New Jersey USA 08086.

Item 11. Executive Compensation.

The compensation provided to our "named executive officers" for 2019 and 2018 is set forth in detail in the Summary Compensation Table and other tables and the accompanying footnotes and narrative that follow this section.

Our named executive officers who appear in the 2019 Summary Compensation Table are:

Howard R. Yeaton	Interim Chief Financial Officer
Christopher C. Schreiber	Executive Chairman of the Board of Directors

Summary Compensation Table

The following table summarizes information regarding the compensation awarded to, earned by or paid to, our Chief Executive Officer, and our other most highly compensated executive officers who earned in excess of $100,000 during 2019 and 2018.

Name and Principal Position	Year	Salary $	Cash Bonus $	Stock Awards $	Option Awards $	All Other Compensation $	Total $
Howard R. Yeaton (1)							
Interim	2019	300,000	-	26,302	-	-	326,302
Chief Financial Officer	2018	71,774	-	20,941	-	-	92,715
Christopher C. Schreiber (2)							
Executive Chairman of the	2019	50,000	-	-	-	-	50,000
Board of Directors	2018	-	-	-	-	-	-

(1) Mr. Yeaton was appointed as Chief Executive Officer and interim Chief Financial Officer on October 5, 2018. During the years ended December 31, 2019 and 2018, both before and after Mr. Yeaton's appointment, FCS, a consulting firm owned by Mr. Yeaton, provided services to us valued at $38,888 and $104,749, respectively. On January 6, 2020, Mr. Yeaton entered into a new employment agreement with us whereby he would serve solely as the interim Chief Financial Officer.
(2) Mr. Schreiber was appointed as a director of our company on August 8, 2017. On November 1, 2019, he was appointed as our Executive Chairman. On January 24, 2020, Mr. Schreiber entered into an employment agreement, under which he would receive an annual salary of $300,000.

Employment Agreements

Effective on October 5, 2018, the Board of Directors appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to us, to serve as our Chief Executive Officer and interim Chief Financial Officer. Mr. Yeaton is the managing principal of FCS and our relationship with FCS shall continue, with FCS continuing to provide accounting services to us. During the year ended December 31, 2019, we paid a total of $49,972to FCS in connection with these services. In connection with his appointment as our Chief Executive Officer and interim Chief Financial Officer, we and Mr. Yeaton entered into an offer of employment, dated October 5, 2018 (the "Employment Agreement") which terminated December 31, 2019. The Employment Agreement provided for the following compensation for Mr. Yeaton: (i) twenty-five thousand dollars ($25,000) per month in base salary, (ii) a monthly grant of one hundred fifty six (156) unrestricted shares of the our common stock pursuant to the Plan, (iii) Mr. Yeaton will be afforded other employee benefits including, health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in our 401(k) Plan, and (iv) will be reimbursed for reasonable and necessary travel and business expenses including the expenses of travel and hotel stays in or near Thorofare, New Jersey.

On January 6, 2020, the Board of Directors appointed Howard R. Yeaton as our interim Chief Financial Officer. In connection with his appointment as our interim Chief Financial Officer, we and Mr. Yeaton entered into a new offer of employment, dated January 6, 2020 for a period of ninety days. Pursuant to such agreement, Mr. Yeaton will receive: (i) twenty-five thousand dollars ($25,000) per month in base salary, (ii) Mr. Yeaton will be afforded other employee benefits including, health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in our 401(k) Plan, and (iii) will be reimbursed for reasonable and necessary travel and business expenses including the expenses of travel and hotel stays in or near Thorofare, New Jersey. We may terminate the Employment Agreement for any reason or no reason, and Mr. Yeaton may voluntarily resign for any reason or no reason with thirty (30) days' notice.

On January 24, 2020, we and Christopher C. Schreiber entered into an executive chairman agreement with Mr. Christopher C. Schreiber (the "Executive Chairman Agreement"). Pursuant to the Executive Chairman Agreement, Mr. Schreiber shall continue to serve as the Executive Chairman of the Board as long as he is a member of the Board of Directors, or until termination of the Executive Chairman Agreement (as described below) or upon his earlier death, incapacity, removal, or resignation. Mr. Schreiber is entitled to receive: (i) an annual base salary of $300,000, payable monthly in equal installments, paid retroactively as of November 1, 2019 (it being agreed that such fee shall be inclusive of any fees associated with Schreiber's services as both a director of our company and in the capacity of Executive Chairman), (ii) employee benefits including, health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in our 401(k) Plan, (iii) annual or other bonuses in cash and/or in securities of our company and/or otherwise, which bonuses, if any, shall be awarded in the complete discretion of the Board of Directors or a designated committee thereof and (iv) reimbursements for pre-approved reasonable business-related expenses incurred in good faith in the performance of the Mr. Schreiber's duties for us.

The Executive Chairman Agreement establishes an "at will" employment relationship pursuant to which Mr. Schreiber serves as Executive Chairman. We may terminate the Executive Chairman Agreement for any reason or no reason, and Mr. Schreiber may voluntarily resign for any reason or no reason with sixty (60) days' notice. The Executive Chairman Agreement also provides that Mr. Schreiber may not compete against us or solicit our employees or customers for a period of one (1) year after termination of the Executive Chairman Agreement or his association with us for any reason.

STOCK AWARDS

Name (a)	Number of Securities Underlying Unexercised Options (#) Exercisable (b)	Number of Securities Underlying Unexercised Options (#) Unexercisable (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g) (9)	Market Value of Shares or Units of Stock That Have Not Vested ($) (h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (#) (j)
Howard R. Yeaton Interim Chief Financial Officer	-	-	-	-		-	-	-	-
Christopher C. Schreiber Executive Chairman of the Board of Directors and Director	-	-	-	-		5,201	121,080	-	-
Josh Silverman Lead Independent Director	-	-	-	-		5,201	121,080	-	-
Bill J. White Director	-	-	-	-		5,201	121,080	-	-
Robert C. Schroeder Director	-	-	-	-		-	-	-	-

On January 23, 2014, the Company adopted the 2013 Stock Incentive Plan ("2013 Plan"). The 2013 Plan was amended by the Board on January 9, 2015 and September 30, 2016, and such amendments were ratified by shareholders on December 7, 2018. The 2013 Plan provides for the issuance of up to 4,323 shares of the Company's common stock.

On August 7, 2017, the shareholders approved, and the Company adopted the 2017 Stock Incentive Plan ("2017 Plan"). The 2017 Plan provides for the issuance of up to 7,031 shares of the Company's common stock. The purpose of the 2017 Plan is to provide additional incentive to those of our officers, employees, consultants and non-employee directors and our parents, subsidiaries and affiliates whose contributions are essential to the growth and success of our business. As of December 31, 2019, grants of restricted stock and options to purchase totaling 3,064 shares of common stock have been issued pursuant to the 2017 Plan and 3,967 shares of common stock remain available for grants under the 2017 Plan.

The 2017 Plan provides for the issuance of shares of our common stock through the grant of non-qualified options, incentive options, restricted stock and unrestricted stock to directors, officers, consultants, attorneys, advisors and employees.

On December 7, 2018, the shareholders approved, and the Company adopted the 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the issuance of up to 78,125 shares of the Company's common stock. As of December 31, 2019, grants of RSUs to purchase 15,603 shares of Common Stock have been issued pursuant to the 2018 Plan, and 62,522 shares of Common Stock remain available for issuance.

On March 29, 2019, the Compensation Committee of the Board of Directors approved the grant of 5,201 RSUs to each of the three directors. Each RSU had a grant date fair value of $23.28 which shall be amortized on a straight-line basis over the vesting period into administrative expenses within the Consolidated Statement of Operations and Comprehensive Loss. Such RSUs were granted under the 2018 Plan, and vested on January 1, 2020.

Director Compensation

The following sets forth the compensation awarded to, earned by, or paid to the named director by us during the year ended December 31, 2019.

Name	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)	Non-equity incentive plan compensation ($)	All other compensation ($)	Total ($)
Christopher C. Schreiber (2)	136,000	121,079(1)	-	-	-	136,000
Josh Silverman (3)	128,000	121,079(1)	-	-	-	128,000
Bill J. White (4)	136,000	121,079(1)	-	-	-	136,000
Robert Schroeder (5)	8,000	-	-	-	-	8,000

(1) On March 29, 2019, we granted each director restricted stock units to purchase 5,201 shares of our common stock, which vested in full on January 1, 2020.

(2) As of December 31, 2019, Mr. Schreiber had 5,201 outstanding RSUs.

(3) As of December 31, 2019, Mr. Silverman had 5,201 outstanding RSUs.

(4) As of December 31, 2019, Mr. White had 5,201 outstanding RSUs.

(5) Mr. Schroeder was appointed as a director, effective November 1, 2019. As of December 31, 2019, Mr. Schroeder did not have any stock awards or option awards outstanding.

Narrative Disclosure to Director Compensation Table

On March 29, 2019, the Compensation Committee of the Board of Directors approved payments to the members of the Board of Directors, which were paid as follows (i) lump sum payment of $64,000 to each of Mr. Schreiber and Mr. White and a lump sum payment of $56,000 to Mr. Silverman, (ii) each of Mr. Schreiber, Mr. White and Mr. Silverman were granted 5,201 Restricted Stock Units ("RSUs"), which vested on January 1, 2020, and (iii) beginning April 2019, each serving director who is not also holding a position as an executive officer shall be paid $8,000 per month. The lump sum payments were paid during April 2019 and the monthly payments to directors have been paid each month. There was no other compensation for directors during the year ended December 31, 2019.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters.

The following table shows information with respect to the Company's Equity Compensation Plan as of the fiscal year ended December 31, 2019.

Equity Compensation Plan Information

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	40	$ 236.16	67,959
Equity compensation plans not approved by security holders	—	$ —	—
Total	40	$ 236.16	67,959

The following table sets forth, as of March 20, 2020, information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of the applicable security, including options that are currently exercisable or exercisable within 60 days of March 20, 2020. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons named in the table below have sole voting and investment power with respect to all shares of common stock shown that they beneficially own, subject to community property laws where applicable.

Our calculation of the percentage of beneficial ownership is based on 2,288,837 shares of our common stock issued and outstanding as of March 20, 2020.

Common stock subject to stock options currently exercisable or exercisable within 60 days of March 20, 2020, are deemed to be outstanding for computing the percentage ownership of the person holding these securities and the percentage ownership of any group of which the holder is a member but are not deemed outstanding for computing the percentage of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Akers Biosciences, Inc., 201 Grove Road, Thorofare, New Jersey USA 08086.

	Shares Beneficially Owned as of March 20, 2020	Percentage of Ownership as of March 20, 2020
Name of Beneficial Owner:		
5% Shareholders:		
Armstice Capital, LLC(3)	190,174	8.31%
Iroquois Capital Management LLC(4)	205,787	8.99%
Hudson Bay Capital Management LP (5)	269,243	11.76%
Named Executive Officers and Directors:		
Bill J. White(2)	5,201	*%
Joshua Silverman(2)	5,201	*%
Christopher C. Schreiber(2)	5,201	*%
Robert C. Schroeder	-	-%
Howard R. Yeaton (1)	2,345	*%
All executive officers and directors as a group (4 person)	17,948	*%

* Less than 1%.

(1) In connection with his appointment as our Chief Executive Officer and interim Chief Financial Officer, we and Mr. Yeaton entered into an offer of employment, dated October 5, 2018 and terminated on December 31, 2019 (the "Employment Agreement"). The Employment Agreement provided for, among other compensation, a monthly grant of one hundred fifty six (156) unrestricted shares of our common stock pursuant to the 2017 Plan. Forty-Five Thousand (1,877) unrestricted shares of the common stock have to date been issued to Mr. Yeaton pursuant to the 2017 Plan.

(2) On March 29, 2019, the Compensation Committee of the Board of Directors granted to each of Mr. Schreiber, Mr. White and Mr. Silverman 5,201 RSUs, which vested on January 1, 2020, for services as directors of our company.

(3) According to a Schedule 13G filed with the SEC on December 13, 2019, Armstice Capital, LLC, a Delaware limited liability company, Armstice Capital Master Fund Ltd., a Cayman Islands exempted company, and Steven Boyd, a citizen of the United States, share voting and dispositive power over the 190,174 shares of common stock reported. The business address for each reporting person is 510 Madison Avenue, 7th Floor, New York, NY 10022.

(4) According to a Schedule 13G filed with the SEC on December 18, 2019, Iroquois Capital Management L.L.C., a Delaware limited liability company ("Iroquois"), Richard Abbe, an individual who is a citizen of the United States of America and Kimberly Page, an individual who is a citizen of the United States of America ("Mr. Abbe" and "Ms. Page," together with Iroquois, the "Reporting Persons"). As of the Schedule 13G, Iroquois Master Fund Ltd. ("Iroquois Master Fund") held 88,000 shares of common stock, Reported Pre-Funded Warrants to purchase 12,000 shares of Common Stock and Reported Warrants to purchase 105,787 shares of common stock and Iroquois Capital Investment Group LLC ("ICIG") held 22,000 shares of common stock, Reported Pre-Funded Warrants to purchase 3,000 shares of Common Stock and Reported Warrants to purchase 33,681 shares of Common Stock. Mr. Abbe shares authority and responsibility for the investments made on behalf of Iroquois Master Fund with Ms. Kimberly Page, each of whom is a director of the Iroquois Master Fund. Each of the Reporting Persons hereby disclaims any beneficial ownership of any such shares of Common Stock except to the extent of their pecuniary interest therein. The principal business office of all of the Reporting Persons is 125 Park Avenue, 25th Floor New York, NY 10017.

(5) According to a Schedule 13G filed with the SEC on January 9, 2020, Hudson Bay Capital Management LP, a Delaware limited partnership and Sander Gerber, a citizen of the United Stated, share voting and dispositive power over 269,243 shares of common stock reported. Hudson Bay Capital Management LP serves as the investment manager to Hudson Bay Master Fund Ltd., in whose name the shares of common stock are held, may be deemed to be the beneficial owner of all shares of common stock held by Hudson Bay Master Fund Ltd and Mr. Gerber serves as the managing member of Hudson Bay Capital GP LLC, which is the general partner of the Hudson Bay Capital Management LP. Mr. Gerber disclaims beneficial ownership of these securities. The address of the business office of each of the reporting persons is 777 Third Avenue, 30th Floor, New York, NY 10017.

Changes in Control

We are not aware of any arrangements that may result in "changes in control" as that term is defined by the provisions of Item 403(c) of Regulation S-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Other than compensation arrangements, the following is a description of transactions to which we were a participant or will be a participant to, in which:

- the amounts involved exceeded or will exceed the lesser of 1% of our total assets or $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Employment of Howard Yeaton

Effective on October 5, 2018, the Board of Directors appointed Howard R. Yeaton, who through Financial Consulting Strategies LLC ("FCS") served previously as a consultant to us, to serve as our Chief Executive Officer and interim Chief Financial Officer. Mr. Yeaton is the managing principal of FCS and we have an ongoing relationship with FCS, with FCS continuing to provide accounting services to us. FCS is considered to be a related party. During the year ended December 31, 2019, we expensed to $38,888 to FCS. During the year ended December 31, 2018, we expensed $104,749 to FCS (including fees incurred prior to the date that Mr. Yeaton began to serve as an officer of our company) in connection with these services. As of December 31, 2019, we owed FCS $18,323. On November 1, 2019, the Board of Directors provided Mr. Howard R. Yeaton with sixty (60) days' notice of its intent to terminate him from each of his officer positions as our Chief Executive Officer and interim Chief Financial Officer.

On January 6, 2020, the Board of Directors appointed Howard R. Yeaton as our interim Chief Financial Officer. In connection with his appointment as our interim Chief Financial Officer, we and Mr. Yeaton entered into a new offer of employment, dated January 6, 2020 for a period of ninety days. Pursuant to such agreement, Mr. Yeaton will receive: (i) twenty-five thousand dollars ($25,000) per month in base salary, (ii) Mr. Yeaton will be afforded other employee benefits including, health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in our 401(k) Plan, and (iii) will be reimbursed for reasonable and necessary travel and business expenses including the expenses of travel and hotel stays in or near Thorofare, New Jersey. We may terminate the Employment Agreement for any reason or no reason, and Mr. Yeaton may voluntarily resign for any reason or no reason with thirty (30) days' notice.

Employment of Christopher C. Schreiber

On January 24, 2020, the Board of Directors independently reviewed and approved entering into an executive chairman agreement with Christopher C. Schreiber (the "Executive Chairman Agreement"). Pursuant to the Executive Chairman Agreement, Mr. Schreiber shall continue to serve as the Executive Chairman of the Board of Directors as long as he is a member of the Board of Directors, or until termination of the Executive Chairman Agreement (as described below) or upon his earlier death, incapacity, removal, or resignation. Pursuant to the Executive Chairman Agreement, Mr. Schreiber is entitled to receive: (i) an annual base salary of $300,000, payable monthly in equal installments, paid retroactively as of November 1, 2019 (it being agreed that such fee shall be inclusive of any fees associated with Schreiber's services as both a director of our company and in the capacity of Executive Chairman), (ii) employee benefits including, health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in our 401(k) Plan, (iii) annual or other bonuses in cash and/or in securities of our company and/or otherwise, which bonuses, if any, shall be awarded in the complete discretion of the Board of Directors or a designated committee thereof and (iv) reimbursements for pre-approved reasonable business-related expenses incurred in good faith in the performance of Mr. Schreiber's duties for us. The Executive Chairman Agreement established an "at will" employment relationship pursuant to which Mr. Schreiber serves as Executive Chairman. We may terminate the Executive Chairman Agreement for any reason or no reason, and Mr. Schreiber may voluntarily resign for any reason or no reason with sixty (60) days' notice. The Executive Chairman Agreement also provides that Mr. Schreiber may not compete against us or solicit our employees or customers for a period of one (1) year after termination of the Executive Chairman Agreement or his association with us for any reason.

Item 14. Principal Accounting Fees and Services.

The following table sets forth the aggregate fees billed for each of the last two fiscal years for professional services rendered by the principal accountant for the audit of our annual financial statements and review of financial statements included in our quarterly reports or services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements for those fiscal years.

Audit-Related fees include services for the review of interim financial statements, tax fees include the preparation of tax returns and other fees include services performed in relation to the preparation of various SEC Forms and advisory services.

Tax fees includes services for the preparation of the Company's income tax returns.

All Other Fees includes included principally due diligence review and preparation of the Audit Comfort Letter for the underwriter for our public offering and shelf registration filings. In 2018, we incurred other fees in support of the preparation of our 2018 restatements of Forms 10-Q/A and 10-K/A and Form S-1 and S-3, as well as due diligence review and preparation of the Audit Comfort Letter for the underwriter for our public offering and shelf registration filings.

	2019	2018
Audit Fees	$ 80,000	$ 100,000
Audit-Related Fees	$ 59,000	$ 232,100
Tax Fees	$ 10,000	$ 10,000
All Other Fees	$ 37,450	$ 4,369
TOTAL	$ 186,450	$ 346,469

Pre Approval Policies and Procedures

The audit and permissible non-audit services were pre-approved in accordance with the pre-approval policy and procedures adopted by the audit committee. The policy requires that requests for all services must be submitted to the audit committee for specific pre-approval and cannot commence until such approval has been granted.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements

F-1 to F-44.

(2) Financial Statements Schedule

None.

(3) Exhibits

We hereby file as part of this Annual Report the exhibits listed in the attached Exhibit Index. Exhibits which are incorporated herein by reference can be obtained on the SEC website at **www.sec.gov**.

Exhibit Number	Description
3.1	Amended & Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.2	Amendment to Certificate of Incorporation dated June 2, 2008 (incorporated herein by reference to Exhibit 3.2 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.3	Amendment to Certificate of Incorporation, Certificate of Designation of Series A Preferred Stock, dated September 21, 2012. (incorporated herein by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.4	Amendment to Certificate of Incorporation dated January 22, 2013 (incorporated herein by reference to Exhibit 3.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
3.5	Amended and Restated By-laws dated August 5, 2013 (incorporated herein by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).

3.6	Amendment to Restated By-laws dated May 11, 2016 (incorporated herein by reference to Exhibit 3.6 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 18, 2016).
3.7	Certificate of Amendment to Certificate of Incorporation, Certificate of Designation of Series B Convertible Preferred Stock, dated December 19, 2017 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 26, 2017).
3.8	Amendment to Amended and Restated By-Laws, dated October 19, 2018 (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2018).
3.9	Certificate of Amendment (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 9, 2018).
3.10	Certificate of Designation of Series C Convertible Preferred Stock, dated December 9, 2019.*
3.11	Certificate of Amendment to the Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2020).
3.12	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
4.1	Form of Underwriters' Warrant (incorporated by reference to Exhibit 4.1 to the to the Company's Registration Statement on Form S-1 filed with the Securities Exchange Commission on November 18, 2013).
4.2	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 10, 2017).
4.3	Form of Purchaser Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
4.4	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
4.5	Form of Purchaser Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 13, 2017).
4.6	Form of Underwriter's Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 15, 2017).
4.7	Form of Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on December 15, 2017).
4.8	Form of Warrant (incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018).
4.9	Form of Series C Convertible Preferred Stock Warrant Certificate (incorporated herein by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
4.10	Form of Pre-Funded Warrant Certificate (incorporated herein by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).

4.11	Form of Placement Agent Warrant Certificate (incorporated herein by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
4.12	Description of Securities.*
10.1	Amended License and Supply Agreement by and between Akers Biosciences, Inc. and Chubeworkx Guernsey Limited (as successor to Sono International Limited) ("Chubeworkx"), (EN)10 (Guernsey) Limited (formerly BreathScan International (Guernsey) Limited) and (EN)10 Limited (formerly BreathScan International Limited), dated June 12, 2013 (incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.2	Share Purchase Agreement by and between Akers Biosciences, Inc. and Chubeworkx, dated June 12, 2013. (incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.3	Subscription Agreement by and between Akers Biosciences, Inc. and Chubeworkx, dated June 12, 2013(incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.4	Subscription Agreement by and between Akers Biosciences, Inc. and Thomas J. Knox, dated September 14, 2012(incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.5	Promissory Note entered into by Thomas J Knox issued in favor of Akers Biosciences, Inc., dated September 14, 2012. (incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 7, 2013).
10.6	License and Supply Agreement by and among the Company, Sono International Limited ("SIL"), BreathScan International (Guersney) Limited and BreathScan International Limited, dated June 19, 2012 (incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013).
10.7	Distribution Agreement by and among the Company and Fisher Healthcare, and Amendment thereto, dated June 15, 2010 and May 1, 2012, respectively. (incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013).
10.8	National Brand Distribution Agreement by and among the Company and Cardinal Health 2000, and Amendment thereto, dated May 1, 2007 and June 1, 2008, respectively. (incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on October 8, 2013).
10.9	2013 Incentive Stock and Award Plan (incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.10	Form of Nonqualified Stock Option Agreement (Non-Employee) (incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.11	Form of Nonqualified Stock Option Agreement (Employee) (incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).

10.12	Form of Restricted Stock Agreement (incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.13	Form of Incentive Stock Option (incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.14	Letter Agreement, dated December 3, 2013, by and between the Company and Mr. Thomas Knox (incorporated herein by reference to Exhibit 10.19 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on December 6, 2013).
10.15	Joint Venture Agreement, dated October 24, 2014, by and between Akers Biosciences, Inc., Hainan Savy Investment Management Ltd, and Thomas Knox (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 29, 2014).
10.16	Amended and Restated 2013 Incentive Stock and Award Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2015).
10.17	Form of Lock Up Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2015).
10.18	Employment Agreement between the Company and John J Gormally, dated December 1, 2015. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 3, 2015).
10.19	First Amendment to the Amended and Restated 2013 Incentive Stock and Award Plan (incorporated by referenced to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 12, 2016).
10.20	Form of Placement Agency Agreement, dated March 30, 2017, by and between Akers Biosciences, Inc. and Joseph Gunnar and Co., LLC (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.21	Form of Securities Purchase Agreement, dated March 30, 2017, by and between Akers Biosciences, Inc. and various purchasers. (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.22	Form Registration Rights Agreement, dated March 30, 2017, by and between Akers Biosciences, Inc. and various purchasers (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 5, 2017).
10.23	Akers Biosciences, Inc. 2017 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 8, 2017).
10.24	Form Warrant Exercise Agreement, dated October 12, 2017 by and between Akers Biosciences, Inc. and various holders (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 13, 2017).
10.25	Form of Resignation Agreement (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 11, 2018).

10.26	Offer of Employment, dated October 5, 2018 (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 11, 2018).
10.27	Form of Securities Purchase Agreement, dated October 31, 2018, by and among the Company and the investors signatory thereto (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 31, 2018).
10.28	Akers Biosciences, Inc. 2018 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 7, 2018).
10.29	Form of Securities Purchase Agreement (incorporated herein by reference to Exhibit 3.10 to the Company's Registration Statement on Form S-1/A filed with the Securities and Exchange Commission on November 29, 2019).
10.30	Offer of Employment, dated January 6, 2020 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2020).
10.31	Offer of Employment, dated January 31, 2020 (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 31, 2020).
10.32	Membership Interest Purchase Agreement ((incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.33	Support Agreement (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.34	Registration Rights Agreement (incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
10.35	License Agreement (incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2020).
21.1	List of Subsidiaries.*
23.1	Consent of Morison Cogen LLP, Independent Registered Public Accounting Firm.*
31.1	Certification of the Principal Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).*
31.2	Certification of the Principal Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).*
32.1	Certification of the Principal Executive Officer and Principal Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. 1350**

* Filed herewith

** Furnished herewith

Item 16. Form 10-K Summary.

Not applicable

SIGNATURES

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

AKERS BIOSCIENCES, INC.

Date: March 24, 2020

By: */S/ Christopher C. Schreiber*
Name: Christopher C. Schreiber
Title: Executive Chairman of the Board of Directors and Director
(Principal Executive Officer)

In accordance with the Exchange Act, this Annual Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/S/ Christopher C. Schreiber Christopher C. Schreiber	Executive Chairman of the Board of Directors and Director (Principal Executive Officer)	March 24, 2020
/S/ Howard R. Yeaton Howard R. Yeaton	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 24, 2020
/S/ Joshua Silverman Joshua Silverman	Director	March 24, 2020
/S/ Bill J. White Bill J. White	Director	March 24, 2020
/S/ Robert C. Schroeder Robert C. Schroeder	Director	March 24, 2020

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Akers Biosciences, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Akers Biosciences, Inc. and Subsidiaries (the Company) as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Morison Cogen LLP

We have served as the Company's auditor since 2010.

Blue Bell, Pennsylvania
March 24, 2020

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2019 and 2018

	As of December 31,	
	2019	**2018**
ASSETS		
Current Assets		
Cash	$ 517,444	$ 181,755
Marketable Securities	9,164,273	5,272,998
Trade Receivables, net	42,881	176,326
Deposits and other receivables	-	9,347
Inventories, net	198,985	585,267
Prepaid expenses	387,231	444,435
Total Current Assets	10,310,814	6,670,128
Non-Current Assets		
Prepaid expenses	252,308	298,256
Restricted Cash	115,094	500,000
Property, Plant and Equipment, net	33,574	83,456
Intangible Assets, net	170,423	243,411
Other Assets	2,722	12,002
Total Non-Current Assets	574,121	1,137,125
Total Assets	$ 10,884,935	$ 7,807,253
LIABILITIES		
Current Liabilities		
Trade and Other Payables	$ 1,529,765	$ 1,973,500
Total Current Liabilities	1,529,765	1,973,500
Total Liabilities	1,529,765	1,973,500
Commitments and Contingencies		
SHAREHOLDERS' EQUITY		
Preferred Stock, No par value, 50,000,000 total preferred shares authorized	-	-
Series C Convertible Preferred stock, 1,990,000 shares designated, no par value and a stated value of $4.00 per share, 0 and 0 shares issued and outstanding as of December 31, 2019 and 2018	-	-
Common Stock, No par value, 100,000,000 shares authorized 1,738,837 and 540,607 issued and outstanding as of December 31, 2019 and 2018	128,920,414	121,554,547
Accumulated Other Comprehensive Income (Loss)	17,886	(25,913)
Accumulated Deficit	(119,583,130)	(115,694,881)
Total Shareholders' Equity	9,355,170	5,833,753
Total Liabilities and Shareholders' Equity	$ 10,884,935	$ 7,807,253

The accompanying notes are an integral part to these consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss

	For the Years Ended December 31,	
	2019	**2018**
Product Revenue	$ 1,577,033	$ 1,665,570
Product Cost of Sales	(1,098,286)	(1,538,285)
Gross Income	478,747	127,285
Administrative Expenses	3,728,514	5,666,018
Sales and Marketing Expenses	238,036	1,782,315
Compliance, Research and Development Expenses	276,788	1,063,253
Litigation Settlement Expenses	141,478	1,505,000
Amortization of Non-Current Assets	40,008	171,108
Loss from Operations	(3,946,077)	(10,060,409)
Other (Income)/Expenses		
Impairment of Intangible Assets	32,980	716,148
Impairment of Other Assets	-	64,092
Loss on Disposal of Property and Equipment	9,576	156,493
Foreign Currency Transaction Loss	5,051	6,726
Other Income	-	(4,172)
(Gain) Loss on Investments	(3,952)	15,178
Interest and Dividend Income	(101,483)	(165,840)
Total Other Expense	(57,828)	788,625
Loss Before Income Taxes	(3,888,249)	(10,849,034)
Income Tax Benefit	-	-
Net Loss	(3,888,249)	(10,849,034)
Other Comprehensive Income (Loss)		
Net Unrealized Gain (Loss) on Marketable Securities	43,799	(25,913)
Total Other Comprehensive Income (Loss)	43,799	(25,913)
Comprehensive Loss	$ (3,844,450)	$ (10,874,947)
Basic and Diluted loss per common share	$ (6.35)	$ (22.28)
Weighted average basic and diluted common shares outstanding	612,672	486,951

The accompanying notes are an integral part to these consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statement of Changes in Shareholders' Equity
For the Years Ended December 31, 2019 and 2018

	Series B Convertible Preferred Shares Issued and Outstanding	Series B Convertible Preferred Stock	Common Shares Issued and Outstanding	Common Stock	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Equity
Balance at January 1, 2018	1,755	$ 1,755,000	251,227	$ 110,647,169	$ (3,469)	$ (104,845,847)	$ -	$ 7,552,853
Net loss	-	-	-	-	-	(10,849,034)	-	(10,849,034)
Exercise of warrants for common stock	-	-	199,055	7,155,200	-	-	-	7,155,200
Conversion of preferred stock to common stock	(1,755)	(1,755,000)	60,943	1,755,000	-	-	-	-
Private offering of common stock, net of offering costs of $50,000	-	-	28,937	1,950,000	-	-	-	1,950,000
Amortization of deferred compensation	-	-	-	-	3,469	-	-	3,469
Issuance of stock grants to officer	-	-	445	27,702	-	-	-	27,702
Stock-based compensation - stock options	-	-	-	6,931	-	-	-	6,931
Stock-based compensation - restricted stock	-	-	-	12,545	-	-	-	12,545
Net unrealized loss on marketable securities	-	-	-	-	-	-	(25,913)	(25,913)
Balance at December 31, 2018	-	$ -	540,607	$ 121,554,547	$ -	$ (115,694,881)	$ (25,913)	$ 5,833,753
Net loss	-	-	-	-	-	(3,888,249)	-	(3,888,249)
Public offering - common stock, net of offering costs of $306,222	-	-	613,500	2,147,778	-	-	-	2,147,778
Public offering - prepaid equity forward contracts, net of offering costs of $688,005	-	-	-	4,817,857	-	-	-	4,817,857
Issuance of stock grants to officer	-	-	1,563	27,367	-	-	-	27,367
Issuance of common stock to vendor for services	-	-	1,667	10,802	-	-	-	10,802
Exercise of prepaid equity forward contracts for common stock	-	-	581,500	58	-	-	-	58
Stock-based compensation - restricted stock units	-	-	-	362,005	-	-	-	362,005
Net unrealized gain on marketable securities	-	-	-	-	-	-	43,799	43,799
Balance at December 31, 2019	-	$ -	1,738,837	$ 128,920,414	$ -	$ (119,583,130)	$ 17,886	$ 9,355,170

The accompanying notes are an integral part to these consolidated financial statements.

AKERS BIOSCIENCES, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2019 and 2018

	For the Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (3,888,249)	$ (10,849,034)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on sale of securities	(3,952)	15,178
Accrued (loss)/income - marketable securities	3,353	(11,011)
Depreciation and amortization	74,064	234,486
Loss on disposal of fixed assets	9,576	156,493
Impairment of intangible assets	32,980	716,148
Impairment of other assets	-	64,092
Reserve for obsolete inventory	371,997	279,029
Reserve for doubtful trade receivables	5,325	156,835
Reserve for doubtful other receivables	100,000	-
Amortization of deferred compensation	-	3,469
Stock-based compensation to employees - options	-	6,931
Stock-based compensation to employees - common stock	27,367	27,702
Stock-based compensation to directors - restricted stock units	362,005	-
Stock-based compensation - shares issued to vendors	10,802	12,545
Changes in assets and liabilities:		
Decrease in trade receivables	128,120	631,510
Decrease in deposits and other receivables	9,347	7,243
Decrease in inventories	14,285	83,316
Decrease/(increase) in prepaid expenses	103,152	(225,586)
Decrease in other assets	9,280	-
Increase (decrease) in trade and other payables	(443,735)	188,462
Net cash used in operating activities	(3,074,283)	(8,502,192)
Cash flows from investing activities		
Purchases of property, plant and equipment	-	(68,214)
Proceeds from the sale of equipment	6,250	-
Short-term note receivable	(100,000)	-
Purchases of marketable securities	(6,704,837)	(6,604,801)
Proceeds from sale of marketable securities	2,857,960	6,313,330
Net cash used in investing activities	(3,940,627)	(359,685)
Cash flows from financing activities		
Net proceeds from issuance of common stock	2,147,778	1,950,000
Net proceeds from issuance of prepaid equity forward contracts for the purchase of common stock	4,817,857	-
Net proceeds from the exercise of prepaid equity forward contracts for the purchase of common stock	58	-
Net proceeds from exercise of warrants for common stock	-	7,155,200
Net cash provided by financing activities	6,965,693	9,105,200
Net increase/(decrease) in cash and restricted cash	(49,217)	243,323
Cash and restricted cash at beginning of year	681,755	438,432
Cash and restricted cash at end of year	$ 632,538	$ 681,755
Supplemental cash flow information:		
Cash paid for:		
Interest	$ -	$ -
Income Taxes	$ -	$ 2,070
Supplemental Schedule of Non-Cash Financing and Investing Activities		
Net unrealized gains/(losses) on marketable securities	$ 43,799	$ (25,913)
Conversion of Series B Preferred Stock to common shares	$ -	$ 1,755,000

The accompanying notes are an integral part to these consolidated financial statements.

Note 1 – Organization and Description of Business

Akers Biosciences, Inc. ("Akers"), is a New Jersey corporation. These consolidated financial statements include two wholly owned subsidiaries, Akers Acquisition Sub, Inc. and Bout Time Marketing Corporation, (together, the "Company"). All material intercompany transactions have been eliminated in consolidation.

On November 7, 2018, the Company announced its intention to explore strategic alternatives in order to maximize shareholder value. As announced, this process will consider a range of potential strategic alternatives including, but not limited to, business combinations and developing new businesses through hiring key personnel, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities.

Furthermore, the Company has undertaken steps to reduce its expenses, including reducing the number of personnel, reducing its office and warehouse footprint, eliminating services from non-critical vendors and has withdrawn its shares from registration on the AIM exchange in the United Kingdom.

The Company's medical device business has as its current focus the production and sale of disposable diagnostic testing devices that can be performed in minutes, to facilitate time sensitive therapeutic decisions. The Company's principal products are a rapid test detecting the antibody causing an allergic reaction to Heparin and breath alcohol detectors used for health and safety.

Note 2 – Significant Accounting Policies

(a) Basis of Presentation

The accompanying consolidated financial statements for the years ended December 31, 2019 and 2018 have been prepared in accordance and in conformity with the accounting principles generally accepted in the United States of America ("U.S. GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding consolidated financial information.

On November 25, 2019, the Company effectuated a reverse stock split of its shares of Common Stock whereby every twenty-four (24) pre-split shares of Common Stock were exchanged for one (1) post-split share of the Company's Common Stock ("Reverse Stock Split"). No fractional shares were issued in connection with the Reverse Stock Split and the remaining fractions were rounded up to the next whole share. Shareholders who would otherwise have held a fractional share of the Common Stock were given one additional full share of the Company's Common Stock. Share amounts presented in these consolidated financial statements have been adjusted to reflect the Reverse Stock Split.

Note 2 - Significant Accounting Policies, continued

(b) Use of Estimates and Judgments

The preparation of financial statements in conformity with US GAAP requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected. Information about significant areas of estimation, uncertainty and critical judgments in applying accounting policies that have the most significant effect on the amounts recognized in the financial statements are included in the following notes for revenue recognition, allowances for doubtful accounts, inventory valuations, impairment of intangible assets and valuation of share-based payments.

(c) Functional and Presentation Currency

These consolidated financial statements are presented in U.S. Dollars, which is the Company's functional currency. All financial information presented in U.S. Dollars has been rounded to the nearest dollar. Foreign Currency Transaction Gains or Losses, resulting from cash balances denominated in Foreign Currencies, are recorded in the consolidated statements of operations and comprehensive loss.

(d) Comprehensive Income (Loss)

The Company follows Financial Accounting Standards Board Accounting Standards Codification ("FASB ASC") 220 in reporting comprehensive income (loss). Comprehensive income is a more inclusive financial reporting methodology that includes disclosure of certain financial information that historically has not been recognized in the calculation of net income.

(e) Cash and Cash Equivalents

The Company considers all highly liquid investments, which include short-term bank deposits (up to 3 three months from date of deposit) that are not restricted as to withdrawal date or use, to be cash equivalents.

(f) Restricted Cash

At December 31, 2019, restricted cash included in non-current assets on the Company's consolidated balance sheet was $115,094 representing cash in trust for the purpose of funding legal fees for certain litigations.

Note 2 - Significant Accounting Policies, continued

(g) Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, receivables and trade and other payables. The carrying value of cash and cash equivalents, receivables and trade and other payables approximate their fair value because of their short maturities.

The framework for measuring fair value provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1) and the lowest priority to unobservable inputs (level 3). The three levels of the fair value hierarchy under FASB ASC 820 are described as follows:

Level 1 Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets that the Company has the ability to access.

Level 2 Inputs to the valuation methodology include:

- quoted prices for similar assets or liabilities in active markets;
- quoted prices for identical or similar assets or liabilities in inactive markets;
- inputs other than quoted prices that are observable for the asset or liability;
- inputs that are derived principally from or corroborated by observable market data by correlation or other means

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3 Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. Valuation techniques maximize the use of relevant observable inputs and minimize the use of unobservable inputs.

Note 2 - Significant Accounting Policies, continued

(g) Fair Value of Financial Instruments, continued

Following is a description of the valuation methodologies used for assets measured at fair value as of December 31, 2019 and December 31, 2018.

U.S. Agency Securities: Valued using pricing models maximizing the use of observable inputs for similar securities. This includes basing value on yields currently available on comparable securities of issuers with similar credit ratings.

	Quoted Prices in Active Markets for Identical Assets or Liabilities (Level 1)	Quoted Prices for Similar Assets or Liabilities in Active Markets (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities at December 31, 2019	$ -	$ 9,164,273	$ -
Marketable securities at December 31, 2018	$ -	$ 5,272,998	$ -

Marketable securities comprise debt securities and include U.S. agency securities, which are classified as available for sale. The debt securities are valued at fair market value. Maturities of the securities are less than one year. Unrealized gains and losses relating to the available for sale investment securities were recorded in the Consolidated Statement of Changes in Shareholders' Equity as comprehensive (loss) income. These amounts were an increase of $43,799 in unrealized gains for the year ended December 31, 2019 and $25,913 in unrealized losses for the year ended December 31, 2018.

Gains and losses resulting from these sales amounted to a gain of $3,952 and a loss of $15,178 for the years ended December 31, 2019 and 2018, respectively.

For the years ended December 31, 2019 and 2018, proceeds from the sale of marketable securities were $2,857,960 and $6,313,330, respectively.

Note 2 - Significant Accounting Policies, continued

(h) Trade Receivables and Allowance for Doubtful Accounts

The carrying amounts of current trade receivables is stated at cost, net of allowance for doubtful accounts and approximate their fair value given their short-term nature.

The normal credit terms extended to customers ranges between 30 and 90 days. Credit terms longer than these may be extended after considering the credit worthiness of the customers and the business requirements. The Company reviews all receivables that exceed terms and establishes an allowance for doubtful accounts based on management's assessment of the collectability of trade and other receivables. A considerable amount of judgment is required in assessing the amount of allowance. The Company considers the historical level of credit losses, makes judgments about the credit worthiness of each customer based on ongoing credit evaluations and monitors current economic trends that might impact the level of credit losses in the future.

As of December 31, 2019, and 2018, allowances for doubtful accounts for trade receivables were $458,902 and $606,835. Bad debt expenses for trade receivables were $5,325 and $185,335 for the years ended December 31, 2019 and 2018.

(i) Deposits and Other Receivables

Further to the Company's pursuit of strategic alternatives, pursuant to an unsecured promissory note dated July 4, 2019, on July 25, 2019 the Company advanced $100,000 to a company in the hemp related industry with which the Company had been considering a potential business transaction. Discussions with this party toward a potential transaction have been suspended. The unsecured promissory note became due on October 2, 2019 and the Company is pursuing collection of the obligation.

For the year ended December 31, 2019, the Company established a reserve of $100,000 which is included in Administrative Expenses in the Consolidated Statement of Operations and Comprehensive Loss.

Note 2 - Significant Accounting Policies, continued

(j) Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash on deposit with financial institutions and accounts receivable. At times, the Company's cash in banks is in excess of the FDIC insurance limit. The Company has not experienced any loss as a result of these cash deposits. These cash balances are maintained with two banks.

Major Customers

For the year ended December 31, 2019, two customers generated 48% and 31% or 79% in the aggregate, of the Company's revenues. For the year ended December 31, 2018, two customers generated 57% and 14%, or 71% in the aggregate, of the Company's revenue.

Five customers accounted for 30%, 18%, 12%, 12% and 11%, or 83% in the aggregate, and two customers accounted for 62% and 37%, or 99% in the aggregate, of trade receivables net of customer credits and allowances for doubtful accounts as of December 31, 2019 and 2018, respectively. These concentrations make the Company vulnerable to a near-term severe impact should these relationships be terminated. To limit such risks, the Company performs ongoing credit evaluations of its customers' financial condition.

Major Suppliers

One supplier accounted for 43% and 14% of the Company's purchases for the years ended December 31, 2019 and 2018, respectively.

None of the Company's suppliers accounted for more than 10% of the Company's outstanding accounts payable as of December 31, 2019 and 2018.

Note 2 - Significant Accounting Policies, continued

(k) Property, Plant and Equipment

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment and are recognized within "other (income)/expense" in the Consolidated Statement of Operations and Comprehensive Loss.

Depreciation is recognized in profit and loss on the accelerated basis over the estimated useful lives of the property, plant and equipment. Leased assets are depreciated over the shorter of the lease term or their useful lives.

The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Plant and equipment	5-12
Furniture and fixtures	5-10
Computer equipment & software	3-5
Leasehold Improvements	Shorter of the remaining lease or estimated useful life

Depreciation methods, useful lives and residual values are reviewed at each reporting date.

Note 2 - Significant Accounting Policies, continued

(l) Intangible Assets

The Company's long-lived intangible assets, other than goodwill, are assessed for impairment when events or circumstances indicate there may be an impairment. These assets were initially recorded at their estimated fair value at the time of acquisition and assets not acquired in acquisitions were recorded at historical cost. However, if their estimated fair value is less than the carrying amount, other intangible assets with indefinite lives are reduced to their estimated fair value through an impairment charge to our Consolidated Statements of Operations and Comprehensive Loss.

Patents and Trade Secrets

The Company has developed or acquired several diagnostic tests that can detect the presence of various substances in a person's breath, blood, urine and saliva. Propriety protection for the Company's products, technology and process is important to its competitive position. As of December 31, 2019, the Company has ten patents from the United States Patent Office in effect Other patents are in effect in Australia through the Design Registry European Union Patents, in Hong Kong and in Japan. Patents are in the national phase of prosecution in many Patent Cooperation Treaty participating countries. Additional proprietary technology consists of numerous different inventions. Management intends to protect all other intellectual property (e.g. copyrights, trademarks and trade secrets) using all legal remedies available to the Company.

Patent Costs

Costs associated with applying for patents are capitalized as patent costs. Once the patents are approved, the respective costs are amortized over their estimated useful lives (maximum of 17 years) on a straight-line basis and assessed for impairment when necessary. Patent pending costs for patents that are not approved are charged to the consolidated statements of operations and comprehensive loss the year the patent is rejected.

In addition, patents may be purchased from third parties. The costs of acquiring the patent are capitalized as patent costs if it represents a future economic benefit to the Company. Once a patent is acquired it is amortized over its remaining useful life and assessed for impairment when necessary.

Other Intangible Assets

Other intangible assets that are acquired by the Company, which have definite useful lives, are measured at cost less accumulated amortization and accumulated impairment losses.

Amortization

Amortization is recognized on a straight-line basis over the estimated useful lives of intangible assets, other than goodwill, from the date that they are available for use. The estimated useful lives for the current and comparative periods are as follows:

	Useful Life (in years)
Patents and trademarks	12-17

Note 2 - Significant Accounting Policies, continued

(m) Recoverability of Long Lived Assets

In accordance with FASB ASC 360-10-35 "Impairment or Disposal of Long-lived Assets", long-lived assets to be held and used are analyzed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable or that the useful lives of those assets are no longer appropriate. The Company evaluates at each balance sheet date whether events and circumstances have occurred that indicate possible impairment.

The Company determines the existence of such impairment by measuring the expected future cash flows (undiscounted and without interest charges) and comparing such amount to the carrying amount of the assets. An impairment loss, if one exists, is then measured as the amount by which the carrying amount of the asset exceeds the discounted estimated future cash flows. Assets to be disposed of are reported at the lower of the carrying amount or fair value of such assets less costs to sell. Asset impairment charges are recorded to reduce the carrying amount of the long-lived asset that will be sold or disposed of to their estimated fair values. Charges for the asset impairment reduce the carrying amount of the long-lived assets to their estimated salvage value in connection with the decision to dispose of such assets.

(n) Investments

In accordance with FASB ASC 323, the Company recognizes investments in joint ventures based upon the Company's ability to significantly influence the operational or financial policies of the joint venture. An objective judgment of the level of influence is made at the time of the investment based upon several factors including, but not limited to the following:

a) Representation on the Board of Directors

b) Participation in policy-making processes

c) Material intra-entity transactions

d) Interchange of management personnel

e) Technological dependencies

f) Extent of ownership and the ability to influence decision making based upon the makeup of other owners when the shareholder group is small.

The Company follows the equity method for valuating investments in joint ventures when the existence of significant influence over operational and financial policy has been established, as determined by management; otherwise, the Company will valuate these investments using the cost method.

Investments recorded using the cost method will be assessed for any decrease in value that has occurred that is other than temporary and the other than temporary decrease in value shall be recognized. As and when circumstances and facts change, the Company will evaluate the Company's ability to significantly influence operational and financial policy to establish a basis for converting the investment accounted for using the cost method to the equity method of valuation.

Note 2 - Significant Accounting Policies, continued

(o) Revenue Recognition

Beginning on January 1, 2019, the Company recognizes revenue under ASC 606, Revenue from Contracts with Customers. The core principle of the revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods and services transferred to the customer. The following five steps are applied to achieve that core principle:

Step 1: Identify the contract with the customer
Step 2: Identify the performance obligations in the contract
Step 3: Determine the transaction price
Step 4: Allocate the transaction price to the performance obligations in the contract
Step 5: Recognize revenue when the company satisfies a performance obligation

The Company does not have any significant contracts with customers requiring performance beyond delivery. Shipping and handling activities are performed before the customer obtains control of the goods and therefore represent a fulfillment activity rather than a promised service to the customer. Revenue and costs of sales are recognized when control of the product transfers to our customer, which generally occurs upon delivery to the customer but can also occur when goods are shipped by the Company, depending on the shipment terms of the contract. The Company's performance obligations are satisfied at that time. The Company has not historically experienced customer returns of its products.

The Company uses the most likely amount approach to determine the variable consideration of the transaction price in order to account for the contractual rebates and incentives that are estimated and adjusted for over time. The Company provides for rebates to its distributors. The Company's accrued rebates and incentives were $20,002 and $23,179, as of December 31, 2019 and 2018, respectively. Accounts receivable will be reduced when the rebates are applied by the customer. The Company recognized $130,577 and $105,247 for the years ended December 31, 2019 and 2018 for rebates, respectively, which is included as a reduction of product revenue in the Consolidated Statement of Operations and Comprehensive Loss.

See Note 13 for disaggregation of revenue by product line and geographic region.

(p) Income Taxes

The Company utilizes an asset and liability approach for financial accounting and reporting for income taxes. The provision for income taxes is based upon income or loss after adjustment for those permanent items that are not considered in the determination of taxable income. Deferred income taxes represent the tax effects of differences between the financial reporting and tax basis of the Company's assets and liabilities at the enacted tax rates in effect for the years in which the differences are expected to reverse.

The Company evaluates the recoverability of deferred tax assets and establishes a valuation allowance when it is more likely than not that some portion or all the deferred tax assets will not be realized. Management makes judgments as to the interpretation of the tax laws that might be challenged upon an audit and cause changes to previous estimates of tax liability. In management's opinion, adequate provisions for income taxes have been made. If actual taxable income by tax jurisdiction varies from estimates, additional allowances or reversals of reserves may be necessary.

Note 2 - Significant Accounting Policies, continued

(p) Income Taxes, continued

Tax benefits are recognized 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 settlement. A liability for "unrecognized tax benefits" is recorded for any tax benefits claimed in the Company's tax returns that do not meet these recognition and measurement standards. For the years ended December 31, 2019 and 2018, no liability for unrecognized tax benefits was required to be reported.

There is no income tax benefit for the losses for the years ended December 31, 2019 and 2018 since management has determined that the realization of the net deferred assets is not assured and has created a valuation allowance for the entire amount of such tax benefits.

The Company's policy for recording interest and penalties associated with tax audits is to record such items as a component of general and administrative expense. There were no amounts accrued for penalties and interest for the years ended December 31, 2019 and 2018. The Company does not expect its uncertain tax position to change during the next twelve months. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

(q) Shipping and Handling Fees and Costs

The Company charges actual shipping costs plus a handling fee to customers, which amounted to $38,131 and $50,518 for the years ended December 31, 2019 and 2018. These fees are classified as product revenue in the Consolidated Statement of Operations and Comprehensive Loss. Shipping and other related delivery costs, including those for incoming raw materials are classified as product cost of sales, which amounted to $46,534 and $93,558 for the years ended December 31, 2019 and 2018, respectively.

(r) Research and Development Costs

In accordance with FASB ASC 730, research and development costs are expensed when incurred.

Note 2 - Significant Accounting Policies, continued

(s) Stock-based Payments

The Company accounts for stock-based compensation under the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 718, "Compensation - Stock Compensation", which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and directors based on estimated fair values on the grant date. The Company estimates the fair value of stock-based awards on the date of grant using the Black-Scholes model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods using the straightline method. In June 2018, the FASB issued ASU No. 2018-07, Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting. The amendments in this Update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Prior to this Update, Topic 718 applied only to share-based transactions to employees. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied.

The Company has elected to account for forfeiture of stock based awards as they occur.

Note 2 - Significant Accounting Policies, continued

(t) Basic and Diluted Earnings per Share of Common Stock

Basic earnings per common share is based on the weighted average number of shares outstanding during the periods presented. Diluted earnings per share is computed using the weighted average number of common shares plus dilutive common share equivalents outstanding during the period. Potential common shares that would have the effect of increasing diluted earnings per share are considered anti-dilutive.

Diluted net loss per share is computed using the weighted average number of common and dilutive potential common shares outstanding during the period. The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	For the Years Ended December 31,	
	2019	2018
Stock Options	40	443
Restricted Stock Units	15,603	-
Warrants to purchase Common Stock	247,215	88,015
Pre-funded Warrants to purchase Common Stock	795,000	-
Warrants to purchase Series C Preferred stock	1,990,000	-
Total potentially dilutive shares	3,047,858	88,458

Note 2 - Significant Accounting Policies, continued

(u) Recently Issued Accounting Pronouncements

Recently Issued Accounting Pronouncements Adopted

As an emerging growth company ("EGC"), Akers had elected to adopt recently issued accounting pronouncements based on effective dates applicable to other than public business entities. The Company lost its EGC status on December 31, 2019 as it was the last day of the fiscal year following the fifth anniversary of the effective date of its registration statement on January 23, 2014. Accordingly, effective January 1, 2020, Akers will adopt recently issued accounting pronouncements on dates applicable to public companies.

In May 2014 and April 2016, the FASB issued ASU No. 2014-09 and ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606). The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In August 2015, FASB issued ASU 2015-14 which deferred the effective date of Update 2014-09 to annual reporting periods beginning after December 15, 2018 for entities other than public business entities, and to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period for public business entities.

The Company has elected to apply the modified retrospective method and the impact was determined to be immaterial on the consolidated financial statements. Accordingly, the new revenue standard was applied prospectively in our consolidated financial statements from January 1, 2019 forward and reported financial information for historical comparable periods will not be revised and will continue to be reported under the accounting standards in effect during those historical periods.

The Company determined that its methods of recognizing revenues were not impacted by the new guidance.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The guidance is effective for public business entities, certain not-for-profit entities, and certain employee benefit plans for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, ASU 2018-07 is effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company early adopted ASC 2018-07 effective January 1, 2019. There was no material impact on the Company's consolidated financial statements upon this adoption.

In July 2018, the FASB issued ASU No. 2018-09, Codification Improvements, to makes changes to a variety of topics to clarify, correct errors in, or make minor improvements to the Accounting Standards Codification. Certain items of the amendments in ASU 2018-09 will be effective for the Company in annual periods beginning after December 15, 2018. The adoption of ASU 2018-09 did not have a material impact on the Company's consolidated financial statements.

Note 2 - Significant Accounting Policies, continued

(u) Recently Issued Accounting Pronouncements, continued

Recently Issued Accounting Pronouncements Not Adopted

In February 2016, the FASB issued ASU 2016-02—Leases (Topic 842) ("ASU-2016-02"), which requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. ASU 2016-02 offers specific accounting guidance for a lessee, a lessor, and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the effect this guidance will have on its consolidated financial statements and related disclosure, and anticipates the guidance to result in increases in its assets and liabilities as its operating lease commitment will be subject to the new standard and recognized as right-of-use assets and lease liabilities.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments ("ASU-2016-13"). ASU 2016-13 affects loans, debt securities, trade receivables, and any other financial assets that have the contractual right to receive cash. The ASU requires an entity to recognize expected credit losses rather than incurred losses for financial assets. ASU 2016-13 is effective for the fiscal year beginning after December 15, 2022, including interim periods within that fiscal year. The Company expects that there would be no material impact on the Company's consolidated financial statements upon the adoption of this ASU.

(v) Reclassifications

Certain reclassifications were made to the reported amounts in these consolidated financial statements as of December 31, 2018 to conform to the presentation as of December 31, 2019.

Note 3 – Recent Developments, Liquidity and Management's Plans

On December 19, 2018, the Company announced its intent to delist from the AIM Market of the London Stock Exchange. The Company believed that due to the relatively low liquidity in the Company's common stock, remaining listed on the AIM Market did not merit the ongoing costs and regulatory complexities associated with maintaining the AIM listing. On March 5, 2019, the Company held a special meeting of shareholders who then voted in favor of the Company delisting from the AIM Market. The delisting took effect on March 29, 2019.

On November 7, 2018, the Company announced that its board of directors had initiated a process to evaluate strategic alternatives to maximize shareholder value. This process will consider a range of potential strategic alternatives including, but not limited to, business combinations, while simultaneously supporting the Company's management and employees in the execution of the Company's current business activities. Such alternatives shall also be to consider initiatives that include making strategic hires of consultants or personnel who would be instrumental to developing new business opportunities. On November 19, 2018, the Company further announced that in its evaluation of strategic alternatives it will consider a range of potential strategic alternatives including, but not limited to, business combinations in sectors different than that currently engaged in, including cannabis and hemp related industries.

On March 23, 2020, the Company entered into a Membership Interest Purchase Agreement with the members of Cystron Biotech, LLC, pursuant to which the Company will acquire 100% of the membership interests of Cystron Biotech, LLC. See Note 15 for discussion of the acquisition of Cystron Biotech, LLC.

Historically, the Company has relied upon public offerings and private placements of common stock to raise operating capital. As of March 19, 2020, the Company had cash and marketable securities of approximately $8.8 million (excluding restricted cash of $115,094) and working capital of approximately $8.3 million, which the Company believes will be sufficient to fund its operations and obligations through approximately March 2021.

Note 4 – Inventories

Inventories are measured at the lower of cost or net realizable value. The cost of inventories is based on the weighted-average principle, and includes expenditures incurred in acquiring the inventories, production or conversion costs and other costs incurred in bringing them to their existing location and condition. In the case of manufactured inventories and work in progress, costs include an appropriate share of production overhead based on normal operating capacity.

Inventories consist of the following:

	December 31,	
	2019	**2018**
Raw Materials	$ 274,551	$ 542,761
Sub-Assemblies	303,461	711,181
Finished Goods	28,223	635,565
Reserve for Obsolescence	(407,250)	(1,304,240)
	$ 198,985	$ 585,267

During the year ended December 31, 2019, incurred charges in the aggregate amount of $371,997 to reserve for the write down to fair value of certain obsolete raw materials, sub-assemblies and finished goods inventory, which is included in cost of goods sold. During the year ended December 31, 2019, the Company disposed of and wrote-off against the reserve $1,268,987 of inventory, resulting in a net decrease of $896,990 in the reserve for obsolescence as of December 31, 2019 as compared to the balance of the reserve for inventory obsolescence as of December 31, 2018.

For the year ended December 31, 2018, the Company reserved $279,031 of inventory, principally in connection with the removal of OxiChek from the market, which is included in cost of goods sold and wrote-off, against the reserve, $187,399 of inventory, principally the expired BreathScan Alcohol products, resulting in a net increase of $91,632 in the reserve for obsolescence as of December 31, 2018 compared to that as of December 31, 2017.

Note 5 – Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31,	
	2019	2018
Computer Equipment	$ 17,514	$ 17,514
Computer Software	7,806	7,806
Office Equipment	39,959	39,959
Furniture & Fixtures	38,357	38,357
Machinery & Equipment	1,138,004	1,153,830
Molds & Dies	645,272	645,272
Leasehold Improvements	249,960	249,960
	2,136,872	2,152,698
Less		
Accumulated Depreciation	2,103,298	2,069,242
	$ 33,574	$ 83,456

Depreciation expense totaled $34,056 and $63,378 for the years ended December 31, 2019 and 2018, respectively.

Note 6 – Intangible Assets

Intangible assets as of December 31, 2019 and 2018 are as follows:

	December 31, 2019		
	Cost or Deemed Cost	Accumulated Amortization and Impairment	Net Book Value
Patents & Trademarks	$ 2,626,996	$ (2,456,573)	$ 170,423
Distributors & Customer Relationships	1,270,639	(1,270,639)	-
Total	$ 3,897,635	$ (3,727,212)	$ 170,423

	December 31, 2018		
	Cost or Deemed Cost	Accumulated Amortization and Impairment	Net Book Value
Patents & Trademarks	$ 2,626,996	$ (2,383,585)	$ 243,411
Distributors & Customer Relationships	1,270,639	(1,270,639)	-
Total	$ 3,897,635	$ (3,654,224)	$ 243,411

Effective on October 9, 2018, the Company pulled the OxiChek product line from the market. This served as a triggering event for testing whether or not our intangible assets were impaired. The Company then performed a recoverability analysis and determined that as of December 31, 2018, there was an impairment of $716,148.

The Company performed an impairment analysis during 2019 and as a result, recorded an impairment charge of $32,980 during the year ended December 31, 2019.

Amortization is recognized on a straight-line basis over the estimated useful lives of intangible assets, other than goodwill, from the date that they are available for use. Amortization expense (not including impairment charges) was $40,008 and $171,108 for the years ended December 31, 2019 and 2018, respectively.

The following is an annual schedule of approximate future amortization of the Company's intangible assets:

Period	Amount
2020	35,497
2021	35,497
2022	35,497
2023	28,414
2024	28,414
Thereafter	7,104
Total	$ 170,423

Note 7 - Trade and Other Payables

Trade and other payables consist of the following:

	December 31,	
	2019	2018
Trade Payables	$ 657,293	$ 686,578
Accrued Expenses	812,722	1,227,172
Deferred Compensation	59,750	59,750
	$ 1,529,765	$ 1,973,500

See also Note 12 for related party information.

Note 8 - Share-based Compensation

Equity incentive Plans

2013 Stock Incentive Plan

On January 23, 2014, the Company adopted the 2013 Stock Incentive Plan ("2013 Plan"). The 2013 Plan was amended by the Board on January 9, 2015 and September 30, 2016, and such amendments were ratified by shareholders on December 7, 2018. The 2013 Plan provides for the issuance of up to 4,323 shares of the Company's common stock. As of December 31, 2019, grants of restricted stock and options to purchase 2,853 shares of Common Stock have been issued pursuant to the 2013 Plan, and 1,470 shares of Common Stock remain available for issuance.

2017 Stock Incentive Plan

On August 7, 2017, the shareholders approved, and the Company adopted the 2017 Stock Incentive Plan ("2017 Plan"). The 2017 Plan provides for the issuance of up to 7,031 shares of the Company's common stock. As of December 31, 2019, grants of restricted stock and options to purchase 3,064 shares of Common Stock have been issued pursuant to the 2017 Plan, and 3,967 shares of Common Stock remain available for issuance.

2018 Stock Incentive Plan

On December 7, 2018, the shareholders approved, and the Company adopted the 2018 Stock Incentive Plan ("2018 Plan"). The 2018 Plan provides for the issuance of up to 78,125 shares of the Company's common stock. As of December 31, 2019, grants of RSUs to purchase 15,603 shares of Common Stock have been issued pursuant to the 2018 Plan, and 62,522 shares of Common Stock remain available for issuance.

Note 8 - Share-based Compensation, continued

Stock Options

The following table summarizes the option activities for the years ended December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2018	443	$ 729.41	$ 417.88	0.43	$ -
Granted	-	-	-	-	-
Exercised	-	-	-	-	-
Forfeited	(284)	703.15	374.92	0.74	-
Canceled/Expired	(119)	957.90	609.87	-	-
Balance at December 31, 2019	40	$ 236.16	$ 151.68	0.99	$ -
Exercisable as of December 31, 2019	40	$ 236.16	$ 151.68	0.99	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $3.20 for the Company's common shares on December 31, 2019. As the closing stock price on December 31, 2019 is lower than the exercise price, there is no intrinsic value to disclose.

As of December 31, 2019, all the Company's outstanding stock options were fully vested and exercisable.

During the years ended December 31, 2019 and 2018, the Company incurred stock option expenses totaling $0 and $6,931, respectively.

Note 8 - Share-based Compensation, continued

Restricted Stock Units

On March 29, 2019, the Compensation Committee of the Board of Directors approved the grant of 5,201 Restricted Stock Units ("RSU") to each of the three directors. Each RSU had a grant date fair value of $23.28 which shall be amortized on a straight-line basis over the vesting period into administrative expenses within the Consolidated Statement of Operations and Comprehensive Loss. Such RSUs were granted under the 2018 Plan, and vested on January 1, 2020. Upon vesting, such RSUs shall be settled with the issuance of common stock. The Company stock underlying these RSUs was subject to a lock-up through March 3, 2020.

	Number of RSUs	Weighted Average Grant Date Fair Value
Balance at December 31, 2018	-	$ -
Granted	15,603	23.28
Exercised	-	-
Forfeited	-	-
Canceled/Expired	-	-
Balance at December 31, 2019	15,603	$ 23.28
Exercisable as of December 31, 2019	-	$ -

During the year ended December 31, 2019, the Company incurred RSU expense of $362,005.

Note 8 - Share-based Compensation, continued

Common Stock Warrants

The table below summarizes the warrant activity for the year ended December 31, 2019:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2018	88,015	$ 74.65	4.20	**$ -**
Granted	159,200	5.00	5.00	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2019	247,215	$ 29.79	4.72	$ -
Exercisable as of December 31, 2019	247,215	$ 29.79	4.72	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $3.20 for the Company's common shares on December 31, 2019. All warrants were vested on date of grant.

Note 8 - Share-based Compensation, continued

Pre-funded Common Stock Warrants

The table below summarizes the pre-funded warrant activity for the year ended December 31, 2019:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2018	-	$ -	-	**$ -**
Granted	1,376,500	0.0001	-	-
Exercised	(581,500)	0.0001	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2019	795,000	$ 0.0001	-	$ -
Exercisable as of December 31, 2019	795,000	$ 0.0001	-	$ -

All pre-funded warrants were vested on date of grant and are exercisable at any time.

Preferred Series 'C' Stock Warrants

The table below summarizes the activity for the warrants issued in December 2019 in connection with a capital raise, for the purchase of preferred series C shares, for the year ended December 31, 2019:

	Number of Warrants	Weighted Average Exercise Price	Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance at December 31, 2018	-	$ -	-	**$ -**
Granted	1,990,000	4.00	5.00	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Canceled/Expired	-	-	-	-
Balance at December 31, 2019	1,990,000	$ 4.00	5.00	$ -
Exercisable as of December 31, 2019	1,990,000	$ 4.00	5.00	$ -

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying awards and the closing stock price of $3.20 for the Company's common shares on December 31, 2019. All preferred series 'C' warrants were vested on date of grant.

Note 9 – Equity

The holders of common shares are entitled to one vote per share at meetings of the Company. On December 30, 2019, the Company's shareholders approved an increase to 100,000,000 of the number of the authorized shares of Common Stock.

During the years ended December 31, 2019 and 2018, pursuant to his October 2018 employment agreement, the Company issued 1,563 and 314 shares of Common Stock under the 2017 Plan to Mr. Yeaton, with a fair value on the date of grant, of $27,367 and $16,702, respectively.

During the year ended December 31, 2018, the Company issued 131 shares of Common Stock to a former executive officer of the Company. These shares had a fair value of $11,000 on date of grant.

On November 2, 2018, the Company entered into the Purchase Agreement pursuant to which the Company agreed to sell an aggregate of 30,070 shares of Common Stock and warrants to purchase approximately 28,937 shares of Common Stock (the "November 2018 Warrants"). The combined purchase price for one share of Common Stock and each Warrant was priced at $69.12 (the "Offering"). The Purchase Agreement contained customary representations, warranties, and covenants by the Company. Through the Offering, which closed on November 2, 2018, the Company raised proceeds of $1,950,000, net of offering costs of $50,000.

Each November 2018 Warrant has an initial exercise price of $90.24 per share, became exercisable immediately after the date of issuance and expires on November 1, 2023. Subject to limited exceptions, a holder of the November 2018 Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's Common Stock outstanding immediately after the exercise. The exercise price of the November 2018 Warrants, and in some cases the number of shares of Common Stock issuable upon exercise of the November Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the Common Stock.

Note 9 – Equity, continued

In addition, the November 2018 Warrants provide that, in the event of a fundamental transaction (as such term is described in the November 2018 Warrant), the holder of such November 2018 Warrant, at the holder's option, may receive, for each warrant share (as such term is described in the November 2018 Warrant) that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of Common Stock for which the November 2018 Warrant is exercisable immediately prior to such fundamental transaction. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the alternate consideration it receives upon any exercise of the November 2018 Warrant following such fundamental transaction. The Company shall cause any successor entity (as such term is described in the November 2018 Warrant), at the option of the holder, to deliver to the holder in exchange for the November 2018 Warrant a security of the successor entity evidenced by a written instrument substantially similar in form and substance to the November 2018 Warrant which is exercisable for a corresponding number of shares of capital stock of such successor entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of the November 2018 Warrant (without regard to any limitations on the exercise of this November 2018 Warrant) prior to such fundamental transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock.

The Offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-214214), previously filed with the Securities and Exchange Commission on October 24, 2016 and declared effective on November 16, 2016.

During the year ended December 31, 2018, 1,755 shares of the Company's Series B Preferred Stock, no par value, were converted into 60,943 shares of Common Stock.

During the year ended December 31, 2018, warrant holders from the December 21, 2017 public offering exercised warrants for the purchase of 199,055 shares of Common Stock with an exercise price of $34.58 per common share, raising net proceeds of $7,155,200.

Note 9 – Equity, continued

On December 9, 2019, the Company entered into that certain "Purchase Agreement" pursuant to which the Company agreed to sell an aggregate of 613,500 shares of Common Stock, 1,376,500 pre-funded warrants (the "Pre-funded Warrants"), Preferred 'C' warrants to purchase approximately 1,990,000 shares of Common Stock (the "Preferred 'C' Warrants") and Underwriter's Warrants to purchase approximately 159,200 shares of Common Stock (the "Underwriter's Warrants"). The combined purchase price for one share of Common Stock was $4.00 and each Pre-funded Warrant was priced at $3.9999 with (the "Offering"). The Purchase Agreement contains customary representations, warranties, and covenants by the Company. Through the Offering, the Company raised proceeds of $6,965,636, net of offering costs of $994,227. Offering costs were allocated on a pro rata basis to the proceeds from the sale of each of the Common Stock and the pre-funded warrants.

Each Pre-Funded Warrant has an initial exercise price of $0.0001 per share, and is exercisable immediately after the date of issuance. Subject to limited exceptions, a holder of the Pre-Funded Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's Common Stock outstanding immediately after the exercise. The exercise price of the Pre-Funded Warrants, and in some cases the number of shares of Common Stock issuable upon exercise of the Pre-Funded Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the Common Stock. The pre-funded warrants represented prepaid equity forward contracts that were equity classified, as they were not subject to ASC 480 and did not meet the definition of a derivative under ASC 815 due to their requiring a substantial upfront payment.

Each Preferred 'C' Warrant has an initial exercise price of $4.00 per share, is exercisable immediately after the date of issuance and will expire five years from December 30, 2019, the date it became exercisable. Subject to limited exceptions, a holder of the Preferred 'C' Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's Common Stock outstanding immediately after the exercise. The exercise price of the Preferred 'C' Warrants, and in some cases the number of shares of Common Stock issuable upon exercise of the Preferred 'C' Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the Common Stock.

Each Underwriter's Warrant has an initial exercise price of $5.00 per share, will be exercisable immediately after the date of issuance and will expire five years from December 30, 2019, the date it became exercisable. Subject to limited exceptions, a holder of the Underwriter's Warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's Common Stock outstanding immediately after the exercise. The exercise price of the Underwriter's Warrants, and in some cases the number of shares of Common Stock issuable upon exercise of the Underwriter's Warrants, will be subject to adjustment in the event of stock splits, stock dividends, combinations, rights offerings and similar events affecting the Common Stock.

Note 9 – Equity, continued

In addition, the Warrants provide that, in the event of a fundamental transaction (as such term is described in the Warrant), the holder of such Warrant, at the holder's option, may receive, for each warrant share (as such term is described in the Warrant) that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of Common Stock for which the Warrant is exercisable immediately prior to such fundamental transaction. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the alternate consideration it receives upon any exercise of the Warrant following such fundamental transaction. The Company shall cause any successor entity (as such term is described in the Warrant), at the option of the holder, to deliver to the holder in exchange for the Warrant a security of the successor entity evidenced by a written instrument substantially similar in form and substance to the Warrant which is exercisable for a corresponding number of shares of capital stock of such successor entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon exercise of the Warrant (without regard to any limitations on the exercise of this Warrant) prior to such fundamental transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock.

The Offering was made pursuant to a registration statement on Form S-1 (Files No. 333-234447 and 333-235359 previously filed with the Securities and Exchange Commission on November 1, 2019 and declared effective on December 5, 2019. Such securities are being offered only by means of a prospectus.

During the year ended December 31, 2019, Pre-Funded Warrant holders from the December 9, 2019 public offering exercised warrants for the purchase of 581,500 shares of Common Stock, with an exercise price of $0.0001 per common share, raising net proceeds of $58.

Note 10 – Income Taxes

The Company's income tax (benefit)/provision is as follows:

	Years Ended December 31,	
	2019	2018
Current	$ -	$ -
Deferred	(738,000)	(2,941,000)
Change in Valuation Allowance	738,000	2,941,000
Income Tax Benefit	$ -	$ -

The reconciliation of income taxes using the statutory U.S. income tax rate and the benefit from income taxes for the years ended December 31, 2019 and 2018 are as follows:

	Years Ended December 31,	
	2019	2018
Statutory U.S. Federal Income Tax Rate	(21.0)%	(21.0)%
New Jersey State income taxes, net of U.S. Federal tax effect	(5.1)%	(5.1)%
True-up for prior year deferred tax assets	5.9%	(0.9)%
Other	1.2%	(0.1)%
Change in Valuation Allowance	19.0%	27.1%
Net	0.0%	0.0%

As of December 31, 2019 and 2018, the Company had Federal net operating loss carry forwards of approximately $79,678,000 and $80,500,000, expiring through the year ending December 31, 2039. As of December 31, 2019 and 2018, the Company had New Jersey state net operating loss carry forwards of approximately $28,855,000 and $29,700,000, expiring through the year ending December 31, 2026. The timing and manner in which the Company can utilize operating loss carryforwards in any year may be limited by provisions of the Internal Revenue Code regarding changes in ownership of corporations. Such limitation may have an impact on the ultimate realization of its carryforwards and future tax deductions.

The principal components of the deferred tax assets and related valuation allowances as of December 31, 2019 and 2018 are as follows:

	Years Ended December 31,	
	2019	2018
Reserves and other	$ 508,000	$ 523,000
Net operating loss carry-forwards	19,196,000	18,417,000
Research and development tax credit	455,000	481,000
Valuation Allowance	(20,159,000)	(19,421,000)
Net	$ -	$ -

Note 10 - Income Tax Expense, continued

The valuation allowance for deferred tax assets as of December 31, 2019 and 2018 was $20,159,000 and $19,421,000. The change in the total valuation for the years ended December 31, 2019 and 2018 were increases of $738,000 and $2,941,000, respectively. In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the net operating losses and temporary differences become deductible. Management considered projected future taxable income and tax planning strategies in making this assessment. Furthermore, during December 2019, the shares issued to investors in the capital raise resulted in a greater than 50% change in ownership under the Internal Revenue Service regulations. This change in ownership will result in limitations to the amount of net operating loss carryforwards that may be utilized in future years to offset future taxable income. The value of the deferred tax assets was fully offset by a valuation allowance, due to the current uncertainty of the future realization of the deferred tax assets.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of January 1, 2019, the Company had no unrecognized tax benefits and no charge during 2019, and accordingly, the Company did not recognize any interest or penalties during 2019 related to unrecognized tax benefits. There is no accrual for uncertain tax positions as of December 31, 2019.

The Company files U.S. federal income tax returns and a state income tax returns. The U.S. and state income tax returns filed for the tax years ending on December 31, 2016 and thereafter are subject to examination by the relevant taxing authorities.

Note 11 – Commitments and Contingencies

Lease Commitments

The Company leases its facility in West Deptford, New Jersey under an operating lease ("Thorofare Lease") which went into effect during 2008 and was amended in January 2013. On November 11, 2019, the Company entered into an extension of the Thorofare Lease extending the term to December 31, 2021 and effective January 1, 2020, providing for an early termination option of the lease with a 150 day notice period. Rent expense for the Thorofare Lease, including related CAM charges for the years ended December 31, 2019 and 2018 totaled $164,233 and $164,996, respectively.

The Company previously maintained an office lease in Ramsey, New Jersey and a warehouse lease in Pitman, New Jersey. These two leases ended during 2019.

Lease expense during the years ended December 31, 2019 and 2018 was $54,761 and $66,225, respectively.

The schedule of lease commitments is as follows:

	Thorofare Lease
Next 12 months	$ 132,000
Next 13-24 months	139,200
	$ 271,200

Advisory Board

On December 4, 2019, the Company formed an advisory board (the "Advisory Board") with expertise in the hemp and minor cannabinoid sectors. The Advisory Board will assist the Board of Directors in its strategic review including, potentially, the extraction, testing, purification and formulation of safe cannabinoids within the hemp industry. During December 2019, the Company appointed two members to the Advisory Board. Compensation over the term of service shall consist of an award of shares of the Company's stock with a value of $25,000 for each advisor.

Note 11 – Commitments and Contingencies, continued

Litigation and Settlements

ChubeWorkx

On August 17, 2016, pursuant to a Settlement Agreement (the "Settlement Agreement") with ChubeWorkx Guernsey Limited ("ChubeWorkx"), which settled all pending claims between the Company and ChubeWorkx. Specifically, the Company and ChubeWorkx agreed to voluntarily dismiss (i) the action in the United States Federal Court, District of New Jersey brought by the Company against ChubeWorkx for outstanding amounts due to the Company under a promissory note and (ii) the action in The High Court of Justice, Queen's Bench Division Commercial Court, Royal Courts of Justice, United Kingdom brought by ChubeWorkx against the Company arising from an exclusive licensing agreement between ChubeWorkx and the Company ("Licensing Agreement").

In return for the Company regaining the full rights to sell breath technology products, under the terms of the Settlement Agreement, ChubeWorkx is entitled to receive a royalty of 5% of the Company's gross revenues (the "ChubeWorkx Royalty") until ChubeWorkx has earned an aggregate $5,000,000, after which point ChubeWorkx will no longer be entitled to receive any royalties from the Company and the Company shall have no further obligation to ChubeWorkx. The Settlement Agreement further allows the Company to retain 50% of the ChubeWorkx Royalty until the full $549,609 cash component of the monies owed by ChubeWorkx to the Company as described above has been satisfied. The Company recorded royalty expenses of $86,519 and $59,584 for the years ended December 31, 2019 and 2018, respectively, which are included in sales and marketing expenses on the Consolidated Statement of Operations and Comprehensive Loss. As of December 31, 2019, the Company owed ChubeWorkx royalties of $4,906 which is included in trade and other payables.

Other terms of the Settlement included: 1) the pledge as security of all earned but unpaid royalties by the Company to ChubeWorkx, all Company assets, worthy to satisfy its obligations, including all inventory and receivables, with the exception of (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; 2) the pledge as security of the settlement sum which remains unpaid by the Company to ChubeWorkx all Company (i) distribution contracts of the Company or any of its affiliates, (ii) customer lists, (iii) manufacturing processes (including all intellectual property required to use those processes and exploit products made thereby), and (iv) all equipment required to perform said manufacturing processes and other equipment; and 3) the grant of voting proxy by ChubeWorkx to the Company which allows the Company to vote ChubeWorkx's shares for corporate formalities under certain conditions.

The pledged assets are only at risk in the event that the Company cannot satisfy any outstanding royalty payment obligations subject to various cure periods and/or through a restructuring and/or liquidation under the United States Bankruptcy laws of the Company in favor of payment of said obligation.

Note 11 – Commitments and Contingencies, continued

Litigation and Settlements

Pulse Health LLC v Akers Biosciences, Inc. No.: 3:16-cv-01919-HZ

On October 17, 2016, the Company was served with a notice that Pulse Health LLC ("Pulse") filed a lawsuit against the Company on September 30, 2016 in United States Federal District Court, District of Oregon, alleging a breach of contract under the settlement agreement entered into by the Company and Pulse on April 8, 2011 which settled all claims and disputes between the Company and Pulse arising from a previously executed Technology Development Agreement entered into by the Company and Pulse and damages resulting from said alleged breach. Additionally, Pulse alleged false advertising and unlawful trade practices in connection with the Company's sales activities related to the Company's OxiChek™ products.

The Company filed a series of motions with the Court seeking (1) to dismiss the Pulse complaint for lack of jurisdiction or, in the alternative, transfer the matter to the District Court for the District of New Jersey, Camden Vicinage and (2) to dismiss the unfair competition claims for failure to state a claim on which relief could be granted. Oral arguments on these motions were heard by the Court on March 10, 2017.

The Court decided by order dated April 14, 2017 in favor of the Company and dismissed with prejudice the claims brought by Pulse for unfair competition (both federal and state counts). The court decided against the Company in its motions for transfer of venue and for lack of jurisdiction. As such, the case proceeded in the District Court of Oregon.

The Company filed a Motion for Summary Judgment on January 24, 2018. On June 21, 2018, the Court ruled in favor of the Company on some issues and determined that other issues warranted a trial. The Court further determined that equitable relief, such as an injunction, "may be warranted." Following such rulings, the Company discovered certain deficiencies in its discovery responses and took appropriate steps to supplement the record and correct these deficiencies.

On September 17, 2018, the Company and Pulse entered into a settlement. Pursuant to the settlement reached between Pulse and the Company, on October 9, 2018 the Company paid $930,000 to Pulse. The Company has also agreed to a permanent injunction and not to make, use, sell or offer to sell the BreathScan OxiChek™ product, any product that detects aldehydes or oxidative stress in exhaled human breath or breath condensate using either basic fuchsin or sodium metabisulfite or any form, analog or equivalent thereof, and the BreathScan Lync device, or any equivalent thereof, as part of a test for aldehydes or oxidative stress in human exhaled breath or breath condensate. There was no material impact on our revenues as a result of the withdrawal of the BreathScan OxiChek™ product from sale. The Settlement Agreement does not contain any admission of liability, wrongdoing, or responsibility by any of the parties.

Note 11 – Commitments and Contingencies, continued

Litigation and Settlements

Faulkner v. Akers Biosciences, Inc., No. 2:18-cv-10521 (D.N.J.) and *Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.)*

On June 13, 2018, Plaintiff Tim Faulkner filed a class action complaint alleging securities violations against the Company, John J. Gormally, and Gary M. Rauch ("Individual Defendants") (together with the Company, "Defendants") on behalf of all persons and entities who purchased publicly traded Akers securities from May 15, 2017 through June 5, 2018 (the "Faulkner Action"). The complaint alleged violations of Section 10(b) of the Exchange Act and Rule 10b-5 against all Defendants, and violations of Section 20(a) of the Exchange Act against the Individual Defendants. In particular, the complaint alleged that Defendants made false and/or misleading statements and/or failed to disclose in its first, second, and third quarter 2017 10-Qs and its 2017 10-K that: (1) Akers was improperly recognizing revenue for the fiscal year ended December 31, 2017; and, (2) Akers had downplayed weaknesses in its internal controls over financial reporting and failed to disclose the true extent of those weaknesses. On June 20, 2018, Plaintiff David Gleason filed a class action complaint under the caption Gleason v. Akers Biosciences, Inc., No. 2:18-cv-10805 (D.N.J.) based on the same allegations and causes of action (the "Gleason Action"). On November 21, 2018, the Faulkner and Gleason Actions were consolidated under the Faulkner Action docket. The parties conducted a mediation on January 10, 2019, and agreed to a settlement in principle disposing of the consolidated action as to all Defendants, including the Individual Defendants. On March 8, 2019, the parties signed a settlement agreement, subject to approval by the Court, whereby the Company agreed to pay $2,250,000 in exchange for full releases and discharge of all claims against the Company. On the same day, Plaintiffs Tim Faulkner and David Gleason filed a motion for preliminary approval of the settlement and to establish notice procedures. On July 3, 2019, the Court granted the motion for preliminary approval and scheduled a final settlement hearing for November 8, 2019. On or about July 24, 2019, the Company's D&O insurer sent the settlement payment of $2,250,000 to the settlement agent for the class. On September 20, 2019, the Court granted the parties' request to adjourn the final settlement hearing and scheduled a final settlement hearing for December 20, 2019, at 11:00 a.m. On October 11, 2019, Lead Plaintiffs filed motions for final approval of the proposed settlement and award of attorneys' fees, and reimbursement of expenses. On December 20, 2019, the Court granted final approval of the settlement and award of attorneys' fees, and reimbursement of expenses.

Note 11 – Commitments and Contingencies, continued

Litigation and Settlements

Watts v. Gormally, et al., No. 2:18-15992 (D.N.J.) *and Chan v. Gormally, et al*., No. 2:19-cv-4989 (D.N.J.)

On November 9, 2018, Cale Watts ("Watts Plaintiff") filed a verified shareholder derivative complaint alleging violations of the Securities Exchange Act of 1934, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on alleged material weaknesses in controls, management, and documentation (the "Watts Action"). On January 14, 2019, the parties reached an agreement in principle to settle the Watts Action that included corporate reforms and a payment of attorneys' fees of $200,000. The parties finalized a Stipulation of Settlement on March 4, 2019. On February 7, 2019, Tiffany Chan, Jasmine Henderson, and Don Danesh ("Chan Plaintiffs") filed a verified shareholder derivative complaint alleging violations of Section 14(a) of the Exchange Act and SEC Rule 14a-9, breach of fiduciary duty, unjust enrichment, and waste of corporate assets based on the same circumstances as the Watts Action (the "Chan Action"). The Chan Action further alleged that the Company should not have settled the Watts Action because the Watts Action plaintiffs lacked standing and the settlement would cause irreparable harm to the Company and its shareholders. On March 22, 2019, the Watts Plaintiff filed a motion for preliminary approval of the proposed settlement, approving the proposed form and method of providing notice of the settlement, scheduling a hearing for final approval of the settlement ("Watts Motion for Preliminary Approval"). On April 1, 2019, the Chan Plaintiffs filed an Opposition to the Motion for Preliminary Approval and a Motion to Intervene and Stay Proceedings ("Motion to Intervene and Stay"). Subsequently, the Watts Plaintiff, Chan Plaintiffs, and Defendants reached an agreement in principle to settle the Watts and Chan Actions that included corporate reforms and a payment of attorneys' fees of $325,000. On October 2, 2019, the Watts Plaintiff filed an Unopposed Motion for Preliminary Approval of the Settlement (the "Omnibus Motion for Preliminary Approval"). The Omnibus Motion for Preliminary Approval was granted on January 8, 2020. Plaintiffs must file a motion for final approval of the proposed settlement by May 7, 2020. The Final Settlement hearing is scheduled for May 28, 2020.

Faulkner, Gleason, Watts and Chan Matters

With respect to the Faulkner, Gleason, Watts and Chan matters, the Company maintains D&O liability insurance coverage, with a company retention of $500,000. The D&O liability insurance coverage provides insurance coverage to both the Company and the Directors and Officers for covered defense and indemnification. Through December 31, 2018, the Company recorded a cumulative charge of $500,000, representing the insurance carrier retention requirement. The insurance carrier has provided notice that it has reserved certain rights, and through the date of the filing of this Annual Report on Form 10-K, the Company may incur additional costs related to these matters, the amounts of which are not able to be determined at this time.

Note 11 – Commitments and Contingencies, continued

Litigation and Settlements

Typenex Medical, LLC v. Akers Biosciences, Inc., JAMS Ref. No. 1450005929

On November 15, 2018, Typenex Medical LLC ("Typenex"), a telemarketing entity with whom the Company had entered into a marketing and commission agreement dated September 30, 2016 (the "Marketing Contract"), filed an arbitration against the Company before JAMS ADR (the "Arbitration"), and an arbiter was appointed to the Arbitration on December 14, 2018. In the Arbitration, Typenex stated that it was seeking "at least" $220,500 based on the allegation that the Marketing Contract entitles Typenex to a commission on sales of certain of the Company's heparin-related products in the period two years from the Marketing Contract's expiration, and in the alternative, Typenex was seeking relief for breach of the implied covenant of good faith and fair dealing, and/or unjust enrichment. On July 19, 2019, the Company and Typenex executed a settlement agreement. Pursuant to the settlement agreement on December 2, 2019, the Company paid Typenex $50,000 in cash and issued 1,667 shares of the Company's common stock, valued at $10,802.

NovoTek Therapeutics Inc. and NovoTek Pharmaceuticals Limited v. Akers Biosciences, Inc.

On June 21, 2019, the Company received a complaint, filed by Novotek Therapeutics Inc., and Novotek Pharmaceuticals Limited (collectively, "Novotek"), Beijing-based entities, in the United States District Court for the District of New Jersey, alleging, among other things, breach of contract. Novotek is seeking, among other things, damages in the amount of $1,551,562, plus interest, disbursements and attorneys' fees. The Company vigorously disputes the allegations in the complaint and has retained counsel to defend it. On September 16, 2019, the Company filed a partial motion to dismiss the complaint, which was fully submitted as of November 4, 2019. The Company is not yet able to determine the amount of the Company's exposure, if any.

Neelima Varma v. Akers Biosciences, Inc. and St. David's Healthcare Partnership, L.P., LLP CAUSE NO: D-1-GN-19-004262

On July 25, 2019, the Company was notified that on July 23, 2019, a complaint was filed by Neelima Varma, against the Company and St. David's Healthcare Partnership, L.P., LLP ("St. David's"), in the district court of Travis County, Texas, alleging, among other things, negligence, gross negligence and strict product liability, breach of express warranty, breach of implied warranty and fraudulent misrepresentation and omission, with respect to a medical device which the Company had sold through one its distributors to St. David's. Ms. Varma is seeking aggregate monetary relief from the Company and St. David's in excess of $1,000,000. On September 20, 2019, the Company filed the original answer to plaintiff's original petition and on October 1, 2019, the Company received from plaintiff their first interrogatories and request for production of documents. The Company carries product liability insurance. The insurance carrier has provided notice that it has reserved certain rights. The Company and its insurance carrier will contest this complaint vigorously. The Company believes that its product liability insurance coverage will be adequate to cover the potential exposure for this matter.

Note 11 – Commitments and Contingencies, continued

Douglas Carrara v. Akers Biosciences, Inc., John Does 1-10, and XYZ Corp. 1-10, Docket No. ESX-L-5272-19 (N.J. Super. Ct., Essex County):

Douglas Carrara, a former executive, has sued the Company over the termination of his employment. The executive seeks contractual severance pay in the amount of $200,000. The executive asserts that the termination was without cause within the meaning of his employment agreement, which provides for severance of one year's salary in the event of termination without cause. The executive also seeks indemnification for approximately $10,000 in attorneys' fees that he contends he incurred in regard to company business. On August 29, 2019, the Company filed an answer to the second amended complaint and the parties have exchanged documents and interrogatories as part of the discovery process. No trial date or discovery cutoff has been set. With regard to both claims, the executive seeks to recover his attorneys' fees under a fee-shifting provision in his employment agreement. With respect to the matter, the Company believes that the ultimate liability from the resolution of this matter will not be material to the Company's consolidated financial statements. Discovery in the case is continuing and is expected to conclude this summer.

The Company intends to establish a rigorous defense of all claims. All legal fees were expensed as and when incurred.

Note 12 – Related Parties

Hainan Savvy

On March 9, 2015, the Company contributed capital of $64,091 to Hainan Savy Akers Biosciences, Ltd. ("Hainan"), a company incorporated in the People's Republic of China, resulting in an initial 19.9% ownership interest. On December 31, 2018, the Company recorded a charge of $64,092 for the full impairment of its investment in Hainan. This investment was included in other assets in the Consolidated Balance Sheet as of December 31, 2018 and the investment was accounted for using the cost method.

The Company began purchasing manufacturing molds and plastic components through Hainan and its related party during the year ended December 31, 2016. The Company purchased a total of $- and $20,936 in such components during the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, the Company owed Hainan and its related party $0 which was included in trade and other payables.

CEO and Interim CFO

Effective on October 5, 2018 and through December 31, 2019, the Board appointed Howard R. Yeaton, to serve as the Chief Executive Officer and interim Chief Financial Officer of the Company. Effective on January 1, 2020, Mr. Yeaton entered into a new agreement with the Company whereby he serves as the Company's Interim Chief Financial Officer. Mr. Yeaton is the managing principal of FCS and the Company's relationship with FCS shall continue, with FCS continuing to provide accounting services to the Company. FCS is considered to be a related party. During the years ended December 31, 2019 and 2018, the Company expensed $38,888 and $104,749, respectively, to FCS in connection with these services. As of December 31, 2019 and 2018, the Company owed FCS $18,323 and $29,407, respectively, which were included in trade and other payables on the Company's Consolidated Balance Sheet.

Note 13 – Revenue Information

Revenue by product lines was as follows:

	Years Ended December 31,	
Product Line	**2019**	**2018**
MicroParticle Catalyzed Biosensor ("MPC")	$ 126,150	$ 123,941
Particle ImmunoFiltration Assay ("PIFA")	1,327,752	1,422,361
Rapid Enzymatic Assay ("REA")	85,000	68,750
Other	38,131	50,518
Total Revenue	$ 1,577,033	$ 1,665,570

The total revenue by geographic area determined based on the location of the customers was as follows:

	Years Ended December 31,	
Geographic Region	**2019**	**2018**
United States	$ 1,559,533	$ 1,576,765
Rest of World	17,500	88,805
Total Revenue	$ 1,577,033	$ 1,665,570

The Company had long-lived assets totaling $194,174 and $312,572 located in the United States and $9,823 and $14,295 located in the Rest of the World as of December 31, 2019 and 2018, respectively.

Note 14 – Employee Benefit Plan

The Company maintains a defined contribution benefit plan under section 401(k) of the Internal Revenue Code covering substantially all qualified employees of the Company (the "401(k) Plan"). Under the 401(k) Plan, the Company matches 100% up to a 3% contribution, and 50% over a 3% contribution, up to a maximum of 5%.

During the years ended December 31, 2019 and 2018, the Company made matching contributions to the 401(k) Plan of $37,252 and $55,360, respectively.

Note 15 – Subsequent Events

Novel Coronavirus

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic which continues to spread throughout the United States. On March 21, 2020 the Governor of New Jersey declared a health emergency and issued an order to close all nonessential businesses until further notice. As a maker of medical devices, Akers is deemed to be an essential business. Nonetheless, out of concern for our workers and pursuant to the government order, Akers has reduced the scope of its operations and where possible, certain workers are telecommuting from their homes. While the Company expects this matter to negatively impact its results of operations, cash flows and financial position, the related impact cannot be reasonably estimated at this time.

Acquisition of Cystron

On March 23, 2020, the Company entered into a Membership Interest Purchase Agreement (the "MIPA") with the members of Cystron Biotech, LLC (individually, each a "Seller," and collectively, the "Sellers"), pursuant to which the Company will acquire 100% of the membership interests (the "Membership Interests") of Cystron Biotech, LLC ("Cystron").

As consideration for the Membership Interests, the Company will deliver to the Sellers: (1) that number of newly issued shares of its common stock equal to 19.9% of the issued and outstanding shares of its common stock and pre-funded warrants as of the date of the MIPA, but, to the extent that the issuance of the Company's common stock would result in any Seller owning in excess of 4.9% of its outstanding common stock, then, at such Seller's election, such Seller may receive "common stock equivalent" preferred shares with a customary 4.9% blocker (with such common stock and preferred stock collectively referred to as "Common Stock Consideration"), and (2) $1,000,000.

Additionally, the Company shall (A) make an initial payment to the Sellers of up to $1,000,000 upon its receipt of cumulative gross proceeds from the consummation of an initial equity offering after the date of the MIPA of $8,000,000, and (B) pay to Sellers an amount in cash equal to 10% of the gross proceeds in excess of $8,000,000 raised from future equity offerings after the date of the MIPA until the Sellers have received an aggregate additional cash consideration equal to $10,000,000. Upon the achievement of certain milestones, including the completion of a Phase 2 study that meets its primary endpoints, Sellers will be entitled to receive an additional 750,000 shares of the Company's common stock or, in the event the Company is unable to obtain stockholder approval for the issuance of such shares, 750,000 shares of non-voting preferred stock that are valued following the achievement of such milestones and shall bear a 10% annual dividend (the "Milestone Shares"). Sellers will also be entitled to contingent payments from the Company of up to $20,750,000 upon the achievement of certain milestones, including the approval of a new drug application by the U.S. Food and Drug Administration ("FDA").

The Company shall also make quarterly royalty payments to Sellers equal to 5% of the net sales of a COVID-19 vaccine or combination product by the Company (the "COVID-19 Vaccine") for a period of five (5) years following the first commercial sale of the COVID-19 Vaccine; provided, that such payment shall be reduced to 3% for any net sales of the COVID-19 Vaccine above $500 million.

In addition, Sellers shall be entitled to receive 12.5% of the transaction value, as defined in the MIPA, of any change of control transaction, as defined in the MIPA, that occurs prior to the fifth (5th) anniversary of the closing date of the MIPA, provided that the Company is still developing the COVID-19 Vaccine at that time. Following the consummation of any change of control transaction, the Sellers shall not be entitled to any payments as described above under the MIPA.

Support Agreement

On March 23, 2020, as an inducement to enter into the MIPA, and as one of the conditions to the consummation of the transactions contemplated by the MIPA, the Sellers entered into a shareholder voting agreement with the Company (the "Support Agreement"), pursuant to which each Seller agreed to vote their shares of the Company's common stock or preferred stock in favor of each matter proposed and recommended for approval by the Company's management at every meeting of the stockholders and on any action or approval by written consent of the stockholders.

Registration Rights Agreement

To induce the Sellers to enter into the MIPA, on March 23, 2020, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Sellers, pursuant to which it shall by the 30th day following the closing of the transactions contemplated by the MIPA, file with the United States Securities and Exchange Commission (the "SEC") an initial Registration Statement on Form S-3 (if such form is available for use by the Company at such time) or, otherwise, on Form S-1, covering all of the shares of our common stock issued, or underlying the preferred stock issued, at closing under the MIPA and to subsequently register the common stock issued or underlying the preferred stock issued at Milestone Shares.

License Agreement

Cystron is a party to a License and Development Agreement (the "Initial License Agreement") with Premas Biotech PVT Ltd. ("Premas"). As a condition to the Company's entry into the MIPA, Cystron amended and restated the Initial License Agreement on March 19, 2020 (as amended and restated, the "License Agreement"). Pursuant to the License Agreement, Premas granted Cystron, amongst other things, an exclusive license with respect to Premas' vaccine platform for the development of a vaccine against COVID-19 and other corona virus infections.

Upon the achievement of certain developmental milestones by Cystron, Cystron shall pay to Premas a total of up to $2,000,000.

Series D Convertible Preferred Stock

On March 24, 2020, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of New Jersey. Pursuant to the Certificate of Designation, in the event of the Company's liquidation or winding up of its affairs, the holders of its Series D Convertible Preferred Stock (the "Preferred Stock") will be entitled to receive the same amount that a holder of the Company's common stock would receive if the Preferred Stock were fully converted (disregarding for such purposes any conversion limitations set forth in the Certificate of Designation) to common stock which amounts shall be paid pari passu with all holders of the Company's common stock. Each share of Preferred Stock has a stated value equal to $0.01 (the "Stated Value"), subject to increase as set forth in Section 7 of the Certificate of Designation.

A holder of Preferred Stock is entitled at any time to convert any whole or partial number of shares of Preferred Stock into shares of the Company's common stock determined by dividing the Stated Value of the Preferred Stock being converted by the conversion price of $0.01 per share.

A holder of Preferred Stock will be prohibited from converting Preferred Stock into shares of the Company's common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of the Company's common stock then issued and outstanding (with such ownership restriction referred to as the "Beneficial Ownership Limitation"). However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to the Company.

Subject to the Beneficial Ownership Limitation, on any matter presented to our stockholders for their action or consideration at any meeting of the Company's stockholders (or by written consent of stockholders in lieu of a meeting), each holder of Preferred Stock will be entitled to cast the number of votes equal to the number of whole shares of the Company's common stock into which the shares of Preferred Stock beneficially owned by such holder are convertible as of the record date for determining stockholders entitled to vote on or consent to such matter (taking into account all Preferred Stock beneficially owned by such holder). Except as otherwise required by law or by the other provisions of the Company's certificate of incorporation, the holders of Preferred Stock will vote together with the holders of the Company's common stock and any other class or series of stock entitled to vote thereon as a single class.

A holder of Preferred Stock shall be entitled to receive dividends as and when paid to the holders of the Company's common stock on an as-converted basis.

Exhibit 3.10

CSC
www.cscglobal.com

CSC- New York
Suite 210
1180 Avenue OF the Americas
New York, NY 10036-8401
212-299-5600
212-299-5656 (Fax)

Matter# Not Provided
Project Id :

Order# 093110-5
Order Date 12/09/2019

Entity Name :	AKERS BIOSCIENCES, INC.
Jurisdiction :	DE-Secretary of State
Request for :	Amendment/Correction/Restated/Designation Filing
File# :	0100408441
File date :	12/09/2019
Result :	Filed

Ordered by EDDIE WANSLEY-PENA at ELLENOFF GROSSMAN & SCHOLE LLP

Thank you for using CSC. For real-time 24 hour access to the status of any order placed with CSC, access our website at www.cscglobal.com.

If you have any questions concerning this order or CSCGlobal, please feel free to contact us.

Camille Silva
csilva@cscinfo.com

STATE OF NEW JERSEY
DEPARTMENT OF TREASURY
FILING CERTIFICATION (CERTIFIED COPY)

AKERS BIOSCIENCES, INC.
0100408441

I, the Treasurer of the State of New Jersey, do hereby certify, that the above named business did file and record in this department a Certificate of Amendment on December 9th, 2019 and that the attached is a true copy of this document as the same is taken from and compared with the original(s) filed in this office and now remaining on file and of record.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 9th day of December, 2019

Elizabeth Maher Muoio
State Treasurer

Certificate Number: 141924371
Verify this certificate online at
https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

FILED
DEC _9 2019
STATE TREASURER

AKERS BIOSCIENCES, INC.

CERTIFICATE OF DESIGNATION OF PREFERENCES RIGHTS AND LIMITATIONS OF SERIES C CONVERTIBLE PREFERRED STOCK

PURSUANT TO THE PROVISIONS OF N.J.S.A. 14A, THE UNDERSIGNED CORPORATION EXECUTES THE FOLLOWING CERTIFICATE OF AMENDMENT TO ITS CERTIFICATE OF INCORPORATION, AS AMENDED: 0100 408441

Akers Biosciences, Inc., a corporation organized and existing under the New Jersey Business Corporation Act (the "Corporation"), certifies that pursuant to the authority contained in Articles of Incorporation, as amended (the "Certificate of Incorporation") and in accordance with the provisions of N.J.S.A. 14A:7-2(2) and (4) of the New Jersey Business Corporation Act, the board of directors of the Corporation (the "Board of Directors") on December 9, 2019, duly approved and adopted the following resolutions by unanimous written consent, which resolution remains in full force and effect on the date hereof:

NOW, THEREFORE, BE IT RESOLVED, that the Board of Directors does hereby provide for the issuance of a series of preferred stock for cash or exchange of other securities, rights or property and does hereby fix and determine the rights, preferences, restrictions and other matters relating to such series of preferred stock as follows:

TERMS OF SERIES C CONVERTIBLE PREFERRED STOCK

Section 1. Designation, Amount and Par Value. The series of preferred stock shall be designated as its Series C Convertible Preferred Stock (the "Preferred Stock") and the number of shares so designated shall be 1,990,000 (which shall not be subject to increase without the written consent of holders of a majority in interest of the Preferred Stock then outstanding (each, a "Holder" and collectively, the "Holders")). Each share of Preferred Stock shall have no par value and a stated value equal to $4.00 (the "Stated Value").

Section 2. Definitions. For the purposes hereof, the following terms shall have the following meanings:

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person, as such terms are used in and construed under Rule 405 of the Securities Act.

"Alternate Consideration" shall have the meaning set forth in Section 7(e).

"Beneficial Ownership Limitation" shall have the meaning set forth in Section 6(d).

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Buy-In" shall have the meaning set forth in Section 6(c)(iv).

"Charter Amendment Date" means, if necessary, the date on which the Corporation publicly announces through the filing of a Current Report on Form 8-K that an amendment to the Corporation's Amended and Restated Certificate of Incorporation, as amended, to sufficiently increase the Corporation's authorized shares of Common Stock to cover the conversion of all outstanding shares of Preferred Stock into Common Stock has been filed with the Secretary of State of the State of New Jersey.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto and all conditions precedent to the Corporation's obligations to deliver the securities in accordance with the terms of the Transaction Documents have been satisfied or waived.

"Commission" means the United States Securities and Exchange Commission.

"Common Stock" means the Corporation's common stock, no par value, and stock of any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Corporation or the Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, rights, options, warrants or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Conversion Amount" means the sum of the Stated Value at issue.

"Conversion Date" shall have the meaning set forth in Section 6(a).

"Conversion Price" shall have the meaning set forth in Section 6(b).

"Conversion Shares" means, collectively, the shares of Common Stock issuable upon conversion of the shares of Preferred Stock in accordance with the terms hereof.

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Fundamental Transaction" shall have the meaning set forth in Section 7(e).

"Holder" shall have the meaning given such term in Section 1.

"Initial Conversion Date" means the next business day after the Charter Amendment Date, provided, however if there are sufficient shares of authorized Common Stock to cover the conversion of all outstanding shares of Preferred Stock into Common Stock as of the Closing Date, the Initial Conversion Date shall be the Closing Date.

"Liquidation" shall have the meaning set forth in Section 5.

"New York Courts" shall have the meaning set forth in Section 8(d).

"Notice of Conversion" shall have the meaning set forth in Section 6(a).

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Preferred Stock" shall have the meaning set forth in Section 1.

"Purchase Agreement" means that certain Securities Purchase Agreement, dated as of December 5, 2019, between the Corporation and the purchasers signatory thereto. "Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Share Delivery Date" shall have the meaning set forth in Section 6(c).

"Stated Value" shall have the meaning set forth in Section 1, as the same may be increased pursuant to Section 3.

"Subsidiary" means any subsidiary of the Corporation as set forth on Exhibit 21 to the Corporation's Annual Report on Form 10-K most recently filed with the Commission.

"Successor Entity" shall have the meaning set forth in Section 7(e).

"Trading Day" means a day on which the principal Trading Market is open for business.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange (or any successors to any of the foregoing).

"Transaction Documents" means this Certificate of Designation, the Purchase Agreement, the Warrants, all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions

contemplated pursuant to the Purchase Agreement.

"Transfer Agent" means VStock Transfer, LLC, the current transfer agent of the Corporation, with a mailing address of 18 Lafayette Place, Woodmere, NY 11598 and any successor transfer agent of the Corporation.

"Underlying Shares" means the shares of Common Stock issued and issuable upon conversion of the Preferred Stock.

"Warrants" means, collectively, the Preferred Stock purchase warrants delivered to the holders on the Closing Date in accordance with the Purchase Agreement, which Warrants shall be exercisable immediately and have a term of exercise which will expire on the five-year anniversary of the Charter Amendment Date.

"Warrant Shares" means the shares of Preferred Stock issuable upon exercise of the Warrants.

Section 3. Dividends. Except for stock dividends or distributions for which adjustments are to be made pursuant to Section 7, Holders shall be entitled to receive, and the Corporation shall pay, dividends on shares of Preferred Stock equal (on an as-if-converted-to-Common-Stock basis) to and in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of the Common Stock. No other dividends shall be paid on shares of Preferred Stock.

Section 4. Voting Rights. Except as otherwise provided herein or as otherwise required by law, the Preferred Stock shall have no voting rights. However, as long as any shares of Preferred Stock are outstanding, the Corporation shall not, without the affirmative vote of the Holders of a majority of the then outstanding shares of the Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Preferred Stock or alter or amend this Certificate of Designation, (b) increase the number of authorized shares of Preferred Stock, or (c) enter into any agreement with respect to any of the foregoing.

Section 5. Liquidation. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "Liquidation"), the Holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation the same amount that a holder of Common Stock would receive if the Preferred Stock were fully converted (disregarding for such purpose any conversion limitations hereunder) to Common Stock which amounts shall be paid pari passu with all holders of Common Stock. The Corporation shall mail written notice of any such Liquidation, not less than 45 days prior to the payment date stated therein, to each Holder.

Section 6. Conversion.

a) Conversions at Option of Holder. Each share of Preferred Stock shall be convertible, at any time and from time to time from and after the Initial Conversion Date at the option of each Holder thereof, into that number of shares of Common Stock (subject to the limitations set forth in Section 6(d)) determined by dividing the Stated Value of such share of Preferred Stock by the Conversion Price. Holders shall effect conversions by providing the Corporation with the form of conversion notice attached hereto as Annex A (a "Notice of Conversion"). Each Notice of Conversion shall specify the number of shares of Preferred Stock to be converted, the number of shares of Preferred Stock owned prior to the conversion at issue, the number of shares of Preferred Stock owned subsequent to the conversion at issue and the date on which such conversion is to be effected, which date may not be prior to the date the applicable Holder delivers such Notice of Conversion to the Corporation (such date, the "Conversion Date"). If no Conversion Date is specified in a Notice of Conversion, the Conversion Date shall be the date that such Notice of Conversion to the Corporation is deemed delivered hereunder. No ink-original Notice of Conversion shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Conversion form be required. The calculations and entries set forth in the Notice of Conversion shall control in the absence of manifest or mathematical error. To effect conversions of shares of Preferred Stock, a Holder shall not be required to surrender the certificate(s) representing the shares of Preferred Stock to the Corporation unless all of the shares of Preferred Stock represented thereby are so converted, in which case such Holder shall deliver the certificate representing such shares of Preferred Stock promptly following the Conversion Date at issue. Shares of Preferred Stock converted into Common Stock in accordance with the terms hereof shall be canceled and shall not be reissued.

b) Conversion Price. The conversion price for the Preferred Stock shall equal $4.00, subject to adjustment herein (the "Conversion Price").

c) Mechanics of Conversion

i) Delivery of Conversion Shares Upon Conversion. Not later than the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined below) after each Conversion Date (the "Share Delivery Date"), the Corporation shall deliver, or cause to be delivered, to the converting Holder (A) the number of Conversion Shares being acquired upon the conversion of the Preferred Stock, which Conversion Shares shall be free of restrictive legends and trading restrictions (except to the extent a Holder is subject to certain restrictions under applicable securities laws) and (B) a bank check in the amount of accrued and unpaid dividends. The Corporation shall deliver the Conversion Shares electronically through the Depository Trust Company or another established clearing corporation performing similar functions. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Corporation's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Conversion.

ii) Failure to Deliver Conversion Shares. If, in the case of any Notice of Conversion, such Conversion Shares are not delivered to or as directed by the applicable Holder by the Share Delivery Date, such Holder shall be entitled to elect by written notice to the Corporation at any time on or before its receipt of such Conversion Shares, to rescind such Conversion, in which event the Corporation shall promptly return to such Holder any original Preferred Stock certificate delivered to the Corporation and such Holder shall promptly return to the Corporation the Conversion Shares issued to such Holder pursuant to the rescinded Conversion Notice.

iii) Obligation Absolute. The Corporation's obligation to issue and deliver the Conversion Shares upon conversion of Preferred Stock in accordance with the terms hereof are absolute and unconditional, irrespective of any action or inaction by a Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by such Holder or any other Person of any obligation to the Corporation or any violation or alleged violation of law by such Holder or any other person, and irrespective of any other circumstance which might otherwise limit such obligation of the Corporation to such Holder in connection with the issuance of such Conversion Shares; provided, however, that such delivery shall not operate as a waiver by the Corporation of any such action that the Corporation may have against such Holder. In the event a Holder shall elect to convert any or all of the Stated Value of its Preferred Stock, the Corporation may not refuse conversion based on any claim that such Holder or anyone associated or affiliated with such Holder has been engaged in any violation of law, agreement or for any other reason, unless an injunction from a court, on notice to Holder, restraining and/or enjoining conversion of all or part of the Preferred Stock of such Holder shall have been sought and obtained, and the Corporation posts a surety bond for the benefit of such Holder in the amount of 150% of the Stated Value of Preferred Stock which is subject to the injunction, which bond shall remain in effect until the completion of arbitration/litigation of the underlying dispute and the proceeds of which shall be payable to such Holder to the extent it obtains judgment. In the absence of such injunction, the Corporation shall issue Conversion Shares and, if applicable, cash, upon a properly noticed conversion. If the Corporation fails to deliver to a Holder such Conversion Shares pursuant to Section 6(c)(I) on the Share Delivery Date applicable to such conversion, the Corporation shall pay to such Holder, in cash, as liquidated damages and not as a penalty, for each $5,000 of Stated Value of Preferred Stock being converted, $50 per Trading Day (increasing to $100 per Trading Day on the third Trading Day and increasing to $200 per Trading Day on the tenth Trading Day after such damages begin to accrue) for each Trading Day after the Share Delivery Date until such Conversion Shares are delivered or Holder rescinds such conversion. Nothing herein shall limit a Holder's right to pursue actual damages for the Corporation's failure to deliver Conversion Shares within the period specified herein and such Holder shall have the right to pursue all remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief. The exercise of any such rights shall not prohibit a Holder from seeking to enforce damages pursuant to any other Section hereof or under applicable law.

iv) Compensation for Buy-In on Failure to Timely Deliver Conversion Shares Upon Conversion. In addition to any other rights available to the Holders, if the Corporation fails for any reason to deliver to a Holder the applicable Conversion Shares by the Share Delivery Date pursuant to Section 6(c)(i), and if after such Share Delivery Date such Holder is required by its brokerage firm to purchase (in an open market transaction or otherwise), or the Holder's brokerage firm otherwise purchases, shares of Common Stock to deliver in satisfaction of a sale by such Holder of the Conversion Shares which such Holder was entitled to receive upon the conversion relating to such Share Delivery Date (a "Buy-In"), then the Corporation shall (A) pay in cash to such Holder (in addition to any other remedies available to or elected by such Holder) the amount, if any, by which (x) such Holder's total purchase price (including any brokerage commissions) for the Common Stock so purchased exceeds (y) the product of (1) the aggregate number of shares of Common Stock that such Holder was entitled to receive from the conversion at issue multiplied by (2) the actual sale price at which the sell order giving rise to such purchase obligation was executed

(including any brokerage commissions) and (B) at the option of such Holder, either reissue (if surrendered) the shares of Preferred Stock equal to the number of shares of Preferred Stock submitted for conversion (in which case, such conversion shall be deemed rescinded) or deliver to such Holder the number of shares of Common Stock that would have been issued if the Corporation had timely complied with its delivery requirements under Section 6(c)(i). For example, if a Holder purchases shares of Common Stock having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted conversion of shares of Preferred Stock with respect to which the actual sale price of the Conversion Shares (including any brokerage commissions) giving rise to such purchase obligation was a total of $10,000 under clause (A) of the immediately preceding sentence, the Corporation shall be required to pay such Holder $1,000. The Holder shall provide the Corporation written notice indicating the amounts payable to such Holder in respect of the Buy-In and, upon request of the Corporation, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Corporation's failure to timely deliver Conversion Shares upon conversion of the shares of Preferred Stock as required pursuant to the terms hereof.

v) Reservation of Shares Issuable Upon Conversion. The Corporation covenants that, following the Charter Amendment Date, if necessary, or as of the Closing Date if the Corporation has sufficient shares of Common Stock authorized at the Closing Date to cover the conversion of all outstanding shares of Preferred Stock, it will at all times reserve and keep available out of its authorized and unissued shares of Common Stock for the sole purpose of issuance upon conversion of the Preferred Stock as herein provided, free from preemptive rights or any other actual contingent purchase rights of Persons other than the Holders, not less than such aggregate number of shares of the Common Stock as shall be issuable (taking into account the adjustments and restrictions of Section 7) upon the conversion of the then outstanding shares of Preferred Stock. The Corporation covenants that all shares of Common Stock that shall be so issuable shall, upon issue, be duly authorized, validly issued, fully paid and nonassessable.

vi) Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the conversion of the Preferred Stock. As to any fraction of a share which a Holder would otherwise be entitled to purchase upon such conversion, the Corporation shall at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Conversion Price or round up to the next whole share.

vii) Transfer Taxes and Expenses. The issuance of Conversion Shares on conversion of this Preferred Stock shall be made without charge to any Holder for any documentary stamp or similar taxes that may be payable in respect of the issue or delivery of such Conversion Shares, provided that the Corporation shall not be required to pay any tax that may be payable in respect of any transfer involved in the issuance and delivery of any such Conversion Shares upon conversion in a name other than that of the Holders of such shares of Preferred Stock and the Corporation shall not be required to issue or deliver such Conversion Shares unless or until the Person or Persons requesting the issuance thereof shall have paid to the Corporation the amount of such tax or shall have established to the satisfaction of the Corporation that such tax has been paid. The Corporation shall pay all Transfer Agent fees required for same-day processing of any Notice of Conversion and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Conversion Shares.

d) Beneficial Ownership Limitation. The Corporation shall not effect any conversion of the Preferred Stock, and a Holder shall not have the right to convert any portion of the Preferred Stock, to the extent that, after giving effect to the conversion set forth on the applicable Notice of Conversion, such Holder (together with such Holder's Affiliates, and any Persons acting as a group together with such Holder or any of such Holder's Affiliates (such Persons, "Attribution Parties")) would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by such Holder and its Affiliates and Attribution Parties shall include the number of shares of Common Stock issuable upon conversion of the Preferred Stock with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which are issuable upon (i) conversion of the remaining, unconverted Stated Value of Preferred Stock beneficially owned by such Holder or any of its Affiliates or Attribution Parties and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Corporation subject to a limitation on conversion or exercise analogous to the limitation contained herein beneficially owned by such Holder or any of its Affiliates or Attribution Parties. Except as set forth in the preceding sentence, for purposes of this Section 6(d), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by each Holder that the Corporation is not representing to such Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and such Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this

Section 6(d) applies, the determination of whether the Preferred Stock is convertible (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and of how many shares of Preferred Stock are convertible shall be in the sole discretion of such Holder, and the submission of a Notice of Conversion shall be deemed to be such Holder's determination of whether the shares of Preferred Stock may be converted (in relation to other securities owned by such Holder together with any Affiliates and Attribution Parties) and how many shares of the Preferred Stock are convertible, in each case subject to the Beneficial Ownership Limitation. To ensure compliance with this restriction, each Holder will be deemed to represent to the Corporation each time it delivers a Notice of Conversion that such Notice of Conversion has not violated the restrictions set forth in this paragraph and the Corporation shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 6(d), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as stated in the most recent of the following: (i) the Corporation's most recent periodic or annual report filed with the Commission, as the case may be, (ii) a more recent public announcement by the Corporation or (iii) a more recent written notice by the Corporation or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request (which may be via email) of a Holder, the Corporation shall within one Trading Day confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Corporation, including the Preferred Stock, by such Holder or its Affiliates or Attribution Parties since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon conversion of Preferred Stock held by the applicable Holder. A Holder, upon notice to the Corporation, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 6(d) applicable to its Preferred Stock provided that the Beneficial Ownership Limitation in no event exceeds 9.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of this Preferred Stock held by such Holder and the provisions of this Section 6(d) shall continue to apply. Any such increase in the Beneficial Ownership Limitation will not be effective until the 61st day after such notice is delivered to the Corporation and shall only apply to such Holder and no other Holder. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 6(d) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation contained herein or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of Preferred Stock.

Section 7. Certain Adjustments.

a) Stock Dividends and Stock Splits. If the Corporation, at any time while this Preferred Stock is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions payable in shares of Common Stock on shares of Common Stock or any other Common Stock Equivalents (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Corporation upon conversion of, or payment of a dividend on, this Preferred Stock), (ii) subdivides outstanding shares of Common Stock into a larger number of shares, (iii) combines (including by way of a reverse stock split) outstanding shares of Common Stock into a smaller number of shares, or (iv) issues, in the event of a reclassification of shares of the Common Stock, any shares of capital stock of the Corporation, then the Conversion Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding any treasury shares of the Corporation) outstanding immediately before such event, and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to this Section 7(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) RESERVED.

c) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 7(a) above, if at any time the Corporation grants, issues or sells any Common Stock Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of shares of Common Stock (the "Purchase Rights"), then each Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which such Holder could have acquired if such Holder had held the number of shares of Common Stock acquirable upon complete conversion of such Holder's Preferred Stock (without regard to any limitations on exercise hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the grant, issue or sale of such Purchase Rights (provided, however, to the extent that such Holder's right to

participate in any such Purchase Right would result in such Holder exceeding the Beneficial Ownership Limitation, then such Holder shall not be entitled to participate in such Purchase Right to such extent (or beneficial ownership of such shares of Common Stock as a result of such Purchase Right to such extent) and such Purchase Right to such extent shall be held in abeyance for such Holder until such time, if ever, as its right thereto would not result in such Holder exceeding the Beneficial Ownership Limitation).

d) Pro Rata Distributions. During such time as any of the Preferred Stock is outstanding, if the Corporation declares or makes any dividend or other distribution of its assets (or rights to acquire its assets) to holders of shares of Common Stock, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Preferred Stock, then, in each such case, each Holder shall be entitled to participate in such Distribution to the same extent that such Holder would have participated therein if such Holder had held the number of shares of Common Stock acquirable upon complete conversion of this Preferred Stock (without regard to any limitations on conversion hereof, including without limitation, the Beneficial Ownership Limitation) immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of shares of Common Stock are to be determined for the participation in such Distribution (provided, however, to the extent that such Holder's right to participate in any such Distribution would result in such Holder exceeding the Beneficial Ownership Limitation, then such Holder shall not be entitled to participate in such Distribution to such extent (or in the beneficial ownership of any shares of Common Stock as a result of such Distribution to such extent) and the portion of such Distribution shall be held in abeyance for the benefit of such Holder until such time, if ever, as its right thereto would not result in such Holder exceeding the Beneficial Ownership Limitation).

e) Fundamental Transaction. If, at any time while any of the Preferred Stock is outstanding, (i) the Corporation, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Corporation with or into another Person, (ii) the Corporation, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Corporation or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (iv) the Corporation, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Corporation, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than 50% of the outstanding shares of Common Stock (not including any shares of Common Stock held by the other Person or other Persons making or party to, or associated or affiliated with the other Persons making or party to, such stock or share purchase agreement or other business combination) (each a "Fundamental Transaction"), then, upon any subsequent conversion of the Preferred Stock, each Holder shall have the right to receive, for each Conversion Share that would have been issuable to such Holder upon such conversion immediately prior to the occurrence of such Fundamental Transaction (without regard to any limitation in Section 6(d) on the conversion of this Preferred Stock), the number of shares of Common Stock of the successor or acquiring corporation or of the Corporation, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of shares of Common Stock for which such Holder's Preferred Stock is convertible immediately prior to such Fundamental Transaction (without regard to any limitation in Section 6(d) on the conversion of this Preferred Stock). For purposes of any such conversion, the determination of the Conversion Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of Common Stock in such Fundamental Transaction, and the Corporation shall apportion the Conversion Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Stock are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then each Holder shall be given the same choice as to the Alternate Consideration it receives upon any conversion of Preferred Stock following such Fundamental Transaction. To the extent necessary to effectuate the foregoing provisions, any successor to the Corporation or surviving entity in such Fundamental Transaction shall file a new Certificate of Designation with the same terms and conditions and issue to the Holders new preferred stock consistent with the foregoing provisions and evidencing the Holders' right to convert such preferred stock into Alternate Consideration. The Corporation shall cause any successor entity in a Fundamental Transaction in which the Corporation is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Corporation under this Certificate of Designation and the other Transaction Documents in accordance with the provisions of this Section 7(e) pursuant to written agreements in form and substance reasonably satisfactory to the Holders and approved by the Holders (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of each Holders of Preferred Stock, deliver to such Holder in exchange for such Holder's Preferred Stock a security of the Successor Entity evidenced by a written

instrument substantially similar in form and substance to the Preferred Stock which is convertible for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the shares of Common Stock acquirable and receivable upon conversion of such Holder's Preferred Stock (without regard to any limitations on the conversion of the Preferred Stock) prior to such Fundamental Transaction, and with a conversion price which applies the conversion price hereunder to such shares of capital stock (but taking into account the relative value of the shares of Common Stock pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such conversion price being for the purpose of protecting the economic value of the Preferred Stock immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to such Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall succeed to, and be substituted for (so that from and after the date of such Fundamental Transaction, the provisions of this Certificate of Designation and the other Transaction Documents referring to the "Corporation" shall refer instead to the Successor Entity), and may exercise every right and power of the Corporation and shall assume all of the obligations of the Corporation under this Certificate of Designation and the other Transaction Documents with the same effect as if such Successor Entity had been named as the Corporation herein.

f) Calculations. All calculations under this Section 7 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 7, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of the number of shares of Common Stock (excluding any treasury shares of the Corporation) issued and outstanding.

g) Notice to the Holders.

i) Adjustment to Conversion Price. Whenever the Conversion Price is adjusted pursuant to any provision of this Section 7, the Corporation shall promptly deliver to each Holder by facsimile or email a notice setting forth the Conversion Price after such adjustment and setting forth a brief statement of the facts requiring such adjustment.

ii) Notice to Allow Conversion by Holder. If (A) the Corporation shall declare a dividend (or any other distribution in whatever form) on the Common Stock, (B) the Corporation shall declare a special nonrecurring cash dividend on or a redemption of the Common Stock, (C) the Corporation shall authorize the granting to all holders of the Common Stock of rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of any stockholders of the Corporation shall be required in connection with any reclassification of the Common Stock, any consolidation or merger to which the Corporation is a party, any sale or transfer of all or substantially all of the assets of the Corporation, or any compulsory share exchange whereby the Common Stock is converted into other securities, cash or property or (E) the Corporation shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Corporation, then, in each case, the Corporation shall cause to be filed at each office or agency maintained for the purpose of conversion of this Preferred Stock, and shall cause to be delivered by facsimile or email to each Holder at its last facsimile or email address as it shall appear upon the stock books of the Corporation, at least twenty (20) calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of the Common Stock for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange, provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Corporation or any of the Subsidiaries, the Corporation shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. Each Holder shall remain entitled to convert the Conversion Amount of such Holder's Preferred Stock (or any part hereof) during the 20-day period commencing on the date of such notice through the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 8. Miscellaneous.

a) Notices. Any and all notices or other communications or deliveries to be provided by the Holders hereunder including, without limitation, any Notice of Conversion, shall be in writing and delivered personally, by facsimile or email, or sent by a nationally recognized overnight courier service, addressed to the Corporation, at the address set forth above

Attention: Chief Executive Officer, e-mail address: hyeaton@akersbio.com, or such other facsimile number, e-mail address or address as the Corporation may specify for such purposes by notice to the Holders delivered in accordance with this Section 8. Any and all notices or other communications or deliveries to be provided by the Corporation hereunder shall be in writing and delivered personally, by facsimile or email, or sent by a nationally recognized overnight courier service addressed to each Holder at the facsimile number, email address or address of such Holder appearing on the books of the Corporation. Any notice or other communication or deliveries hereunder shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via email at the email address set forth in this Section prior to 5:30 p.m. (New York City time) on any date, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number or via email at the email address set forth in this Section on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (iii) the second Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service, or (iv) upon actual receipt by the party to whom such notice is required to be given.

b) Absolute Obligation. Except as expressly provided herein, no provision of this Certificate of Designation shall alter or impair the obligation of the Corporation, which is absolute and unconditional, to pay liquidated damages and accrued dividends, as applicable, on the shares of Preferred Stock at the time, place, and rate, and in the coin or currency, herein prescribed.

c) Lost or Mutilated Preferred Stock Certificate. If a Holder's Preferred Stock certificate shall be mutilated, lost, stolen or destroyed, the Corporation shall execute and deliver, in exchange and substitution for and upon cancellation of a mutilated certificate, or in lieu of or in substitution for a lost, stolen or destroyed certificate, a new certificate for the shares of Preferred Stock so mutilated, lost, stolen or destroyed, but only upon receipt of evidence of such loss, theft or destruction of such certificate, and of the ownership hereof reasonably satisfactory to the Corporation.

d) Governing Law. All questions concerning the construction, validity, enforcement and interpretation of this Certificate of Designation shall be governed by and construed and enforced in accordance with the internal laws of the State of New Jersey, without regard to the principles of conflict of laws thereof. Each party agrees that all legal proceedings concerning the interpretation, enforcement and defense of the transactions contemplated by this Certificate of Designation (whether brought against a party hereto or its respective Affiliates, directors, officers, shareholders, employees or agents) shall be commenced in the state and federal courts sitting in the City of New York, Borough of Manhattan (the "New York Courts"). The Corporation and each Holder hereby irrevocably submits to the exclusive jurisdiction of the New York Courts for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of such New York Courts, or such New York Courts are improper or inconvenient venue for such proceeding. The Corporation and each Holder hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Certificate of Designation and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by applicable law. The Corporation and each Holder hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Certificate of Designation or the transactions contemplated hereby. If any party shall commence an action or proceeding to enforce any provisions of this Certificate of Designation, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred in the investigation, preparation and prosecution of such action or proceeding.

e) Waiver. Any waiver by the Corporation or a Holder of a breach of any provision of this Certificate of Designation shall not operate as or be construed to be a waiver of any other breach of such provision or of any breach of any other provision of this Certificate of Designation or a waiver by any other Holders. The failure of the Corporation or a Holder to insist upon strict adherence to any term of this Certificate of Designation on one or more occasions shall not be considered a waiver or deprive that party (or any other Holder) of the right thereafter to insist upon strict adherence to that term or any other term of this Certificate of Designation on any other occasion. Any waiver by the Corporation or a Holder must be in writing.

f) Severability. If any provision of this Certificate of Designation is invalid, illegal or unenforceable, the balance of this Certificate of Designation shall remain in effect, and if any provision is inapplicable to any Person or circumstance, it shall nevertheless remain applicable to all other Persons and circumstances. If it shall be found that any interest or other amount deemed interest due hereunder violates the applicable law governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum rate of interest permitted under applicable law.

g) Next Business Day. Whenever any payment or other obligation hereunder shall be due on a day other than a Business Day, such payment shall be made on the next succeeding Business Day.

h) Headings. The headings contained herein are for convenience only, do not constitute a part of this Certificate of Designation and shall not be deemed to limit or affect any of the provisions hereof.

i) Status of Converted or Redeemed Preferred Stock. If any shares of Preferred Stock shall be converted, redeemed or reacquired by the Corporation, such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series C Convertible Preferred Stock.

****

IN WITNESS WHEREOF, the Corporation has executed this Certificate this 9th day of December, 2019.

AKERS BIOSCIENCES, INC.

By: _____
Name: Howard Yeiton
Title: Chief Executive Officer

ANNEX A

NOTICE OF CONVERSION

(TO BE EXECUTED BY THE REGISTERED HOLDER IN ORDER TO CONVERT SHARES OF PREFERRED STOCK)

The undersigned hereby elects to convert the number of shares of Series C Convertible Preferred Stock indicated below into shares of common stock, no par value (the "Common Stock"), of Akers Biosciences, Inc., a New Jersey corporation (the "Corporation"), according to the conditions hereof, as of the date written below. If shares of Common Stock are to be issued in the name of a Person other than the undersigned, the undersigned will pay all transfer taxes payable with respect thereto. No fee will be charged to the Holders for any conversion, except for any such transfer taxes.

Conversion calculations:

Date to Effect Conversion: _____

Number of shares of Preferred Stock owned prior to Conversion: _____

Number of shares of Preferred Stock to be Converted: _____

Stated Value of shares of Preferred Stock to be Converted: _____

Number of shares of Common Stock to be Issued: _____

Applicable Conversion Price: _____

Number of shares of Preferred Stock subsequent to Conversion: _____

Address for Delivery: _____
or

DWAC Instructions:
Broker no: _____
Account no: _____

[HOLDER]

By: _____
Name:
Title:

Exhibit 4.12

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 23, 2020, Akers Biosciences, Inc., a New Jersey corporation ("we," "our" and the "Company") has our common stock, no par value per share registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The foregoing description is intended as a summary and is qualified in its entirety by reference to our amended and restated certificate of incorporation, as amended (the "Amended & Restated Certificate of Incorporation") and the amended and restated by-laws, as amended (the "By-laws") as currently in effect, copies of which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein.

Authorized Capital Stock

Our authorized capital stock consists of 150,000,000 shares, of which 100,000,00 are common stock, without par value, and 50,000,000 are preferred stock, without par value, of 10,000,000 of which have been designated as Series A Convertible Preferred Stock, 1,990,000 of which have been designated as Series C Convertible Preferred Stock and 211,353 of which have been designated as Series D Convertible Preferred Stock. As of March 23, 2020, there were 2,700,240 shares of common stock issued and outstanding, no shares of Series A Convertible Preferred Stock and Series C Convertible Preferred Stock issued and outstanding. Pursuant to our acquisition of Cystron Biotech, LLC referenced in this Annual Report that closed on March 23, 2020, 211,353 shares of Series D Convertible Preferred Stock were issued.

Common Stock

Voting Rights

Each stockholder has one vote for each share of common stock held on all matters submitted to a vote of stockholders. A stockholder may vote in person or by proxy. Elections of directors are determined by a plurality of the votes cast and all other matters are decided by a majority of the votes cast by those stockholders entitled to vote and present in person or by proxy.

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our Amended & Restated Certificate of Incorporation and By-laws provide that stockholder actions may be effected at a duly called meeting of stockholders or pursuant to written consent of the majority of stockholders. A special meeting of stockholders may be called by the President, Chief Executive Officer or the Board of Directors pursuant to a resolution approved by the majority of the Board of Directors.

Dividend Rights

The holders of outstanding shares of common stock are entitled to receive dividends out of funds legally available at the times and in the amounts that our board of directors may determine, provided that required dividends, if any, on preferred stock have been paid or provided for. However, to date we have not paid or declared cash distributions or dividends on our common stock and do not currently intend to pay cash dividends on our common stock in the foreseeable future. We intend to retain all earnings, if and when generated, to finance our operations. The declaration of cash dividends in the future will be determined by the board of directors based upon our earnings, financial condition, capital requirements and other relevant factors.

No Preemptive or Similar Rights

Holders of our common stock do not have preemptive rights, and common stock is not convertible or redeemable.

Right to Receive Liquidation Distributions

Upon our dissolution, liquidation or winding-up, the assets legally available for distribution to our stockholders and remaining after payment to holders of preferred stock of the amounts, if any, to which they are entitled, are distributable ratably among the holders of our common stock subject to any senior class of securities.

The NASDAQ Capital Market Listing

Our common stock is listed on the NASDAQ Capital Market ("NASDAQ") under the symbol "AKER."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

Options, Warrants and RSUs

As of March 23, 2020, we had 40 shares of common stock issuable upon exercise of outstanding options, 492,215 shares of common stock issuable upon the exercise of warrants, 15,603 shares of common stock issuable upon the vesting of RSUs and 1,990,000 shares of common stock issuable upon conversion of the Series C Preferred Stock that is issuable upon the exercise of the warrants. The shares issuable upon the vesting of RSUs are not issuable until the increase in the number authorized shares of common stock is approved by the stockholders of the Company. There are no other outstanding warrants, options or RSUs at this time.

Preferred Stock

We may issue any class of preferred stock in any series. Our board of directors has the authority, subject to limitations prescribed under New Jersey law, to issue preferred stock in one or more series, to establish from time to time the number of shares to be included in each series and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations and restrictions. Our board of directors can also increase or decrease the number of shares of any series, but not below the number of shares of that series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the market price of common stock and the voting and other rights of the holders of common stock.

Series C Convertible Preferred Stock

Rank

The Series C Preferred Stock ranks (1) on parity with common stock on an "as converted" basis, (2) senior to any series of our capital stock hereafter created specifically ranking by its terms junior to the Series C Preferred Stock, (3) on parity with any series of our capital stock hereafter created specifically ranking by its terms on parity with the Series C Preferred Stock, and (4) junior to any series of our capital stock hereafter created specifically ranking by its terms senior to the Series C Preferred Stock in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntary or involuntary.

Conversion Rights

Each share of the Series C Preferred Stock is convertible into one (1) share of common stock, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of common stock if, as a result of such conversion, the holder would own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock, or, at the election of a holder, together with its affiliates, would own more than 9.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of the shares of common stock issuable upon conversion of the Series C Preferred Stock. The conversion rate of the Series C Preferred Stock is subject to proportionate adjustments for stock splits, reverse stock splits and similar events, but is not subject to adjustment based on price anti-dilution provisions.

Dividend Rights

In addition to stock dividends or distributions for which proportionate adjustments will be made, holders of Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal, on an as-if-converted-to-common-stock basis, to and in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock. No other dividends are payable on shares of Series C Preferred Stock.

Voting Rights

Except as provided in the Certificate of Designation or as otherwise required by law, the holders of Series C Preferred Stock will have no voting rights. However, we may not, without the consent of holders of a majority of the outstanding shares of Series C Preferred Stock, alter or change adversely the powers, preferences or rights given to the Series C Preferred Stock, increase the number of authorized shares of Series C Preferred Stock, or enter into any agreement with respect to the foregoing.

Liquidation Rights

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of Series C Preferred Stock are entitled to receive, pari passu with the holders of common stock, out of the assets available for distribution to stockholders an amount equal to such amount per share as would have been payable had all shares of Series C Preferred Stock been converted into common stock immediately before such liquidation, dissolution or winding up, without giving effect to any limitation on conversion as a result of the Beneficial Ownership Limitation, as described above.

Exchange Listing

We do not plan on making an application to list the shares of Series C Preferred Stock on the NASDAQ, any national securities exchange or other nationally recognized trading system. Our common stock issuable upon conversion of the Series C Preferred Stock is listed on the NASDAQ under the symbol "AKER."

Failure to Deliver Conversion Shares

If we fail to timely deliver shares of common stock upon conversion of the Series C Preferred Stock (the "Conversion Shares") within the time period specified in the Certificate of Designation (within two trading days after delivery of the notice of conversion, or any shorter standard settlement period in effect with respect to trading market on the date notice is delivered), then we are obligated to pay to the holder, as liquidated damages, an amount equal to $50 per trading day (increasing to $100 per trading day after the third trading day and $200 per trading day after the tenth trading day) for each $5,000 of Conversion Shares for which the Series C Preferred Stock converted which are not timely delivered. If we make such liquidated damages payments, we are not also obligated to make Buy-In (as defined below) payments with respect to the same Conversion Shares.

Compensation for Buy-In on Failure to Timely Deliver Shares

If we fail to timely deliver the Conversion Shares to the holder, and if after the required delivery date the holder is required by its broker to purchase (in an open market transaction or otherwise) or the holder or its brokerage firm otherwise purchases, shares of common stock to deliver in satisfaction of a sale by the holder of the Conversion Shares which the holder anticipated receiving upon such conversion or exercise (a "Buy-In"), then we are obligated to (A) pay in cash to the holder the amount, if any, by which (x) the holder's total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased exceeds (y) the amount obtained by multiplying (1) the number of Conversion Shares that we were required to deliver times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the holder, either reinstate the portion of the Series C Preferred Stock and equivalent number of Conversion Shares for which such conversion was not honored (in which case such conversion shall be deemed rescinded) or deliver to the holder the number of shares of common stock that would have been issued had we timely complied with its conversion and delivery obligations.

Subsequent Rights Offerings; Pro Rata Distributions

If we grant, issue or sell any common stock equivalents pro rata to the record holders of any class of shares of common stock (the "Purchase Rights"), then a holder of Series C Preferred Stock will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the holder could have acquired if the holder had held the number of shares of common stock acquirable upon conversion of the Series C Preferred Stock (without regard to any limitations on conversion). If we declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of common stock, then a holder of Series C Preferred Stock is entitled to participate in such distribution to the same extent as if the holder had held the number of shares of common stock acquirable upon complete conversion of the Series C Preferred Stock (without regard to any limitations on conversion).

Fundamental Transaction

If, at any time while the Series C Preferred Stock is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another person, (ii) the Company, directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another person) is completed pursuant to which holders of common stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding common stock, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the common stock or any compulsory share exchange pursuant to which the common stock is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another person whereby such other person acquires more than 50% of the outstanding shares of common stock (not including any shares of common stock held by the other person or other persons making or party to, or associated or affiliated with the other persons making or party to, such stock or share purchase agreement or other business combination) (each a "Series C Preferred Stock Fundamental Transaction"), then upon any subsequent conversion of Series C Preferred Stock, the holder will receive, for each Conversion Share that would have been issuable upon such conversion immediately prior to the occurrence of such Series C Preferred Stock Fundamental Transaction (without regard to the Beneficial Ownership Limitation), the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Series C Preferred Stock Alternate Consideration") receivable as a result of such Series C Preferred Stock Fundamental Transaction by a holder of the number of shares of common stock for which the Series C Preferred Stock is convertible immediately prior to such Series C Preferred Stock Fundamental Transaction (without regard to the Beneficial Ownership Limitation). For purposes of any such conversion, the determination of the conversion ratio will be appropriately adjusted to apply to such Series C Preferred Stock Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one share of common stock in such Series C Preferred Stock Fundamental Transaction. If holders of common stock are given any choice as to the securities, cash or property to be received in a Series C Preferred Stock Fundamental Transaction, then the holder will be given the same choice as to the Series C Preferred Stock Alternate Consideration it receives upon automatic conversion of the Series C Preferred Stock following such Fundamental Transaction.

Anti-Takeover Provisions

The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us.

These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

In addition, we are subject to Section 14A-10A of the New Jersey Shareholders Protection Act, a type of anti-takeover statute designed to protect stockholders against coercive, unfair or inadequate tender offers and other abusive tactics and to encourage any person contemplating a business combination with the Company to negotiate with the Board for the fair and equitable treatment of all stockholders. Subject to certain qualifications and exceptions, the statute prohibits an interested stockholder of a corporation from effecting a business combination with the corporation for a period of five years unless the corporation's board of directors approved the combination prior to the stockholder becoming an interested stockholder or after the stockholder becoming an interested stockholder if the corporation's board of directors approved both the transaction causing a person to become an interested stockholder and the subsequent business combination. In addition, but not in limitation of the five-year restriction, if applicable, corporations covered by the New Jersey statute may not engage at any time in a business combination with any interested stockholder of that corporation unless the combination is approved by the board of directors prior to the interested stockholder's stock acquisition date, the combination receives the approval of two-thirds of the voting stock of the corporation not beneficially owned by the interested stockholder or the combination meets minimum financial terms specified by the statute.

An "interested stockholder" is defined to include any beneficial owner of 10% or more of the voting power of the outstanding voting stock of the corporation and any affiliate or associate of the corporation who within the prior five year period has at any time owned 10% or more of the voting power of the then outstanding stock of the corporation.

The term "business combination" is defined to include a broad range of transactions including, among other things:

- the merger or consolidation of the corporation with the interested stockholder or any corporation that is or after the merger or consolidation would be an affiliate or associate of the interested stockholder,
- the sale, lease, exchange, mortgage, pledge, transfer or other disposition to an interested stockholder or any affiliate or associate of the interested stockholder of 10% or more of the corporation's assets, or
- the issuance or transfer to an interested stockholder or any affiliate or associate of the interested stockholder of 5% or more of the aggregate market value of the stock of the corporation.

The effect of the statute is to protect non-tendering, post-acquisition minority stockholders from mergers in which they will be "squeezed out" after the merger, by prohibiting transactions in which an acquirer could favor itself at the expense of minority stockholders. The statute generally applies to corporations that are organized under New Jersey law.

Exhibit 21.1

Subsidiaries of the Registrant[1]

Name of Company	Jurisdiction of Organization
Akers Acquisition Sub, Inc.	New Jersey
Bout Time Marketing Corporation	New Jersey

[1] This information is as of December 31, 2019.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-234447 and 333-235359) of Akers Biosciences, Inc. of our report dated March 24, 2020 relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ Morison Cogen LLP

Blue Bell, Pennsylvania
March 24, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Christopher C. Schreiber, certify that:

1. I have reviewed this Form 10-K of Akers Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 24, 2020

By: */s/ Christopher C. Schreiber*
Christopher C. Schreiber
Executive Chairman of the Board of Directors and Director (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Howard Yeaton, certify that:

1. I have reviewed this Form 10-K of Akers Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 24, 2020

By: */s/ Howard Yeaton*
Howard Yeaton
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. §1350), the undersigned, Christopher C. Schreiber, Executive Chairman of the Board of Directors of Akers Biosciences, Inc., a New Jersey corporation (the "Company"), and Howard Yeaton, interim Chief Financial Officer of the Company, do hereby certify, to his and her knowledge, that:

The Annual Report on Form 10-K for the year ended December 31, 2019 of the Company (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 24, 2020

By: */s/ Christopher C. Schreiber*

Christopher C. Schreiber, Executive Chairman of the Board of Directors and Director
(Principal Executive Officer)

Date: March 24, 2020

By: */s/ Howard Yeaton*

Howard Yeaton, Interim Chief Financial Officer
(*Principal Financial and Accounting Officer*)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.