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

FORM 10-K

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

For the fiscal year ended September 30, 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 **001-36745**

APPLIED DNA SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**59-2262718**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

50 Health Sciences Drive, Stony Brook, New York	**11790**	**(631) 840-8800**
(Address of principal executive offices)	(Zip Code)	(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.001 par value	APDN	The Nasdaq Capital Market

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by a check mark if the registrant has elected to not use the extended transition period of 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 Act). ☐ Yes ☒ No

The aggregate market value of the Registrant's voting and non-voting common stock held by non-affiliates of the Registrant, based upon the last sale price of the common stock reported on The Nasdaq Capital Market as of the last business day of the Registrant's most recently completed second fiscal quarter (March 31, 2019), was approximately $21 million. Shares of the Registrant's common stock held by each executive officer and director and by each entity or person that, to the Registrant's knowledge, owned 5% or more of the Registrant's outstanding common stock as of March 31, 2019 have been excluded in that such persons may be deemed to be affiliates of the Registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of December 6, 2019, the Registrant had outstanding 3,485,399 shares of common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the 2020 Annual Meeting of Shareholders, to be filed within 120 days after the end of the fiscal year ended September 30, 2019 and incorporated by reference in Part III hereof. Except with respect to information specifically incorporated by reference in the Annual Report on Form 10-K, the Proxy Statement is not deemed to be filed as part hereof.

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PART I

Forward-looking Information

This Annual Report on Form 10-K (including but not limited to Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations") contains "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 are intended to qualify for the "safe harbor" created by those sections. In addition, we may make forward-looking statements in other documents filed with or furnished to the Securities and Exchange Commission ("SEC"), and our management and representatives may make forward-looking statements orally or in writing to analysts, investors, representatives of the media and others. Forward-looking statements can generally be identified by the fact that they do not relate strictly to historical or current facts and include, but are not limited to, statements using terminology such as "can", "may", "could", "should", "assume", "forecasts", "believe", "designated to", "will", "expect", "plan", "anticipate", "estimate", "potential", "position", "predicts", "strategy", "guidance", "intend", "seek", "budget", "project" or "continue", or the negative thereof or other comparable terminology regarding beliefs, plans, expectations or intentions regarding the future. You should read statements that contain these words carefully because they:

- discuss our future expectations;
- contain projections of our future results of operations or of our financial condition; and
- state other "forward-looking" information.

We believe it is important to communicate our expectations. However, forward-looking statements are based on our current expectations, assumptions, estimates and projections about our business and our industry and are subject to known and unknown risks, uncertainties and other factors. Accordingly, our actual results and the timing of certain events may differ materially from those expressed or implied in such forward-looking statements due to a variety of factors and risks, including, but not limited to, those set forth under Item 1, "Business," Item 1A, "Risk Factors," Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements and notes thereto included in this report, those set forth from time to time in our other filings with the SEC, and the following factors and risks:

- public reactions to our press releases, other public announcements and filings with the SEC;
- changes in financial estimates or recommendations by securities analysts, or their ceasing to publish research or reports about our business;
- the possibility we may fail to make timely payment on our secured convertible notes and as a result, the noteholders enforcing their remedies and ultimately realizing on their collateral which includes substantially all of our assets, including our intellectual property;
- our lack of significant revenues;
- our operating and financial performance and prospects;
- our quarterly or annual earnings or those of other companies in our industry or those that investors deem comparable to us;
- our limited experience in commercializing, marketing, and distributing our products including our large-scale polymerase chain reaction ("PCR") based manufacturing platform;
- our history of net losses, which may continue, and our potential inability to achieve profitability;
- difficulty in obtaining or inability to obtain, additional financing if such financing becomes necessary;
- the appeal and current level of investor interest in the biotechnology/biopharmaceutical capital market sector and in companies in general with business, research strategies and product development pipelines which are similar to us;
- our commercial opportunities in pharmaceuticals and biologics may be limited;
- dependence on a limited number of key customers;
- lack of acceptance of our products and services by potential customers and potential failure to introduce new products and services;
- loss of strategic relationships, including with suppliers;
- expenses or losses associated with lack of widespread market acceptance of our solutions;
- difficulty or failure in expanding and/or maintaining our sales, marketing and support organizations and our distribution arrangements necessary to enable us to reach our goals with respect to increasing market acceptance of our products and services;
- inability to attract and retain qualified scientific, production and managerial personnel, including Dr. James A. Hayward, our Chairman, Chief Executive Officer and President ("CEO");
- conflicts of interest with affiliates and related parties with whom we have engaged or entered into transactions;

- competition from products and services provided by other companies, including competition in the principal markets for our drug and biologic candidates and linear DNA;
- seasonality in revenues related to our cotton customer contracts;
- fluctuations in quarterly results due to adverse changes in worldwide or domestic economic, political or business conditions;
- shifting enforcement priorities of U.S. federal laws relating to cannabis;
- inability to obtain and maintain regulatory approval in the pharmaceutical and biologic markets;
- inability of our collaborators, licensees, and customers to develop, obtain approval for and successfully commercialize products that incorporate our technology;
- inability of us, our collaborators or customers to develop and timely manufacture complex biologic products and their components to exacting quality and safety standards;
- dependence on our collaborators' and customers' demand for our manufacturing services;
- inability to compete effectively in the industries in which we operate;
- lack of success in our research and development efforts for new products;
- inability to license new technologies;
- failure to manage our growth in operations and acquisitions of new technologies and businesses;
- various uncertainties and risks should we or our competitors explore or engage in future business combinations or other transactions;
- economic, political, regulatory, legal, operational, and other risks as a result of our international operations;
- inability to attract qualified scientific, production and managerial personnel;
- inability to protect our intellectual property rights;
- intellectual property litigation against us or other legal actions or proceedings in which we may become involved;
- accidents related to our use of hazardous materials;
- potential product liability claims;
- litigation brought by customers, former employees, officers and directors, former distributors and sales representatives, former consultants and vendors and service providers;
- business disruption due to natural or manmade disaster or other business interruptions;
- general weakening or decline in the global economy or a period of economic slowdown;
- unauthorized disclosure of sensitive or confidential data (including customer data) and cybersecurity breaches;
- the reverse stock split, as effected on Friday, November 1, 2019, may adversely impact the market price of our common stock;
- the reverse stock split may decrease the liquidity of the shares of our common stock and the resulting market price of our common stock may not attract or satisfy the investing requirements of new investors, including institutional investors;
- the effective increase in the number of shares of our common stock available for issuance as a result of our reverse stock split could result in further dilution to our existing stockholders and have anti-takeover implications;
- failure to maintain the listing on, or the delisting of our securities from, The Nasdaq Stock Market LLC ("Nasdaq");
- unpredictability of regulatory approval as it relates to our product candidates;
- potential difficulties and failures in clinically developing and manufacturing our products, or causation of undesirable side effects;
- variance in regulatory approval across jurisdictions;
- regulatory scrutiny of our products;
- healthcare legislative measures;
- noncompliance with regulatory standards and requirements;
- noncompliance with healthcare legislation;
- noncompliance with laws or regulatory standards by our suppliers;
- sales of common stock by us, our directors, officers or large stockholders;
- the large number of shares of common stock underlying outstanding options and warrants and potential repurchase requirements of certain warrants;

- the expiration of any applicable contractual lock-up agreements;
- the possibility that we may require additional financing, which may involve the issuance of additional shares of common stock or securities exercisable for common stock and dilute the percentage of ownership held by our current stockholders;
- changes in our capital structure;
- dilution to our stockholders due to conversion of our convertible notes into common stock;
- the possibility we may fail to make timely payments on our secured convertible notes and, as a result, the noteholders enforcing their remedies and ultimately realizing on their collateral which includes substantially all of our assets, including our intellectual property;
- the occurrence of any potential material weakness in internal controls over financial reporting;
- changes in accounting standards, policies, guidance, interpretations or principles;
- future short selling and/or manipulation of the price of our common stock;
- volatility in the price and/or trading volume of our common stock, or other securities we may issue from time to time;

All forward-looking statements and risk factors included in this Annual Report on Form 10-K are made as of the date hereof, or in the case of documents incorporated by reference, the original date of any such documents, based on information available to us as of such date, and we assume no obligations to update any forward-looking statement or risk factor, unless we are required to do so by law. If we do update one or more forward-looking statements, no inference should be drawn that we will make updates with respect to other forward-looking statements or that we will make any further updates to those forward-looking statements at any future time.

Forward-looking statements may include our plans and objectives for future operations, including plans and objectives relating to our products and our future economic performance, projections, business strategy and timing and likelihood of success. Assumptions relating to the foregoing involve judgments with respect to, among other things, future economic, competitive and market conditions, future business decisions, and the time and money required to successfully complete development and commercialization of our technologies, all of which are difficult or impossible to predict accurately and many of which are beyond our control.

Any of the assumptions underlying the forward-looking statements contained in this Annual Report on Form 10-K could prove inaccurate and, therefore, we cannot assure you that the results contemplated in any of such forward-looking statements will be realized. Based on the significant uncertainties inherent in these forward-looking statements, the inclusion of any such statement should not be regarded as a representation or as a guarantee by us that our objectives or plans will be achieved, and we caution you against relying on any of the forward-looking statements contained herein.

Our trademarks in the United States include Applied DNA Sciences®, SigNature® molecular tags, SigNature® T molecular tags, fiberTyping®, DNAnet®, digitalDNA®, SigNify®, BackTrac®, Beacon® and CertainT®. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. All trademarks, service marks and trade names included or incorporated by reference in this Annual Report on Form 10-K are the property of their respective owners, including, without limitation, the PimaCott®, HomeGrown® LoneStar™ and HomeGrown Acala™ marks owned by Himatsingka America, Inc. and/or its affiliates.

ITEM 1. BUSINESS.

Overview

Using its proprietary large-scale PCR based manufacturing technology and systems, Applied DNA Sciences Inc. ("Applied DNA", the "Company" or "we") manufactures large quantities of linear DNA for use in its proprietary products as well as for sale to third parties. The Company manufactures non-biological DNA-based molecular taggants for use in its proprietary supply chain security, anticounterfeiting, brand protection and law enforcement products. With secure non-biological taggants, high-resolution DNA authentication, and comprehensive reporting, the Company's SigNature® molecular taggant technologies deliver what we believe to be the greatest levels of security, deterrence and legal recourse strength, making Applied DNA a leader in supply chain provenance technologies. The Company's 98% percent owned subsidiary LineaRx, Inc. ("LRx") manufactures larger DNA constructs used in preclinical biotherapeutic applications, which are primarily sold to third parties. Through LRx, the Company supplies PCR produced linear DNA for use in preclinical biotherapeutic applications including CAR T/TCR, RNA manufacture, DNA-based vaccines and gene therapies, as well as in vitro diagnostics. LRx seeks to supplant the use of plasmid derived DNA with PCR-produced linear DNA in biotherapeutic and diagnostic applications, and to develop, acquire and commercialize, alone or with partners, a diverse portfolio of nucleic acid-based biotherapeutics and diagnostics that we believe will improve the efficacy, safety and cost of existing and newly developed biotherapeutics and diagnostics.

SigNature® molecular tags, the core of our supply chain security technology platform, are what we believe to be nature's ultimate means of authentication and supply chain security. We believe our precision-engineered molecular tags have not been broken. Additional layers of protection and complexity are added to the mark in a proprietary manner. SigNature® molecular tags in various carriers have proven highly resistant to UV radiation, heat, cold, vibration, abrasion and other extreme environments and conditions. We work closely with our customers to develop solutions that will be optimized to their specifications to deliver maximum impact. Our products and technology are protected by what we believe to be a robust portfolio of patents and trademarks.

Using our tagging products and technology, manufacturers, brands, and other stakeholders can ensure authenticity and protect against diversion throughout a product's journey from manufacturer to use.

The core technologies of our supply chain security business are supplied as tag, test and track solutions for large complex supply chains. Our tag, test and track solutions allow our customers to use molecular tags to mark objects in a unique manner that we believe cannot be replicated, and then identify these objects by detecting the absence or presence of the molecular tag. We believe that our disruptive tracking platform offers broad commercial relevance across many industry verticals. Our underlying strategy in the tagging business is to become a solutions provider for supply chains of process industries in which contracts for our products and services are typically larger and of longer duration as compared to our historic norms, where the benefits to customers and consumers are more significant, and where our forensic security and traceability offer a unique and protected value. Consumers, governments and companies are demanding details about the systems and sources that deliver their goods. They worry about quality, safety, ethics, and the environmental impact. Farsighted organizations are directly addressing new threats and opportunities presented by this question: Where do these goods come from? This is the question and the concerns we are beginning to address for a growing number of companies. We supply key building blocks for creating secure supply chains with traceability of goods, which in turn can help ensure integrity in supply, honest sales and marketing claims, and ethical and sustainable sourcing.

Customers using our PCR-produced linear DNA products for use in *in vitro* medical diagnostics, preclinical biotechnology research and preclinical drug and biologic development and manufacturing receive a DNA product we believe is made cleaner and faster than historical manufacturing methods, thereby offering the opportunity for increased efficiency and turnaround times in their processes. We are also engaged in preclinical and animal drug candidate development activities focusing on therapeutically relevant DNA constructs manufactured via our PCR-based production platform. We seek to develop, acquire and commercialize, alone or with partners, a diverse portfolio of nucleic acid based drugs and biologics based on PCR-produced linear DNA which we believe will improve existing nucleic acid based therapeutics or create new nucleic acid based therapeutics that address unmet medical needs.

Corporate History

We are a Delaware corporation, which was initially formed in 1983 under the laws of the State of Florida as Datalink Systems, Inc. In 1998, we reincorporated in the State of Nevada, and in 2002, we changed our name to our current name, Applied DNA Sciences, Inc. In December 2008, we reincorporated from Nevada to the State of Delaware. LineaRx, Inc. was incorporated in Delaware on September 11, 2018.

Our corporate headquarters are located at the Long Island High Technology Incubator at Stony Brook University in Stony Brook, New York, where we established laboratories for the manufacture of molecular tags, product prototyping, molecular tag authentication and bulk DNA production. The address of our corporate headquarters is 50 Health Sciences Drive, Stony Brook, New York 11790, and our telephone number is (631) 240-8800. We maintain a website at *www.adnas.com* where general information about us is available. The information on, or that may be accessed through, our website is not incorporated by reference into and should not be considered a part of this report.

Industry Background

Supply chain security

Supply chains are the systems used by companies to obtain products and services for resale, their own consumption or as a component in a product or service that they then resell. Supply chains often include the sourcing of raw materials, their processing in various stages to create products, and transportation and logistics to move goods both within the supply chain process and to the final consumer. Many different companies may be part of a supply chain, and often the owner of the supply chain has limited ability to oversee and supervise all components of its supply chain. Supply chain security refers to efforts to enhance the security of the supply chain. It combines traditional practices of supply chain management with the security requirements driven by threats such as terrorism, piracy and theft. We focus on two particular parts of supply chain security, the identity of goods to detect substitution of specified inputs with something else, often a cheaper, inferior input and the traceability of goods to a point in its lifecycle. For example, a company might specify that sheets be made of high quality pima cotton but the company that wove the material for the sheets substituted cheaper and inferior upland cotton. We call a supply chain with such security problems a leaky supply chain. Leaky supply chains create significant and growing problems to companies in a wide range of industries as well as governments and individuals worldwide. Large retailers assemble sprawling networks of suppliers in developing countries to produce their goods at cheaper cost, underscoring the difficulties of policing a global supply chain. This is a global problem that only appears to be increasing. Leaky supply chains allow materials to become diluted, diverted or counterfeited, devaluing corporate reputations, potentially causing health and safety concerns, and hindering investment, and may cost hundreds of thousands of people their livelihood every year. In addition, a company with a leaky supply chain has essentially been cheated, since they paid a premium price for an inferior substitution.

As more and more companies begin to address the problem of supply chain security, we expect that different systems will compete to be the leading standards by which products can be tracked across world markets. To ensure only genuine products are entering the marketplace requires cutting edge technology. Historically, leaky supply chains and other types of fraud have been combated by embedding various authentication systems and rare and easily distinguishable materials into products; technologies such as radio frequency identification ("RFID") devices, holograms or integrated circuit chips onto packaging; magnetic strips in automatic teller machine cards; banknote threads on currency; elemental taggants in explosives; and radioactivity and rare molecules in crude oil. We believe each of these techniques offer a trade-off for the user among security level, application variety, cost, ease of implementation, ease of use, information content, and other parameters.

Brand Protection

Establishing a strong brand is pivotal to business success, as it is how a company is perceived by the customer. We believe that protecting that brand is as important. Counterfeiting affects brands across the globe and effective brand protection strategy has become imperative for companies. Many customers do not even realize that they have a counterfeit product, attributing the poor quality to the brand thus tarnishing its name. A recent Organization for Economic Co-operation and Development (OECD) report (June 23, 2017) reiterates a number of trends that have been evident for more than a decade – virtually all brands are being counterfeited, and counterfeit and pirated products are originating from virtually all economies on all continents. Counterfeiters are improving their logistics networks, manipulating transit routes, exploiting governance gaps and taking advantage of the huge growth in online shopping, thereby underlining the need for secure supply chains to protect brands. Consumer safety and satisfaction, brand reputation and revenues can be adversely impacted by counterfeiting. Our SigNature molecular tags can be applied to many products, affording quick and definitive identification of authentic products, and aiding in brand protection efforts.

Nucleic Acid-Based Therapeutics

Nucleic acid-based therapeutics have emerged as a new class of drugs and biologics for treating unmet medical needs. Nucleic acid-based therapeutics, which includes adoptive cell therapy, gene therapy, DNA-based vaccines and RNA-based therapies, are in our opinion the foundation for the current fast-paced medical revolution. All nucleic acid-based therapeutics are driven by DNA, which is required in large scale. As of January 2018, almost 2600 nucleic acid-based therapeutic clinical trials have been completed, are ongoing or have been approved worldwide (The Journal of Gene Medicine: Gene Therapy Clinical Trials Worldwide to 2017; An Update -March 25, 2018). To date, DNA for nucleic acid-based therapeutics has been supplied via bacterial plasmids. Bacterial plasmid must be purified to remove bacterial toxins and native bacterial DNA before therapeutic use, a process that increases manufacturing time and complexity. We believe PCR-produced DNA is a better alternative than plasmid DNA for use in nucleic acid-based therapeutics because it does not use bacteria in its manufacturing process. Through the use of our PCR-based technology and systems, we feel we are well situated to supply DNA to the growing nucleic acid-based therapeutics market. Therapeutics utilizing our PCR produced linear DNA will require clinical trials and approval by the Food and Drug Administration ("FDA") which may not occur for many years, if at all.

Non-Biological Tagging and Security Products and Services

SigNature® molecular tags, SigNature® T molecular tags, fiberTyping®, SigNify® Beacon® and CertainT® comprise our principal tagging and security technology platform.

Signature Molecular Tags

SigNature® Molecular Tags. The SigNature® molecular tag is our patented molecular taggant technology, at the core of our platform. It provides forensic power and protection for a wide array of applications. Highly secure, robust and durable, SigNature® molecular tags are an ingredient that can be used to fortify brand protection efforts; strengthen supply chain security; and mark, track and convict criminals. Through our SigNature® molecular tags, custom DNA sequences can be embedded into a wide range of host carriers including natural and synthetic fibers, ink, varnish, thread, metal coatings, and pharmaceuticals and nutraceuticals. SigNature® molecular tags can be made resistant to challenging environments such as heat, cold, vibration, abrasion, organic solvents, chemicals, UV radiation and other extreme environmental conditions, and so can be identified for numerous years after being embedded directly, or into media applied or attached to the item to be marked. Each individual molecular tag is recorded and stored in a secure database so that we can later detect it using a simple in-field test, or in our laboratories to obtain definitive proof of the presence or absence of a specific SigNature® molecular tag (e.g., one designed to mark a particular product). Our in-lab forensic testing capability delivers an expert witness Certificate of DNA Authentication ("CODA"). Because DNA is one of the densest information carriers known, and can be amplified with high fidelity, only minute quantities of SigNature® molecular tags are necessary for successful analysis and authentication. As a result, SigNature® molecular tags can fold seamlessly into production and logistics workflows at extremely low concentrations.

SigNature® molecular tags have been subjected to rigorous testing by the Idaho National Laboratory, a U.S. National Laboratory, by CALCE (the Center for Advanced Life Cycle Engineering), the largest electronic products and systems research center focused on electronics reliability, and by verified procedures in our laboratories. The molecular tag has passed all tests across a broad spectrum of materials and substrates, and has met key military stability standards. SigNature® molecular tags have also passed a strenuous "red-team" vetting on behalf of the U.S. Defense Logistics Agency.

SigNature® molecular tags now exist on hundreds of millions of commodity quantities ranging from consumer product packaging to microcircuits to cotton and synthetic fibers; to our knowledge, none has ever been copied.

SigNature® T Molecular Tags and fiberTyping®

SigNature® T Molecular Tags. SigNature® T molecular tags are a unique patented tagging and authentication system specifically designed for textiles and apparel. Specially engineered to adhere tenaciously to textile substrates, including natural and synthetic fibers, SigNature® T molecular tags are resistant to standard textile production conditions. The result: an enduring forensic level molecular tag that remains present from the fiber stage through to the finished product.

Our SigNature® T technology allows for better quality control and assurance at any point in the supply chain. SigNature® T molecular tags are currently used for brand protection efforts and raw material source compliance programs. For example, American grown cotton fibers can be tagged at the gin in the United States, verified as "American grown" and then traced through every step of the supply chain.

fiberTyping®. Our patented cotton genotyping platform, known as "fiberTyping," complements our SigNature® T molecular tag system. fiberTyping® is employed to identify the genus and species of the fibers before or after they are tagged with SigNature® T molecular tags. fiberTyping® cannot be used to provide the unique identity of a specific cotton through the supply chain.

fiberTyping® is not a molecular tag, but a genotyping test of native cotton fiber DNA, which gives a clear result that determines whether the intended "nature-made" endogenous cotton DNA is present in fiber, yarn or fabric. Samples from the primary material are sent to our forensic labs for DNA analysis and authentication. Cotton classification and the authentication of cotton species after cotton has left its place of origin are issues of global significance, important to brand owners and to governments that must regulate the international cotton trade. We believe that the use of endogenous DNA to identify the cotton fiber content in textile supply chains, along with the SigNature® T molecular tag system, to identify traceability, is a significant opportunity for brand license holders to control their intellectual property, for brands to shield themselves against legal liabilities, and for governments to improve their ability to enforce compliance with trade agreements between nations.

We believe that our proprietary DNA extraction protocols and methodologies are more effective than existing forensic systems. We believe that the combination of our SigNature® T molecular tags and fiberTyping® solutions cover the forensic authentication market for textiles.

Smart DNA

Recognizing that DNA-based evidence is the cornerstone of modern-era law enforcement, we have developed what we believe to be the ultimate crime fighting tools – currently being used in vehicle and home asset marking, as well as other commercial and government applications.

These molecular tags can be used to definitively link evidence and offenders to specific crime scenes. As the crime is investigated, the fluorescing molecular marker can assist police in linking the offender and stolen items to a specific crime scene, creating a greater ability to identify and convict.

These long-lasting tagging solutions contain unique molecular tags that can help return stolen or lost property to its rightful owner.

Beacon®

Beacon® locked optical markers deliver secure real-time inspection capabilities. A unique patented encrypted mechanism creates a protected, covert screening tool that can be easily adapted to packaging, security labels and high-value assets through inks, varnishes and coatings. When Beacon® locked optical markers are combined with SigNature® molecular tags, a strong and flexible security and screening solution is created where authenticity and provenance can be determined with confidence.

SigNify®

Developing a secure method for real-time, in-field screening of molecularly-tagged items has long been a priority for us. We believe that standard fluorophores, up-converting phosphors, holograms and other more-traditional screening tools provide little to no defense against counterfeiting. We believe that secure in-field inspection backed with forensic-level molecular tag authentication is the key to maintaining a well-defended supply chain or asset management program.

SigNify® IF portable DNA readers and SigNify consumable reagent test kits provide definitive real-time authentication of SigNature® and SigNature® T molecular tags in the field. With SigNify® IF, Signature® molecular tags become a true, front-line solution for supply chain integrity.

Information Technology Systems

Applied DNA Sciences Portal. CertainT® and other customer applications include the use of a software platform that enables customers to manage the security of company-marked goods from point of marking to point of authentication or validation to end of life. The base platform is configurable to customer requirements which differ by vertical market, company business process and IT environment. Basic functions offered include molecular tag inventory management, program training and communications, a database of marked items information, associated documents and images, chain of custody and location tracking, sample authentication processing and CODA downloads, and other administrative functions. Designed for either cloud or local operation, the system supports mobile data capture using bar codes or other technologies. The system is architected as the controller and repository for other validation and authentication devices such as our SigNify® DNA Readers, DNA Transfer Systems, Cannabis Tracking Systems and other third-party devices and is designed to share data with third party applications through standard interfaces.

DNA Transfer Systems and Cannabis Tracking System. Our patent pending DNA Transfer System and patent pending Cannabis Tracking System are developed for DNA marking applications which are high volume with a need for monitoring and control. They are computer based, fully automated, offer remote internet access for real-time monitoring and can be configured for application-specific alerts and reporting online. Our DNA Transfer Systems were used to mark cotton at five U.S. cotton gins and one gin in Egypt in the 2018-2019 ginning season.

CertainT® Supply Chain Platform

CertainT® helps brands confirm their product's authenticity and origin with certified, trust, transparency and traceability through the seamless amalgamation of several of our platform technologies to tag, test and track. The CertainT® trademark indicates use of the CertainT® tagging, testing and tracking platform to enable proof of product claims for any material, item or product. Secure and proven, the CertainT® Platform helps manufacturers, brands or other commercial organizations deliver on their promise that customers are buying products that are ethically-sourced, safe and authentic.

Biotherapeutic Contract Research and Contract Manufacturing Products and Services

Large-scale production of specific DNA sequences using PCR.

Our patented Triathlon™ continuous flow PCR systems and other proprietary PCR production technology and post-processing systems allow for the large-scale production of specific DNA sequences. The systems are computer-controlled, self-contained and modular. DNA sequences produced through our processes and systems are currently being used by customers as components *of in vitro* diagnostic tests. We believe we have the ability to manufacture longer DNA sequences valuable in nucleic acid-based therapeutics such as adoptive cell therapies (CAR T and TCR therapies), DNA vaccines, RNA therapies, gene therapy and *in vitro* diagnostics, with what we believe is a distinct competitive advantage in cost, cleanliness, and time-to-market. These types of DNA are distinct from our DNA-based molecular taggants marketed under our SigNature® and SigNature® T trademarks, and represent a potential new entry into biotherapeutics markets, where we believe there are opportunities for our broader platform.

Contract Research

Through LRx, we act as a preclinical contract research organization for the nucleic acid-based therapeutic markets. LRX is currently working with biotech companies to convert plasmid-based and/or viral transduction based preclinical biotherapeutics into PCR produced linear DNA-based forms. In addition, LRx is providing contract research services to several RNA based drug and biologic customers for preclinical studies. These services include the design, development and manufacture of PCR-produced DNA templates for RNA.

Nucleic Acid Theraputics

We seek to develop, acquire, and commercialize, ourselves or with partners, a diverse portfolio of nucleic acid-based therapeutics based on PCR-produced linear DNA to improve existing nucleic acid-based therapeutics or to create new nucleic acid-based therapeutics that address unmet medical needs. We are also engaged in preclinical and animal drug candidate development activities focusing on therapeutically relevant DNA constructs manufactured through our large-scale PCR production systems. LRx uses its PCR systems to rapidly produce customized DNA for use by our contract research organization/contract manufacturing organization clients, our preclinical nucleic acid-based therapeutic clients and partners, and for our own nucleic acid-based therapeutic candidates under preclinical development in the field of CAR T-cell immunotherapy. LRx's proprietary processes enable very large, gram-scale production of DNA through PCR for nucleic acid-based therapeutics which include adoptive cell therapies, gene therapies, RNA-based therapies, DNA-based vaccines (including cancer), clustered regularly interspaced short palindromic repeats(CRISPR) based therapies and other nucleic acid-based therapies. We believe linear DNA does not require recombination, therefore, there is no need for a virus or for plasmids. We believe this reduces the risk of unwanted DNA or other contaminants that would need to be removed.

Invasive Circulating Tumor Cell Capture and Identification

We seek to further develop, manufacture and commercialize our Vita-Assay™ invasive circulating tumor cell capture and identification technology (the "iCTC Technology") recently acquired from Vitatex, Inc. See "Diagnostics and Reagents." Our iCTC Technology uses a patented functional assay to capture live invasive circulating tumor cell and associated lymphocytes that can be identified and expanded for further analysis, including genetic sequencing. We believe our iCTC technology can be used as an early cancer diagnostic tool, to facilitate cancer disease progression monitoring and to assess metastatic tumor risk. Our iCTC Technology has been used in a human cancer drug candidate clinical trial to monitor cancer disease progression in the trial subjects. We believe our iCTC Technology has several advantages over existing *in vitro* circulating tumor cell diagnostic technologies that do not capture live iCTC cells.

Our Strategy

The core technologies of our supply chain security business are supplied as tag, test and track solutions for large complex supply chains. Our tag, test and track solutions allow our customers to use molecular tags to mark objects in a unique manner that we believe cannot be readily replicated, and then identify these objects by detecting the absence or presence of the molecular tag. We believe that our disruptive tracking platform offers broad commercial relevance across many industry verticals. Our underlying strategy in the tagging business is to become a solutions provider for supply chains of process industries in which contracts for our products and services are typically larger and of longer duration as compared to our historic norms, where the benefits to customers and consumers are more significant, and where our forensic security and traceability offer a unique and protected value. Consumers, governments and companies are demanding details about the systems and sources that deliver their goods. They worry about quality, safety, ethics, and the environmental impact. Farsighted organizations are directly addressing new threats and opportunities presented by this question: Where do these goods come from? This is the question and the concerns we are beginning to address for a growing number of companies. We supply key building blocks for creating secure supply chains with traceability of goods, which in turn can help ensure integrity in supply, honest sales and marketing claims, and ethical and sustainable sourcing.

Biotechnology customers using our PCR-produced linear DNA products and services for use in *in vitro* medical diagnostics, preclinical biotechnology research and preclinical drug and biologic development and manufacturing in the fields of adoptive cell therapies, gene therapies, RNA-based therapies, DNA-based vaccines (including cancer), clustered regularly interspaced short palindromic repeats (CRISPR) based therapies and other nucleic acid-based therapies receive a DNA product we believe is made cleaner and faster than historical manufacturing methods, thereby offering the opportunity for increased efficiency and turnaround times in their processes. We are also engaged in preclinical and animal drug candidate development activities focusing on therapeutically relevant DNA constructs manufactured via our PCR-based production platform. We seek to develop, acquire and commercialize, alone or with partners, a diverse portfolio of nucleic acid-based therapeutics based on PCR-produced linear DNA which we believe will improve existing nucleic acid-based therapeutics or create new nucleic acid-based therapeutics that address unmet medical needs.

Our products and services are offered in the United States, Europe and Asia. At the present time, we are focusing our efforts on textile and apparel, pharmaceuticals and nutraceuticals, microcircuits and other electronics, legal cannabis and hemp (as well as other derivative products) and PCR-produced linear DNA products, as well as DNA manufacturing services for *in vitro* medical diagnostics, preclinical biotechnology research and preclinical biotherapeutic manufacturing. Currently, approximately thirty-five percent of our annual revenue comes from the textile market. The basic technology we use in various markets is very similar, and we believe our solutions are adaptable for many types of products and markets. In the future, we plan to expand our focus to include additional consumer products and industrial materials. The cotton ginning season in the United States takes place between September and March each year; therefore, revenues from our cotton customer contracts may be seasonal and recognized primarily during our first and fourth fiscal quarters, which may cause operating results to fluctuate significantly quarterly and annually. To date, the substantial portion of our revenues has been generated from sales of our SigNature® and SigNature® T molecular tags, our principal supply chain security and product authentication solutions. We expect to grow revenues from sales of our SigNature® molecular tags, SigNature® T molecular tags, SigNify® and CertainT® offerings as we work with companies and governments to secure supply chains for various types of products and product labeling throughout the world. In addition, we expect to continue to grow revenues from PCR-produced linear DNA products and services using our patented Triathlon™ and other proprietary PCR production and post-processing systems. We are also seeking to establish a revenue stream from our iCTC Technology.

Target Potential High-Volume Markets

We will continue to focus our efforts on target vertical markets that are characterized by a high level of vulnerability to leaky supply chains, product diversion and a lack of security. We also intend to expand into additional related high-volume markets.

Pursue Strategic Acquisitions and Alliances

We intend to pursue strategic acquisitions of companies and technologies that strengthen and complement our core technologies, improve our competitive positioning, allow us to penetrate new markets, and grow our customer base. We also intend to work in collaboration with potential strategic partners in order to continue to market and sell new product lines derived from, but not limited to, non-biologic DNA tagging technologies, other supply chain provenance technologies, biotherapeutics and *in vitro* diagnostics.

Markets

Textiles and Apparel

Textile identity and the authentication of a product's origin, are issues of global significance, important to brand owners for quality assurance and compliance, and to governments that must regulate international trade, enforce textile labeling, and protect consumers. We believe that CertainT®, an integrated platform to Tag, Test, and Track fiber, yarn, fabrics all the way to finished goods, enables brands and manufacturers to preserve the integrity authenticity and quality of the source materials in a global supply chain. As a result, consumers will have confidence that claims and ingredients listed on the label are proven in the finished product. CertainT® molecular business solutions are relevant to natural fibers like cotton, wool, cashmere, down and feather, and leather, as well as man-made fiber, recycled polyester, viscose and other synthetic products used in apparel, footwear and home textiles globally. The molecular tag is robust, and inert. It has no impact on the form or function of raw materials or end products and is persistent throughout the manufacturing process. The information content of each unique SigNature® T tag can be assigned with precision to a supply chain objective. Thus, SigNature® T tagged materials have their own identity and may offer, for example, a unique story of where, when, and/or how they were made. The flexible nature of SigNature® T technology facilitates easy addition of the tag at virtually any stage of textile production. Molecular tag analysis verifies goods identity as the corner stone of the platform. Testing can be conducted at Applied DNA's ISO 17025 accredited forensic laboratories in Stony Brook, New York, or in the field, for some validated products, using portable processes and equipment.

Our Market Response

As part of the CertainT® platform, our patented SigNature® T molecular tag technology for molecular tagging and authentication has been proven to be scalable and commercially applicable in integrated textile supply chains, in cotton as well as recycled polyester and is currently in use by our customers. Our SigNature® T molecular tag commercial program involves the creation of unique SigNature® T molecular tags that can be used to tag a customer's cotton fiber at the ginning stage. Our fully automated, secure DNA Transfer Systems allow for traceability and monitoring of all molecularly-tagged cotton at multiple gins in Arkansas, Texas, California Australia and Egypt.

Once tagged, the cotton fiber may be authenticated for textile identity from grower to ginner to spinner to manufacturer to distributor to retailer. At each step of the process, its textile identity will be tested to link the original cotton fiber to finished product, preserving the authenticity of the product and the integrity of the supply chain. SigNature® T DNA tags are being used to mark premium Pima cotton fiber, known as PimaCott® and are also used to mark Upland cotton under the HomeGrown™ trademark. As the cotton ginning in the U.S. takes place sometime between September and March each year, it is possible that revenues from this business will be seasonal.

In June 2017, we entered into a new licensing agreement with Himatsingka America, Inc., which is part of the Himatsingka Group. ("Himatsingka America"), a leading supplier of home textiles. This agreement terminates an earlier licensing agreement dated March 25, 2015 between Divatex Home Fashion, Inc. (a predecessor to Himatsingka America) and the Company. Under the terms of the Agreement, Himatsingka America will be solely responsible for promoting, marketing and selling on a worldwide basis the Company's technology with respect to finished and unfinished cotton products. The Agreement grants Himatsingka America an exclusive license to use our technology in respect of cotton, subject to certain carve-outs including governmental users, non-commercial trade associations and others. The Agreement has a term that continues until June 23, 2042, except in the case of patents, in which case the term continues with respect to a patent until such patent is no longer in effect. The Agreement also provides that Himatsingka America will make royalty payments on a quarterly basis in arrears in the event that our technology is used on non-home products. Himatsingka America is responsible for the inspection and compliance within the supply chain.

Himatsingka America is generally required to use our technology during the term of the Agreement, subject, among other things, to their customers' requirements. We have established an independent testing laboratory in Ahmedabad, India, which is required by the agreement. Finished products made from this tagged fiber have been offered for sale under the PimaCott®, HomeGrown®, LoneStar™ and HomeGrown Acala™ content branded labels. The Agreement includes customary mutual indemnification provisions. See also the information under the caption "—Distribution of our Products and Commercial Agreements—Himatsingka America."

In January 2016, we signed a cooperative research and development agreement ("CRADA") with the United States Department of Agriculture ("USDA") to collaborate on the development of genotyping assays for cultivars from specific geographic regions of the world. This agreement was extended on April 1, 2018 for an additional five years. It is important to be able to differentiate cotton based on country of origin to identify cultivars of the species identified through our fiberTyping® protocols, genetically-modified organism strains (GMO) and to help avoid "Conflict Cotton", cotton grown using child labor or other undesirable practices. We believe this will assist the cotton industry in protecting the quality and traceability of the products and help protect their economic investments.

For recycled polyester, over 20 million pounds of fiber have been tagged with our SigNature® T molecular tagging technology.

On June 28, 2017, we signed a multi-year license agreement with GHCL Limited, a global manufacturer of home textiles, to provide CertainT platform services in connection with source-verified, polyethylene terephthalate (PET) and recycled PET (rPET post-consumer) in select home textile products. PET is the clear plastic best known for its use in water bottles, and is the most widely recycled plastic in the world. GHCL is using our CertainT platform in connection with PET and/or recycled PET blended bed sheets, pillowcases, and shams products sold in-store or online in the United States. GHCL has also licensed our CertainT trademark for use on its products, as well as for promotional, marketing and sales materials. The agreement provides for guaranteed minimum annual revenues in order to maintain exclusivity during the renewal period, as well as trademark licensing royalties to us. GHCL is using our CertainT platform for verifying PET and recycled PET authenticity from source to retail shelf. With this platform, GHCL assures that any of its textile products using PET and recycled PET will contain the original source raw materials. We will provide our patented and proprietary tagging, testing and tracking services to GHCL as a CertainT licensee. As part of the platform, Applied DNA's molecular tag is extruded into recycled components that create recycled PET fiber, with no impact to performance or quality of the fiber or filament yarns. Thereafter, any piece of CertainT-tagged textiles can be forensically authenticated by detecting the molecular tag in the recycled PET fiber, ensuring its authenticity and origin. During April 2019, GHCL Ltd. announced the launch of the "REKOOP" range of bedding products on Amazon.com. REKOOP utilizes ecologically conscious practices through the molecular tagging of the recycled fiber that comprise its product line through our CertainT® platform that secures provenance and complete traceability across the supply chain. Reliance Industries Ltd., India's largest private sector company, is GHCL Ltd.'s fiber-manufacturing partner and supplies the ecofriendly recycled polyester fiber – Recon® Green Gold, which is used in REKOOP bedding. New products under REKOOP with CertainT® are anticipated to be marketed and sold in the U.S. and internationally.

On July 11, 2017 we signed a new multi-year exclusive license agreement with Loftex Home, LLC ("Loftex"), a well-respected manufacturer of high-quality towels and home textiles. Under a prior agreement entered into during March 2017, we agreed to provide our CertainT platform services to Loftex to verify the authenticity and origin of rPET (post-consumer) used in bath and beach towels. This new multi-year agreement between the two companies is now exclusive for bath and beach towels in the United States, non-exclusive for plush throws and bath rugs, and provides for long term minimum annual revenues, in order to maintain exclusivity, as well as trademark licensing royalties to us. In 2019, Loftex products labeled with the CertainT mark are sold in Walmart and Home Depot.

For information on our statement of work with American & Efird and research project with BLC, please see "Distribution of our Products and Commercial Agreements."

Pharmaceutical Supply Chain

From cyber-attacks in large pharmaceutical companies like the one that affected a large global healthcare leader earlier this year to the rising opioid crisis, the pharmaceutical supply chain has more risk inherent than ever before. Reducing supplier risk to help boost patient safety is becoming more important than ever to pharmaceutical companies.

The pharmaceutical industry also faces major problems relative to counterfeit, diluted, or falsely labeled drugs that make their way through healthcare systems worldwide, posing a health threat to patients and a financial threat to drug makers and distributors. Counterfeit prescription pharmaceuticals are a growing trend, widely recognized as a public health risk and a serious concern to public health officials, private companies, and consumers. The National Association of Boards of Pharmacy estimates that counterfeit drugs account for 1% of all drugs sold in the United States. In some African countries, counterfeit prescription drugs comprise as much as 70% of the drug supply and have been responsible for thousands of deaths in some of the world's most impoverished nations, according to the WHO. The global pharmaceuticals and food anti-counterfeiting market is expected to reach $160 billion by 2020. (Radiant Insights, "Global Pharmaceuticals and Food Anti-Counterfeiting Market Is Expected to Reach USD 160.32 Billion by 2020" (September 28, 2015))

In 2012, the WHO reported that in over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit (WHO: Medicines: Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines Fact Sheet June 2012). According to the WHO, counterfeiting can apply to both branded and generic products and counterfeit pharmaceuticals may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients.

Based on this growing threat, many countries have started to address vulnerabilities in the supply chain by enacting legislation which, among other things, requires a comprehensive system, most often referred to as serialization or in the United States as the Drug Supply Chain Security Act enacted by Congress on November 27, 2013.

Nearly 40 percent of the drugs Americans take are made outside of the United States, and about 80 percent of manufacturing sites of active pharmaceutical ingredients (APIs) used in drugs manufactured in the United States are located outside our borders—in more than 150 countries, many with less sophisticated manufacturing and regulatory systems than our own. In addition to the sheer volume of imports and foreign facilities, there has been an increase in the variety of sources, shippers, methods of transportation, and supply chain complexity of products. Combined, these factors create great challenges to the FDA and industry in ensuring that all drugs and drug components are high quality and travel safely throughout their complex supply chains. These factors also provide opportunities for criminals to adulterate drugs for economic or other malevolent reasons making it more important than ever that supply chains be secured around the world. (U.S. Food and Drug Administration, "Counterfeit Drugs: Fighting Illegal Supply Chains" (February 27, 2014))

Our Market Response

On March 31, 2018, we entered into a License and Cooperation Agreement and a related Supply Agreement with Colorcon, Inc. ("Colorcon") for the use of our molecular tags in Colorcon's product offerings and access to our associated authentication technologies. Under the terms of the Agreements, we granted Colorcon exclusive worldwide right to use our molecular tags and associated authentication technologies in film coatings for solid oral dosage form ("SOD") applications, for which Colorcon is the largest global supplier, and non-exclusive rights to use our technologies in inks and colorants for SOD applications. Pursuant to the Agreements, we will supply taggant and authentication materials to Colorcon in exchange for long-term royalties on the sale of Colorcon products incorporating our molecular tags and on the sale of authentication services related thereto. Further, the first of two milestone payments was payable to us at the signing of the Agreements. We will receive the second milestone payment upon initial approval by a regulatory authority for application in a Solid Oral Dosage Form (SODF) pharmaceutical or nutraceutical product application. The Agreements generally expire on the later of October 1, 2032 or the last expiration date of any patent licensed pursuant to the Agreements.

In April 2018, we filed our Drug Master File with the U.S. FDA to allow confidential information about the chemistry, manufacturing and controls processes of our product to be made available to the FDA for inspection should an end-user company choose to have the FDA review the addition of SigNature molecular tag to their product. In May 2018, the FDA acknowledged receipt of our filing. We have completed the formulation of our SigNature® tags with Colorcon, following the October 2011, the FDA Final Guidance document on the use of so called "Physical-Chemical Identifiers" (PCIDs). The FDA Guidance stipulates that a PCID should be pharmacologically inactive and present no risk of adverse reaction. The PCID cannot affect the efficacy of the drug. In addition, 11 categories of information about the PCID must be satisfactorily addressed. We believe SigNature® DNA may be able to fulfill these requirements. In addition, DNA identifier molecular taggants can be embedded at parts per billion onto film coatings that cover many of the world's leading brands of tablets. By integrating the Applied DNA molecular tags within already utilized film coatings of tablets, we are believe we will be able to offer a seamless solution for pharmaceutical company customers.

Our unique DNA identifier mark-embedded in the ink of a unique serialized barcode used on packaging can provide a layered security foundation for a customer solution in this market. Strengthening the bar codes to be utilized in the serialization process can be a potent approach to protecting the patient and bringing greater confidence to the brand of the pharmaceutical company.

Cannabis

The legal cannabis industry is one of the fastest growing industries in the world. With a global CAGR of over 23%, it is projected to be a $66 billion industry by 2025. Therefore, the legal cannabis industry represents an exciting opportunity for leveraging Applied DNA Sciences core capabilities in supply chain management. By using our molecular tagging and tracking technologies, we believe we are very well positioned to address provenance concerns within the global cannabis supply chain and its stakeholders.

In the United States, proof of provenance as to the origin of cannabis is an essential element of value in state-legal programs. Under the shadow and oversight of the federal government, since cannabis remains a Schedule-1 drug, any state program must be cognizant of the tenets under which they operate their cannabis program. By federal law, it remains illegal to transport cannabis across state lines and hence any state program has need to be able to discriminate if challenged between cannabis and products produced and sold within the state and all others that may not be legal within the state.

Many international countries are already embarking on plans for their own cultivation and/or importation of cannabis and/or cannabis by-products and are not saddled with the unique United States situation.

Our Market Response

During January 2018, we entered into an initial two-year $1 million contract for the development of molecular tracking systems for legal cannabis worldwide with TheraCann International Benchmark Corporation, ("TheraCann"), a leading full service cannabis consultancy with operations in the US, Canada, Australia, Europe and South America, for the integration of the Company's SigNature® molecular tagging and testing technology into TheraCann's seed-to-sale Enterprise Resource Platform (ERP) for legal cannabis operations. Under the terms of the contract, the companies entered into a development and marketing agreement whereby we developed the technologies necessary to tag and authenticate legal cannabis throughout the supply chain and seamlessly integrate tagging and authentication data into TheraCann's ERP and blockchain.

During March 2019, we, with our wholly-owned subsidiary, APDN (B.V.I.), Inc., entered into a Patent and Know-How License and Cooperation Agreement with ETCH BioTrace S.A. ("ETCH"), a wholly-owned subsidiary of TheraCann, (the "TheraCann Agreement"). The TheraCann Agreement granted ETCH the exclusive world-wide right and license, with rights to sublicense, to use, offer to sell, sell and import our proprietary or patented DNA tagging, DNA tag application and DNA tag authentication technologies marketed under SigNature® and/or CertainT® (the "Technology") within the global *cannabis sativa L* and *cannabis sativa L* derivative product markets, excluding use in textiles. The TheraCann Agreement further granted ETCH the non-exclusive right and license, with rights to sublicense, to use, offer to sell, sell and import the Technology within the global *cannabis sativa L* market and *cannabis sativa L* derivative product markets for use in textiles. The TheraCann Agreement also granted ETCH the limited use of trademarks owned by us solely for the purpose of promoting, marketing and disclosing the Technology, with all goodwill and benefit arising from such use inuring to the exclusive benefit of us. Under the TheraCann Agreement, a $5,000,000 non-refundable up-front licensing fee was payable to us over a four-month period, with $1,000,000 paid in April 2019, $2,000,000 that was due on or before June 30, 2019 and $2,000,000 that was due on or before August 15, 2019. Under the TheraCann Agreement we were to jointly market and sell the Technology with ETCH, with profits to be shared between the parties after specified gross profit minimums were reached.

To date, we have not received the June 30, 2019 and August 15, 2019 payments totaling $4,000,000 described above. On September 5, 2019, we sent a notice of continuing breach to TheraCann with respect to the TheraCann Agreement. The September 5, 2019 notice stated that (i) if we do not receive the June 30, 2019 payment by September 24, 2019, we have the option to terminate the TheraCann Agreement for such failure to pay and TheraCann will have no obligation to make further payments to us; and (ii) if we receive the June 30, 2019 payment by September 24, 2019 but do not receive the August 15, 2019 payment by November 8, 2019, we have the option to terminate the TheraCann Agreement for such failure to pay and TheraCann will have no obligation to make further payments to us. Thereafter, on September 30, 2019, we extended both the September 24, 2019 and November 8, 2019 cure dates set by the September 5, 2019 notice to December 3, 2019. On December 4, 2019, we sent notice to TheraCann that the TheraCann Agreement is terminated, in its entirety effective December 4, 2019 (the "Termination Notice"). TheraCann retains no rights to the Technology and we will not receive any future payments pursuant to the TheraCann Agreement.

Diagnostics and Reagents

DNA-based diagnostics is an emerging application area in the in-vitro diagnostics industry. DNA–protein adducts are popular across the medical diagnostics industry, where these molecules aid in the determination of the incidence of a suspected disease caused by an organism or pathogen. Based on the amount of target DNA present, probes can be used either directly to detect target DNA, facilitate the performance of targeting proteins or indirectly to target DNA through amplification that creates a number of copies of a specific nucleotide. Increased automation of diagnostic tests, discovery of new diagnostic markets, rising investments in pharmaceutical and pharmacogenomics research, and advancements in DNA array technologies are major growth facilitators for the DNA probes-based diagnostic products market.

According to an article from BCC Research, ("DNA Diagnostics Market to Almost Double by 2022 with 14.3% CAGR"), the DNA Diagnostics market will reach $23.8 billion in 2022. The potential to provide accurate diagnosis and cost effectiveness over alternative diagnostic techniques are factors that supplement the growth of the DNA diagnostics market. Recent figures suggest that globally, approximately 32.5 million people are living with cancer (as of 2012) with 14.5 million people in the U.S. living with cancer (as of 2014) and 36.7 million with HIV/AIDS (as of 2015) (International Agency for Research on Cancer, Cancer Fact Sheets, All Cancers (excluding non-melanoma skin cancer), Estimated Incidence, Mortality and Prevalence Worldwide in 2012; World Health Organization, Global Health Observatory (GHO) Data, Cancer Facts and Figures 2017, amFAR). These numbers, we believe are set to increase consistently; however, advanced automated DNA diagnostics technologies such as next generation sequencing could play a crucial role in diagnosing and curbing these diseases. (Allied Market Research, "DNA Diagnostics Market is Expected to Reach $19 Billion by 2020" (August 28, 2014))

Our Market Response

Our PCR-produced linear DNA is used by customers who provide patient diagnosis through the *in vitro* examination of specimens, such as blood. All of the linear DNA we provide to our *in vitro* diagnostic customers is produced through our large-scale PCR process, using our proprietary technology, with optimized performance for the final diagnostic assay. In addition to performance optimization, we believe that the production of linear DNA in large lots with quantifiable reproducibility improves the efficiency of our customer's quality control for incoming raw materials and improve the overall quality, accuracy and reproducibility of their diagnostic products. Cell-based DNA production methods are often complicated by impurities. In contrast, we believe our PCR-based production method offers a high degree of purity and efficiency. In April 2017, we were awarded a five-year supply agreement with FUJIFILM Wako Pure Chemical Corp. (formerly Wako Pure Chemical Industries, Ltd.) for the manufacture of bulk DNA for in vitro medical diagnostics. This supply agreement includes quarterly DNA shipments and optional three-year renewals. Under this multi-year contract, our DNA is utilized in a medical diagnostic tool that aids in assessing disease. We currently also have a number of new linear DNA amplicons being evaluated by customers for potential use in the *in vitro* diagnostic market.

On August 8, 2019 we announced that LRx acquired the assets and intellectual property of Vitatex, Inc, which included the iCTC Technology. As part of the Vitatex, Inc. asset acquisition, we entered into an Amended and Restated License Agreement with the Research Foundation for the State University of New York relating to a patent estate covering the iCTC technology. See "Collaboration and Licensing Agreements." We seek to further develop, manufacture and commercialize the iCTC Technology to address the growing circulating tumor cell *in vitro* diagnostics market. The acquired iCTC Technology uses a patented functional assay to capture live invasive circulating tumor cell and associated lymphocytes that can be identified and expanded for further analysis, including genetic sequencing. We believe our recently acquired iCTC technology can be used as an early cancer diagnostic tool, to facilitate cancer disease progression monitoring and to assess metastatic tumor risk. The acquired iCTC Technology has been used in a human cancer drug candidate clinical trial to monitor cancer disease progression in the trial subjects. We believe the acquired iCTC Technology has several advantages over existing *in vitro* circulating tumor cell diagnostic technologies that do not capture live iCTC cells.

Nucleic Acid-Based Therapeutics

Nucleic acid-based drugs and biologics have emerged as a new class of treatments for unmet medical needs. Through LRx, we are currently pursuing several types of nucleic acid-based therapeutic applications for PCR-produced DNA. These applications include: (i) adoptive cell therapy; (ii) DNA vaccines; (iii) RNA-based therapeutics and (iv) gene therapies. To date, the most prominent use of adoptive cell therapy is for CAR T-cell immuno-oncology therapies, wherein autologous or allogeneic cells are collected and genetically modified to kill cancer cells. Two CAR T-cell therapies have recently been approved by the FDA for treatment of B-cell malignancies. These approved therapies have demonstrated high efficacy in published studies. The CAR T-cell market is undergoing rapid growth, with over $20 billion in recent M&A activity (January 2018, Juno Therapeutics acquired by Celgene for $9 billion; August 2017, Kite Pharma acquired by Gilead Sciences for $11.9 billion). Current CAR T-cell therapies are manufactured via bacterial plasmid and viral vector-based methods. These manufacturing methods are extremely expensive, time-consuming and may have public health concerns. We believe that production of CAR T-cell therapies via a PCR-based platform, without plasmid or viral vectors, may lead to reduced manufacturing times, reduced costs and mitigation of public health concern.

DNA vaccines may we believe hold numerous advantages over conventional vaccination methods. DNA vaccines are able to trigger a wide range of immune responses, leading to broad applications. DNA vaccines we believe are cheaper and easier to manufacture when compared to convention vaccines. Current DNA vaccines are manufactured via bacterial plasmids. Production via our PCR-based platform may reduce DNA vaccine costs and manufacturing timeframes.

There are two types of RNA therapeutics. mRNA-based therapeutics, which result in protein production, and antisense/interfering RNA-based therapeutics, which interfere with or inhibit gene expression. This dual functionality allows RNA-based therapeutics to target a wide range of indications. RNA-based therapeutics are typically manufactured from a DNA template obtained from a bacterial plasmid. We believe creating RNA-based therapeutics from a DNA template obtained from our PCR-based platform may reduce RNA-based therapeutic costs and manufacturing timeframes.

Gene therapy is designed to introduce genetic material into a subject's cells to compensate for abnormal genes or to make a beneficial protein. Currently, gene therapy is accomplished through the viral transduction of a subject's cells via the use of a recombinant viral vector manufactured from plasmid-derived DNA. Recently, several gene therapies have been approved for use in the United States. We believe recombinant viral vectors manufactured in whole or in part from PCR-produced DNA may reduce manufacturing complexities, timelines and costs.

Our Market Response

During September 2018, we formed a new, wholly owned subsidiary LineaRx, Inc. (LRx) to develop and commercialize our extensive experience in the design, manufacture and chemical modification of DNA via large scale PCR-based production systems in the fields of nucleic acid-based therapeutics, including drugs and biologics. We believe our PCR-produced linear DNA products and services are made cleaner and faster than historical manufacturing methods. We are also engaged in preclinical and animal drug candidate development, directly and with collaborators focusing on therapeutically relevant DNA constructs manufactured via our PCR-based production platform. We seek to develop, acquire and commercialize, previously alone and now along with partners, a diverse portfolio of nucleic acid-based therapeutics based on PCR-produced linear DNA to improve existing nucleic acid-based therapeutics or to create new nucleic acid-based therapeutics that address unmet medical needs.

Also, in September 2018, LRx signed a Joint Development Agreement with Takis S.R.L. and Evvivax S.R.L. (Takis/Evvivax) to develop PCR-produced DNA expression vectors for two of Takis/Evvivax's DNA-based anti-cancer vaccine candidates. Under the Joint Development Agreement, PCR-produced-linear DNA amplicons carrying the DNA sequences for Takis/Evvivax vaccine candidates will be delivered to preclinical and animal models via Takis/Evvivax's proprietary electroporation technology. Antigen-specific immune responses aimed at achieving therapeutic effects will be studied. See "Collaboration and Licensing Agreements."

On October 16, 2018 we announced that LRx entered into an exclusive licensing and research services agreement with iCell Gene Therapeutics, Inc. ("iCell") under which LRx licensed iCell's anti-CD19 CAR T-cell immuno-oncology therapy candidate for B-cell malignancies. LRx will develop the in-licensed anti-CD19 CAR T-cell immuno-oncology therapy under a PCR-based, plasmid and viral free manufacturing platform. See "Collaboration and Licensing Agreements."

Microcircuits and other electronics

The vast majority of counterfeits discovered in military equipment are semiconductors, the stamp-sized silicon wafers that act as the "brains" of nearly every type of modern electronic system. According to an article in DefenseOne (Counterfeits Can Kill U.S. Troops. So Why Isn't Congress and DoD Doing More to Stop it? — August 8, 2013), the U.S. military is an important consumer of these tiny products; a single F-35 Joint Strike Fighter jet is controlled by more than 2,500 semiconductors.

One of the reasons counterfeit microcircuits are a major concern in weapons procurement is because the chips, which control targeting accuracy and other critical parameters, can wreak havoc if they do not perform to specifications. They can also be a means of sabotaging weapon systems if covertly supplied by a hostile government through seemingly legitimate companies.

The Defense Logistics Agency (DLA) is the nation's combat support agent for logistics. DLA The Agency manages over 5 million parts, supports more than 2,300 weapon systems, and accounts for nearly 85% of the spare parts for our military forces. DLA's reach extends far beyond DoD. The Agency supports Foreign Military Sales (FMS) to more than 100 nations. DLA provides significant support to worldwide humanitarian relief, the Federal Emergency Management Agency (FEMA), and other federal, state, and local customers. The problem is not limited to the defense industry.

Our Market Response

On November 15, 2012, DLA began to require that defense contractors provide certain items that have been marked with DNA produced by us or our authorized licensees. This requirement was in place for items falling within Federal Supply Class (FSC) 5962, Electronic Microcircuits, which have been determined to be at high risk for counterfeiting.

Beginning on December 15, 2014, DLA's Electronic Product Test Center ("PTC") in Columbus, Ohio began DNA marking all FSC 5962 microcircuits. This change created a centralized, streamlined DNA marking process within DLA. On November 13, 2014, we were awarded a contract by DLA to provide DLA with SigNature DNA molecular tags and related equipment, services and training. This contract was then extended through October 13, 2018. An additional follow-on two-year contract (plus one exercise year) to ensure there is no lapse in support of the current DNA program at DLA's PTC was signed on September 6, 2018.

In addition, on June 6, 2017, we were awarded a two-year, approximately $1.5 million competitive-bid development contract. The award, funded by the Office of the Secretary of Defense on behalf of the DLA, ran from June 1, 2017 to May 31 2019, and was granted via a Rapid Innovation Fund (RIF) that provided DLA with innovative technologies that can be rapidly inserted into acquisition programs to meet specific defense needs. Management oversight for this RIF contract was from DLA HQ located in Fort Belvoir, Virginia. This firm-fixed price contract followed our prior RIF contract, described further below, that enabled us to develop counterfeit mitigation technologies based upon our proprietary DNA platforms, that protect plastics, silicone elastomers, oils, bearings, fasteners and many other high-risk commodities that are procured by DLA on behalf of DoD. This contract extended our authentication platform to demonstrate hand-held micro-array tickets for DNA authentication in minutes, to complete commercial-scale tagging and authentication pilots for bearings and their preservatives, and to finalize development of continuous inkjet marking to facilitate broader protection in high-risk or mission-critical material purchased by DLA. This contract expired on May 31, 2019.

This contract together with prior development contracts have strengthened our core capabilities to offer supply chain risk management solutions across an expanded range of critical components used in defense, industrial and consumer markets.

As a subcontract to the RIF contract described above, on November 20, 2017 we signed a CRADA with the U.S. Army Research, Development and Engineering Command's Edgewood Chemical Biological Center ("ECBC") to study the commercialization of ECBC's innovative rapid, in-field DNA microarray technology for use in military and commercial supply chains. ECBC is the nation's primary DoD technical research organization for non-medical chemical and biological warfare defense. This contract expired on May 31, 2019.

Printing and Packaging

The scourge of counterfeiting in packaging has greatly intensified in recent years. Counterfeiting has spiked, causing detrimental health concerns for consumers, safety concerns for law enforcement agencies, and financial concerns for businesses worldwide. As a result, the global anti-counterfeit packaging market is estimated to reach approximately $206.57 billion by the year 2021, according to Markets and Markets.

Billions of dollars per year are at stake for companies as they seek ways to ensure that the products sold with their logos and branding are authorized and authentic. The proliferation of counterfeiting requires brand owners and their converter/printer partners to work together to create a multi-layered protection plan so that their packaging and labels protect their brands and deter those trying to profit at their (and their reputation's) expense.

Counterfeiters have become so good at their unlawful activity that spotting the difference between legitimate and counterfeit products can be daunting. They have many ways to subvert legitimate brands. They may take an out-of-date — but legitimate — product and sell it in packaging and labels that have been faked. Sometimes, everything — including the packaging, labels and product itself — is counterfeit. Criminals might also use legitimate packaging with knock-off products.

Our Market Response

Our integrated platform of forensic level molecular tags and optical and digital technologies offers a high level of security and flexibility in a cost-effective and easy-to-use format to suit the requirements and budget of most companies. They can be added to the varnish, ink or toner in labels and packaging to act as a trace without impacting the quality of the substrate. Our SigNify IF reader or forensic laboratory process is required to detect the molecular tags and verify that a label is authentic. Proprietary optical and digital technologies complement SigNature molecular tags with more rapid screening capability.

During September 2017 we entered into a strategic partnership with Videojet Technologies Inc. (Videojet). We have collaborated with Videojet in the design of co-branded SigNature® molecular-tagged Videojet inks, and a co-branded printer that electronically restricts the use of ink cartridges to only those that contain SigNature® molecular tagged inks. The relationship brings the potential to empower the tagging of countless commercial items, all of which are candidates for a CertainT® licensing agreement, enabling traceability along the entire supply chain.

Integrating the technologies from both companies creates what we believe is a world-class solution that will be offered to the many industries in which both companies are already engaged. Videojet's 325,000-installed base of printers, which code and mark well over ten billion products each day, is a testament to the power of continuous inkjet printing (CIJ) technology. The initial offering utilizes Videojet's 1860 printer, which will be co-branded with us, along with co-branded Videojet inks that will incorporate our unique SigNature molecular tag into each individual ink cartridge. The SigNature-enabled inks may be brand-specific, enabling each brand to tag, test and track their products from source to shelf under a CertainT® platform. Gaining this additional traceability, transparency, and ultimately trust between value chain partners will allow brands to offer a new level of certainty to their customers that the products they are buying are authentic.

On August 7, 2019, we signed a Master Services Agreement with Schreiner Group's MediPharm division which specializes in innovative, functional labels and integrated security solutions for the Pharmaceutical Industry. Applied DNA will supply its SigNature DNA forensic molecular tag with Beacon screening feature for Schreiner MediPharm's high-end security label portfolio for product and brand protection of its customers' supply chains. Schreiner MediPharm will also provide authentication services to its customers using the Applied DNA SigNify® portable DNA readers.

Sales and Marketing

We have seven employees engaged in sales and marketing, of which five are directly involved with sales.

Research and Development

Our research and development efforts are primarily focused on incorporating DNA molecular tags into carriers (such as ink or textiles and more recently the incorporation of DNA into the body of materials such as thermoplastics and pharmaceuticals) and then authenticating DNA obtained from those marked products both in our laboratories and in the field, with the use of portable infield DNA readers and proprietary reagents. As part of this effort, we typically conduct feasibility and pilot testing to ensure that DNA tagging methods are compatible with the customer's manufacturing and logistic processes, and that they can be implemented in a cost-effective manner. In some cases, the DNA incorporation methods may undergo wash-out and/or adherence tests to ensure that DNA can be authenticated on a product even if it is subjected to aggressive processing techniques. We are also actively involved in developing new DNA formulations and new methods to incorporate those new DNA formulations into products, to provide for better adhesion of DNA onto surfaces and when appropriate, better blending of the DNA into the body of a product material. We also continue development in the area of genotyping of cotton, down to the cultivar level to detect more specific information about cotton type. In short, we have considerable experience working with DNA in a wide range of carriers and substrates, and authenticating them even years after they have been applied onto the surface or inside of product materials. We believe that our continued development of new and enhanced technologies relating to our core business is essential to our future success. We incurred approximately $3.0 million and $2.8 million on research and development activities for the fiscal years ended September 30, 2019 and 2018, respectively.

Under LRx, our research and development efforts are focused on the development of PCR-produced linear DNA expression vectors for use in nucleic acid-based therapies including drugs and biologics and associated PCR-based methods of linear DNA expression vector manufacture. Methods for viral free transfection, high-level cellular expression and episomal persistence of linear DNA expression vectors are under development. In addition, we are developing PCR producible linear DNA expression vectors for our anti-CD19 CAR T-cell immuno-oncology therapy candidate licensed from iCell, as well as several cancer vaccine candidates in collaboration with Takis/Evvivax.

Raw Materials and Suppliers

Our sources of raw materials include synthesized sources of DNA which we are able to replicate to use in our product offerings and that are available from multiple sources.

Manufacturing

We have the capability to manufacture specific sequences of SigNature DNA molecular tags using PCR at large scale and to produce all of the resulting finished products at our laboratories in Stony Brook. We also have in-house capabilities to complete all authentications in our Stony Brook location and textile authentications in our India location.

Distribution of our Products and Commercial Agreements

Our products are distributed in the following ways:

- directly to the customer;
- through channel partners; and
- through licensed distributors.

We have entered into the following agreements and arrangements for the distribution of our products, among others:

DLA. On November 13, 2014, we were awarded a contract by DLA to provide DLA with SigNature DNA molecular tags and related equipment, services and training. Beginning on December 15, 2014, DLA's Electronic Test Laboratory in Columbus, Ohio began DNA marking all FSC 5962 microcircuits. This created a centralized, streamlined DNA marking process within DLA. This contract was extended through October 13, 2018. An additional follow-on two-year contract (plus one exercise year) to ensure there is no lapse in support of the current DNA program at DLA's PTC was signed on September 6, 2018.

Himatsingka America. In June 2017, we announced that we had entered into a new licensing agreement with Himatsingka America, Inc., which is part of the Himatsingka Group ("Himatsingka America"), a leading supplier of home textiles. This agreement terminates an earlier licensing agreement dated March 25, 2015 between Divatex Home Fashion, Inc. (a predecessor to Himatsingka America) and the Company. Under the terms of the Agreement, Himatsingka America will be solely responsible for promoting, marketing and selling on a worldwide basis the Company's technology with respect to finished and unfinished cotton products. The Agreement grants Himatsingka America an exclusive license to use our technology in respect of cotton, subject to certain carve-outs including governmental users, non-commercial trade associations and others. The Agreement has a term that continues until June 23, 2042, except in the case of patents, in which case the term continues with respect to a patent until such patent is no longer in effect. The Agreement also provides that Himatsingka America will make payments for the use of our taggant technology on a net 60 basis. In addition, Himatsingka America will make royalty payments on a quarterly basis in arrears in the event that our technology is used on non-home products. Himatsingka America is responsible for the inspection and compliance within the supply chain.

Himatsingka America is generally required to use our technology during the term of the Agreement, subject, among other things, to their customers' requirements. As required by the agreement, we have established a testing laboratory in Ahmedabad, India. Finished product made from this tagged fiber is offered for sale under the PimaCott®, HomeGrown® and HomeGrown Acala™ content-branded labels.

GHCL Limited. On June 28, 2017, we signed a multi-year license agreement with GHCL Limited ("GHCL"), a global manufacturer of home textiles, to provide CertainT platform services in connection with source-verified, polyethylene terephthalate (PET) and recycled PET (rPET post-consumer) in select home textile products. PET is the clear plastic best known for its use in water bottles, and is the most widely recycled plastic in the world. GHCL will use our CertainT platform in connection with PET and/or recycled PET blended bed sheets, pillowcases, and shams products sold in-store or online in the United States. GHCL has also licensed our CertainT trademark for use on its products, as well as for promotional, marketing and sales materials. The agreement provides for guaranteed minimum annual revenues in order to maintain exclusivity during the renewal period, as well as trademark licensing royalties to us. GHCL will use our CertainT platform for verifying PET and recycled PET authenticity from source to retail shelf. With this platform, we believe that GHCL is assured that any of its textile products using PET and recycled PET will contain the original source raw materials. We will provide our patented and proprietary tagging, testing and tracking services to GHCL as a CertainT licensee. As part of the platform, our molecular tag is extruded into recycled components that create recycled PET fiber, with no impact to performance or quality of the fiber or filament yarns. Thereafter, any piece of CertainT-tagged textiles can be forensically authenticated by detecting the molecular tag in the recycled PET fiber, ensuring its authenticity and origin. During April 2019, GHCL Ltd. announced the launch of the "REKOOP" range of bedding products on Amazon.com. REKOOP utilizes ecologically conscious practices through the molecular tagging of the recycled fiber that comprise its product line through our CertainT® platform that secures provenance and complete traceability across the supply chain. Reliance Industries Ltd., India's largest private sector company, is GHCL Ltd.'s fiber-manufacturing partner and supplies the ecofriendly recycled polyester fiber – Recon® Green Gold, which is used in REKOOP bedding. New products under REKOOP with CertainT® are anticipated to be marketed and sold in the U.S. and internationally.

Loftex Home. On July 11, 2017 we signed a new multi-year exclusive license agreement with Loftex Home, LLC ("Loftex"), a manufacturer of high-quality towels and home textiles. Under a prior agreement entered into during March 2017, we agreed to provide our CertainT™ platform services to Loftex to verify the authenticity and origin of rPET (post-consumer) used in bath and beach towels. This multi-year agreement between the two companies is exclusive for bath and beach towels in the United States, non-exclusive for plush throws and bath rugs, and provides for long term guaranteed minimum annual revenues, in order to maintain exclusivity, as well as trademark licensing royalties to us. During April 2019, Loftex, announced that the first retail introduction of their bath towels including recycled PET (r-PET) source-verified by the CertainT® platform became available at Walmart and Home Depot.

American & Efird (A&E). During April 2018, we entered into a statement of work with American & Efird ("A&E"), one of the world's leading manufacturers and distributors of industrial and consumer sewing thread, embroidery thread and technical textiles, to evaluate our Beacon® technology for use in CertainT® enhanced secure sewing threads for brand protection. During May 2019, A&E previewed its new line of advanced identification threads, branded "Integrity." A&E publicly displayed the molecular-tagged thread solution at the Texprocess trade show in Frankfurt, Germany in May 2019 and again in October 2019 at the Gerber Technology Summit.

TheraCann International. During March 2019, we, with our wholly-owned subsidiary, APDN (B.V.I.), Inc., entered into a Patent and Know-How License and Cooperation Agreement with ETCH BioTrace S.A. ("ETCH"), a wholly-owned subsidiary of TheraCann International Benchmark Corporation ("TheraCann"), a legal cannabis and hemp consultancy, (the "TheraCann Agreement"). The TheraCann Agreement granted ETCH the exclusive right and license, with rights to sublicense, to use, offer to sell, sell and import our proprietary or patented DNA tagging, DNA tag application and DNA tag authentication technologies marketed under SigNature® and/or CertainT® (the "Technology") within the global *cannabis sativa L* and *cannabis sativa L* derivative product markets, excluding use in textiles. The TheraCann Agreement further granted ETCH the non-exclusive right and license, with rights to sublicense, to use, offer to sell, sell and import the Technology within the global *cannabis sativa L* market and *cannabis sativa L* derivative product markets for use in textiles. The TheraCann Agreement also granted ETCH the limited use of trademarks owned by us solely for the purpose of promoting, marketing and disclosing the Technology, with all goodwill and benefit arising from such use inuring to the exclusive benefit of us. Under the TheraCann Agreement, a $5,000,000 non-refundable up-front licensing fee was payable to us over a four-month period, with $1,000,000 paid in April 2019, $2,000,000 that was due on or before June 30, 2019 and $2,000,000 that was due on or before August 15, 2019. The TheraCann Agreement also provided for specified annual cash payment minimums to us, which TheraCann must pay to us to maintain its license exclusivity. On September 5, 2019, we sent a notice of continuing breach to TheraCann with respect to the TheraCann Agreement. The September 5, 2019 notice stated that (i) if we do not receive the June 30, 2019 payment by September 24, 2019, we have the option to terminate the TheraCann Agreement for such failure to pay and TheraCann will have no obligation to make further payments to us; and (ii) if we receive the June 30, 2019 payment by September 24, 2019 but do not receive the August 15, 2019 payment by November 8, 2019, we have the option to terminate the TheraCann Agreement for such failure to pay and TheraCann will have no obligation to make further payments to us. On September 30, 2019 we extended both the September 24, 2019 and November 8, 2019 cure dates set by the September 5, 2019 notice to December 3, 2019. On December 4, 2019, we sent notice to TheraCann that the TheraCann Agreement is terminated in its entirety, effective December 4, 2019 (the "Termination Notice"). After the issuance of the Termination Notice, TheraCann retains no rights to the licensed technology.

Colorcon, Inc. On March 31, 2018, we entered into definitive licensing and cooperation agreement as well as a related supply agreement with Colorcon, Inc. ("Colorcon") for molecular tagging in the pharmaceutical and nutraceutical markets. Colorcon plans to use our SigNature molecular tags in its product offerings along wiht access to our associated authentication technologies. These Agreements follow the memorandum of understanding (MOU) announced on December 18, 2017.

Under the terms of the Agreements, Applied DNA grants Colorcon exclusive worldwide right to use the Company's molecular tags and associated authentication technologies in film coatings for solid oral dosage form ("SOD") applications, for which Colorcon is the largest global supplier, and non-exclusive rights to use our technologies in inks and colorants for SODF applications. Pursuant to the Agreements, we will supply taggant and authentication materials to Colorcon in exchange for long-term royalties on the sale of Colorcon products incorporating the Company's molecular tags and on the sale of authentication services related thereto. Further, the first of two milestone payments was payable to us with the signing of the Agreements. We will receive the second milestone payment upon initial approval by a regulatory authority for application in a SOD pharmaceutical or nutraceutical product application. The Agreements generally expire on the later of October 1, 2032 or the last expiration date of any patent licensed pursuant to the Agreements.

Tyme Technologies. During November 2019, the Company's majority-owned subsidiary, LRx signed a definitive agreement with Tyme Technologies, Inc. to supply the Company's Vita-AssayTM invasive Circulating Tumor Cell (iCTC) capture assay and associated services for use in the pivotal stage of the TYME-88-PANC clinical trial for patients with third-line pancreatic cancer.

Under the terms of the Agreement, TYME has the option to purchase from the Company up to 3,000 Vita-Assay kits and associated iCTC analytical and storage services over the course of treatment of up to 250 patients.

Collaboration and Licensing Agreements

Takis S.R.L. and Evvivax S.R.L. During September 2018 we signed a joint development agreement with Takis S.R.I. and Evvivax S.R.L. ("Takis/Evvivax"), biotechnology companies focused on the discovery and development of DNA based anti-cancer vaccines for the human and animal targets, respectively. Under the terms of the agreement, we will jointly develop linear DNA expression vectors for two of Takis/Evvivax's anti-cancer vaccines candidates utilizing our linear DNA technology. Linear DNA amplicons carrying the DNA sequences for Takis/Evvivax's vaccine candidates will be delivered to preclinical animal models via Takis/Evvivax's proprietary electroporation technology. Antigen-specific immune responses aimed at achieving therapeutic effects will be studied.

iCell Gene Therapeutics, Inc. During October 2018, we entered into an exclusive North American licensing agreement and a research services agreement with iCell Gene Therapeutics, Inc. ("iCell") under which iCell licensed to us an anti-CD19 CAR T therapy candidate for non-viral delivery. We intend to utilize our non-viral, plasmid free platform, along with the in-licensed anti-CD19 CAR T therapy to develop, manufacture and commercialize LinCART19, a non-viral, plasmid free anti-CD19 CAR T therapeutic candidate. During April 2019, we announced that LRx had improved expression levels and survival rates of linear DNA constructs delivered without viruses or plasmids to human T cells. In collaboration with Avectas, a cell engineering technology business enabling the manufacture of cell therapies, LRx has achieved a greater than four-fold increase in cell survival and a more than 50% increase in linear gene expression of a model amplicon. Results were presented by Avectas at the Cell & Gene Meeting on the Mediterranean in April 2019, which was attended by more than 50 companies. The Company expects to continue its preclinical research relating to LinCART19 with its partners to increase cellular expression without the use of viral transduction.

The Research Foundation for the State University of New York. During August 2019, in conjunction with the acquisition of the assets of Vitatex, Inc. we entered into an Amended and Restated Exclusive Licensing Agreement with The Research Foundation for the State University of New York (the "RF") for a patent estate relating to the iCTC Technology. Under the terms of the Amended and Restated Exclusive Licensing Agreement, LRx is provided exclusive world-wide rights to the iCTC Technology patent estate that was previously licensed from the RF by Vitatex, Inc.

Customer Concentration

Our revenues earned from sale of products and services for the fiscal year ended September 30, 2019 includes 27%, 26% and 15%, respectively from three customers. These three customers accounted for approximately 83% of our total accounts receivable at September 30, 2019. At September 30, 2019, one customer accounted for 77% of our accounts receivable. Our revenues earned from sale of products and services for the fiscal year ended September 30, 2018 included 24%, 16%, 14% and 11%, respectively from four customers. These four customers accounted for approximately 96% of our total accounts receivable at September 30, 2018. At September 30, 2018, one customer accounted for an aggregate of 80% of our total accounts receivable. Generally, our customers do not have an obligation to make purchases from us and may stop ordering our products and services or may terminate existing orders or contracts at any time with little or no financial penalty. The loss of any of our significant customers, any substantial decline in sales to these customers, or any significant change in the timing or volume of purchases by our customers, could result in lower revenues and could harm our business, financial condition or results of operations.

Competition

The principal markets for our offerings are intensely competitive. We compete with many existing suppliers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing products that are more effective than the products that we have or may develop and may be more successful than us in producing and marketing their existing products. Some of our competitors that operate in the anti-counterfeiting and fraud prevention markets include: 3DTL Inc., AlpVision Sa, Authentix Inc., Brandwatch Technologies, Chromologic LLC, Collectors Universe Inc., DataDot Technology, De La Rue Plc., Digimarc Corp., DNA Technologies, Inc., FractureCode Corporation, Haelixa, ICA Bremen GmbH, Ipsidy Inc., IEHCorporation Informium AG, Eastman Kodak Company, IDEMIA, opSec Security Group plc., MicroTag Temed Ltd., Nanotech Security Corp., Nokomis, Inc., Oritain Global Limited, Prooftag SAS, SafeTraces Inc., Selectamark Security Systems plc, Spectra Systems Corp., SmartWater Technology, Inc., Sun Chemical Corp, TraceTag International, TruTag Technologies Inc., Tailorlux gmbH and YottaMark Inc. Some of our competitors that operate in the drugs, biologics and DNA manufacturing markets include: Intrexon Corp., Aldervron, LLC, Cobra Biologics, Limited, Integrated DNA Technologies, Inc., Ziopharm Oncology, Inc., MaxCyte Inc., Touchlight Genetics Ltd., Novartis AG, Kite Pharma, Inc. and Juno Therapeutics, Inc

Some examples of competing security products include:

- *near field communications chips* (integrated circuit chips that receive and, if authentic, send a correct electric signal back to the reader);
- *optically variable microstructures* (these include holograms, which display images in three dimensions and are generally difficult to reproduce using advanced color photocopiers and printing techniques, along with other devices with similar features);
- *elemental taggants and fluorescence* (elemental taggants are various unique substances that can be used to mark products and other items, and are revealed by techniques such as x-ray fluorescence); and
- *radioactivity and rare molecules* (radioactive substances or rare molecules which are uncommon and readily detected).

We expect competition with our products and services to continue and intensify in the future. We believe competition in our principal markets is primarily driven by:

- product performance, features and liability;
- price;
- timing of product introductions;
- ability to develop, maintain and protect proprietary products and technologies;
- sales and distribution capabilities;
- technical support and service;
- brand loyalty;
- applications support; and
- breadth of product line.

If a competitor develops superior technology or cost-effective alternatives to our products, our business, financial condition and results of operations could be significantly harmed.

Proprietary Rights

We believe that our approximately 125 patents, 44 patent applications, 48 trademark registrations, and 5 trademark applications, and our trade secrets, copyrights and other intellectual property rights are important assets for us. Our patents will expire at various times between 2021 and 2035. The duration of our trademark registrations varies from country to country. However, trademarks are generally valid and may be renewed indefinitely as long as they are in use and/or their registrations are properly maintained.

On May 31, 2017, 3SI granted a non-exclusive license to us to exploit, including the rights to have manufactured and have assembled and offer for sale, sell, market, advertise and distribute nucleic acid tags suitable for use in any product or system covered by one or more valid claims in any unexpired patents worldwide. On September 11, 2015, as part of the Vandalia Asset Acquisition, Marshall University Research Corporation consented to the assignment and transfer of Vandalia's exclusive worldwide right and license under patents to manufacture, use, produce, sell and have sold, market and develop the Triathlon DNA production system or derivatives therefrom to us.

On October 12, 2018, iCell Gene Therapeutics, Inc. granted us an exclusive North America license to make, have made, use, offer to sell, sell and important its anti-CD19 CAR T-cell immuno-oncology therapeutic candidate in the field of non-virally mediated transfection of non-plasmid derived DNA. See "Collaboration and Licensing Agreements."

On August 7, 2019 we entered into an Amended and Restated Exclusive Licensing Agreement with The Research Foundation for the State University of New York (the "RF") for a patent estate relating to the iCTC Technology. Under the terms of the Amended and Restated Exclusive Licensing Agreement, LRx is provided exclusive world-wide rights to the iCTC Technology patent estate that was previously licensed from the RF by Vitatex, Inc. See "Collaboration and Licensing Agreements."

However, there are events that are outside of our control that pose a threat to our intellectual property rights as well as to our products and services. For example, effective intellectual property protection may not be available in every country in which our products and services are distributed. The efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights could harm our business or our ability to compete. Protecting our intellectual property rights is costly and time consuming. Any increase in the unauthorized use of our intellectual property could make it more expensive to do business and harm our operating results. Although we seek to obtain patent protection for our innovations, it is possible we may not be able to protect some of these innovations. Given the costs of obtaining patent protection, we may choose not to protect certain innovations that later turn out to be important. There is always the possibility that the scope of the protection gained from one of our issued patents will be insufficient or deemed invalid or unenforceable. We also seek to maintain certain intellectual property as trade secrets. This secrecy could be compromised by third parties, or intentionally or accidentally by our employees, which would cause us to lose the competitive advantage resulting from these trade secrets.

Litigation regarding patents and other intellectual property rights is extensive in the biotechnology industry. In the event of an intellectual property dispute, we may be forced to litigate. This litigation could involve proceedings instituted by the U.S. Patent and Trademark Office or the International Trade Commission, as well as proceedings brought directly by affected third parties. Intellectual property litigation can be extremely expensive, and these expenses, as well as the consequences should we not prevail, could seriously harm our business. If a third party claims an intellectual property right to technology we use, we might need to discontinue an important product or product line, alter our products and processes, pay license fees or cease our affected business activities. Although we might under these circumstances attempt to obtain a license to this intellectual property, we may not be able to do so on favorable terms, or at all.

Government Approvals of Commercial Products

We do not require any governmental approvals of our currently commercialized products or services, none of which are drug or biologic products subject to government approval.

Government Approvals of Drug and Biologic Products

Some of our products may be incorporated into drug and biologic products which are subject to extensive regulation by FDA and other regulatory agencies in the United States and by comparable authorities in foreign countries. Biologics include a wide range of products such as vaccines, gene therapy, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins or nucleic acids or complex combinations of these substances. They may also be living entities such as cells or tissue. Our products that are incorporated into drugs and biologics will be subject to regulation as described in the next section. Some of our products may be drugs or biologics that are subjected to regulation as described in the following section. In either case, we are unlikely to receive material revenues until the related drug or biologic receives regulatory approval. The FDA and other authorities regulate among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of drug and biologic products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to file a marketing application, to issue Complete Response letter or to not approve pending New Drug Applications ("NDAs") or biologic product license applications ("BLAs"), or to issue warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, litigation, government investigation and criminal prosecution.

Drug and biologic products that must undergo preclinical and clinical evaluation relating to product safety and efficacy before they are approved as commercial therapeutics products. The regulatory authorities having jurisdiction in the countries in which our collaborators and customers intend to market their products may delay or put on hold clinical trials, delay approval of a product or determine that the product is not approvable. The FDA and comparable government authorities having jurisdiction in the countries in which our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance, safety, efficacy or the product is deemed adulterated or misbranded.

Government Regulation of Pharmaceutical and Biologic Products

In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs or BLAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board ("IRB") at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Current Good Clinical Practices ("cGCPs"), requirements to establish the safety and efficacy of the proposed drug or biologic product for each indication;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biologic product is produced to assess compliance with current good manufacturing practice ("GMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with cGCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post-approval studies.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to initiate.

Clinical Trials

Clinical trials involve the administration of the investigational new drug or biologic product to human subjects under the supervision of qualified investigators in accordance with cGCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it initiates at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug or biologic is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The drug or biologic is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

- Phase 3: The drug or biologic is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA or BLA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA or BLA, for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA or BLA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

The FDA also may require submission of a REMS plan to ensure that the benefits of the drug or biologic outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs or BLA within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA or BLA to determine, among other things, whether the drug or biologic is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug or biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with cGCP requirements.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA or BLA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug or biologic's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs or biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There are continuing, annual user fee requirements for any marketed products and the establishments where such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval of a drug or biologic is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs or biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In many foreign countries, drugs and biologics are subject to regulatory requirements in addition to and sometimes different than the U.S. requirements described herein.

Laboratory Developed Tests

The FDA is currently exercising enforcement discretion over the regulation of Laboratory Developed Test ("LDT"), such as our iCTC capture assay. If the FDA were to begin enforcement, our product would potentially be subject to extensive regulation as a medical device under federal law. In order to market a medical device, a company must first receive either FDA clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act or approval of a PMA application from the FDA, unless an exemption applies. The process of obtaining PMA approval is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Following FDA clearance or approval, medical devices are subject to continuing regulatory requirements, including those related to manufacturing, labeling, advertising and promotion, restrictions on sale, distribution and use, and surveillance of safety issues and product complaints.

Clinical Laboratory Improvement Amendments

The Clinical Laboratory Improvement Amendments ("CLIA") is a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Clinical laboratories must be certified under CLIA in order to perform testing on human specimens, unless they fall within an exception to CLIA certification, such as research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients. CLIA certification is also required to be eligible to bill Federal and State healthcare programs, as well as many private third-party payers, for diagnostic testing and services. In addition, proprietary tests must also be recognized as part of an accredited program under CLIA so that they can be offered in a CLIA-certified laboratory.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales and marketing programs for drugs and biologics. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect such operations include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value;

- federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibits anyone from, among other things, knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services that are false or fraudulent;

- provisions of the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- the federal Physician Payments Sunshine Act requirements, under the Patient Protection and Affordable Care Act ("ACA"), which require manufacturers of certain drugs and biologics to track and report to Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value they make to U.S. physicians and teaching hospitals as well as physician ownership and investment interests in the manufacturer.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval for drugs and biologics are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. Sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse laws.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical and biologic products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Coverage and Reimbursement

Sales of our drug and biologic products will depend, in part, on the extent to which such products will be covered by third party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug products or biologics exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The United States government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs or biologics. For example, the ACA contains provisions that may reduce the profitability of drug products or biologics through increased rebates for drugs or biologics reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Adoption of general controls and measures, coupled with the tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceutical drugs or biologics.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs or biologics furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. CMS has proposed to expand Medicaid rebate liability to the territories of the United States as well.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan likely will be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug prices are determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

As noted above, the marketability of any drug or biologic products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. An emphasis on cost containment measures in the United States has increased, and we expect will continue to increase, the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in most foreign countries, the proposed pricing for a drug or biologic must be approved before it may be lawfully marketed. The requirements governing drug and biologic pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Impact of Other Government Regulation

We and our products are subject to regulation by various U.S. federal regulatory agencies such as the Federal Trade Commission and are subject to regulation by the Occupational Safety and Health Administration ("OSHA") concerning employee safety and health matters. Such regulations principally relate to the ingredients, labeling, packaging, advertising and marketing of our products. There are no significant capital expenditures for government regulation matters either planned in the current year or expected in the near future.

Compliance with Environmental Law

We believe that we are in compliance with all applicable environmental law and do not have any material costs of compliance.

Employees

As of September 30, 2019 we had a total of 51 employees, consisting of 3 in management, 14 in research and development, 5 in forensics, 5 in quality assurance and compliance, 3 in finance and accounting, 6 in operations, 7 in sales and marketing, 1 in human resources, 1 in shared services, 5 in information services, and 1 in product development. Expenses related to travel, marketing, salaries, and general overhead will be increased as necessary to support our growth in revenue. Any projected increase in human capital is dependent upon our ability to generate revenues and obtain sources of funding. Since June 2012, we have been working with Insperity Inc. to assist in managing many of our back-end administrative human resources, benefits, and payroll responsibilities. We are an at-will employer and generally do not enter into employment agreements requiring our employees to continue in our employment for any period of time, with the exception of our Chief Executive Officer, Dr. James A. Hayward. The initial term of Dr. Hayward's current employment agreement is July 1, 2016 through June 30, 2017, and this employment agreement automatically renews for one-year periods subject to ninety days' prior notice of non-renewal by Dr. Hayward or us in accordance with the terms of the employment agreement. As of June 30, 2019, the employment contract automatically renewed for an additional year.

Available Information

We are subject to the informational requirements of the Exchange Act, which requires us to file our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to such reports and other information with the SEC. This information is available at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. Because we file documents electronically with the SEC, you may also obtain this information by visiting the SEC's website at: *www.sec.gov*. Our website is located at: *www.adnas.com*. The information on, or that may be accessed through, our website is not incorporated by reference into and should not be considered a part of this report.

ITEM 1A. RISK FACTORS.

Because of the following factors, as well as other variables affecting our operating results and financial condition, past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. In addition to the factors discussed elsewhere in this report and our other reports and documents filed with the SEC, the following are important factors that could cause actual results or events to differ materially from those contained in any forward-looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we may currently deem immaterial also may impair our business, financial condition, operating results and/or stock price. If any of the following risks or such other risks actually occurs, our business, financial condition, operating results and/or stock price could be harmed. In the following factors, "volatility in our share price", "adverse impact on the price (or value) of our shares", "decline in the price of our common stock" and similar terms also refer to our warrants and shares to be received upon exercise of our warrants.

Risks Relating to Our Business:

We have not produced significant revenues. This makes it difficult to evaluate our future prospects and increases the risk that we will not be successful.

Our operations since inception have produced limited revenues, and may not produce significant revenues in the near term, or at all, which may harm our ability to obtain additional financing and may require us to reduce or discontinue our operations. If we create significant revenues in the future, we expect to derive most of such revenues from the sale of supply chain security and product authentication solutions. You must consider our business and prospects in light of the risks and difficulties we will encounter as a company operating in a rapidly evolving industry. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results, and financial condition.

We have a history of net losses which may continue, and which may harm our ability to obtain financing and continue our operations.

We incurred net losses of $8.6 million and $11.7 million for the fiscal years ended September 30, 2019 and 2018, respectively. These net losses have principally been the result of the various costs associated with our selling, general and administrative and research and development expenses as we expanded operations, acquired, developed and validated technologies and expanded marketing activities. Our operations are subject to the risks and competition inherent in a company that moved from the development stage to an operating company. We may not generate sufficient revenues from operations to achieve or sustain profitability on a quarterly, annual or any other basis in the future. Our revenues and profits, if any, will depend upon various factors, including whether our existing products and services or any new products and services we develop will achieve market acceptance. If we continue to incur losses, then our accumulated deficit will continue to increase which may significantly impair our ability to obtain additional financing. As a result, our business, results of operations and financial condition would be significantly harmed, and we may be required to reduce or terminate our operations.

If we are unable to obtain additional financing our business operations may be harmed or discontinued.

Our continuation as a going concern is dependent upon our future revenues and our ability to commercialize more products, obtain additional capital and attain profitable operations. We will require additional funds to complete the continued development and commercialization of our products, product manufacturing, and to fund expected additional losses from operations, until revenues are sufficient to cover our operating expenses. If we are unsuccessful in obtaining any necessary additional financing, we will most likely be forced to reduce or terminate our operations.

Our opportunities in pharmaceuticals and biologics will require substantial additional funding. We may not be successful in our efforts to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify, finance and develop product candidates, our commercial opportunities in pharmaceuticals and biologics may be limited.

We have no pharmaceutical or biologic products approved for commercial sale and have not generated any revenue from pharmaceutical or biologic product sales. Identifying, developing, obtaining regulatory approval and commercializing pharmaceutical and biologic product candidates will require substantial additional funding beyond our current available resources and is prone to the risks of failure inherent in drug or biologic development. Developing product candidates is expensive, and we expect to spend substantial amounts as we fund our early-stage research projects, engage in preclinical development of early-stage programs and, in particular, advance program candidates through preclinical development and clinical trials.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

Investment in pharmaceutical and biologic product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any product candidates through the development process or, if approved, successfully commercialize any product candidates.

Even if we are able to generate revenue from the sale of any approved pharmaceutical and biologic products, we may not become profitable and may need to obtain additional funding to continue operations. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations, and cause a decline in the value of our common stock, all or any of which may adversely affect our viability.

Our operating results could be adversely affected by a reduction in business with our significant customers.

Our revenue earned from the sale of products and services for the fiscal year ended September 30, 2019 included an aggregate of 68% of our total revenues from three customers. These three customers accounted for approximately 82% of our total accounts receivable at September 30, 2019. At September 30, 2019, one customer accounted for an aggregate of 77% of our total accounts receivable. Our revenues earned from sale of products and services for the fiscal year ended September 30, 2018 included an aggregate of 65% from four customers of our total revenues. These four customers accounted for approximately 96% of our total accounts receivable at September 30, 2018. At September 30, 2018, one customer accounted for 80% of our total accounts receivable. Generally, our customers do not have an obligation to make purchases from us and may stop ordering our products and services or may terminate existing orders or contracts at any time with little or no financial penalty. The loss of any of our significant customers, any substantial decline in sales to these customers, or any significant change in the timing or volume of purchases by our customers could result in lower revenues and could harm our business, financial condition or results of operations.

If our existing products and services are not accepted by potential customers or if we fail to introduce new products and services, our business, results of operations and financial condition will be harmed.

There has been limited market acceptance of our DNA based technology, encapsulation, embedment and authentication products and services to date. Some of the factors that will affect whether we achieve market acceptance of our solutions include:

- availability, quality and price relative to competitive solutions;
- customers' opinions of the solutions' utility;
- ease of use;
- consistency with prior practices;
- scientists' opinions of the solutions' usefulness; and
- general trends in anti-counterfeit and security solutions' research.

Dependence on channel partners exposes us to certain risks that could harm our business, results of operations and financial condition.

Our future growth will depend to a material extent on the successful advocacy of our technology by channel partners to their members and customers, and implementation of our technology in solutions propagated by channel partners and provided by third parties. Our business has relied on the success of business partners. Our continuing success is largely dependent on a new generation of business partners involved in our tagging technology.

If our channel partners are not successful in advocating and deploying our technology, we may not be able to achieve and sustain profitable operations. If other business partners who include our technology in their products or otherwise license our intellectual property for use in their products cease to do so, or we fail to obtain other partners who will incorporate, embed, integrate or bundle our technology, or these partners are unsuccessful in their efforts, expanding deployment of our technology and increasing revenues will be adversely affected. Consequently, our ability to increase revenue could be adversely affected and we may suffer other adverse effects to our business. In addition, if our technology does not perform according to market expectations, our future sales would suffer as customers seek and employ alternative technologies.

Many of our business endeavors can be impeded or frustrated by larger, more influential companies or by standard-setting bodies or institutions downplaying, minimizing or rejecting the value or use of our technology. A negative position by such companies, bodies or institutions, could result in obstacles for us that we would be incapable of overcoming and may block or impede the adoption of our technology. In addition, potential customers may delay or reject initiatives that relate to deployment of our technology. Such a development would make the achievement of our business objectives in this market difficult or impossible.

The expenses or losses associated with lack of widespread market acceptance of our solutions may harm our business, operating results and financial condition.

Rapid technological changes and frequent new product introductions are typical in the markets we serve. Our future success may depend in part on continuous, timely development and introduction of new products that address evolving market requirements. We believe successful new product introductions may provide a significant competitive advantage because customers invest their time in selecting and learning to use new products, and once invested in the new technology, are often reluctant to switch products. To the extent we fail to introduce new and innovative products, we may lose any market share we then have to our competitors, which will be difficult or impossible to regain. Any inability, for technological or other reasons, to successfully develop and introduce new products could reduce our growth rate or damage our business. We may experience delays in the development and introduction of products. We may not keep pace with the rapid rate of change in anti-counterfeiting and security products' research, and any new products acquired or developed by us may not meet the requirements of the marketplace or achieve market acceptance.

We need to expand our sales, marketing and support organizations and our distribution arrangements to increase market acceptance of our products and services.

We currently have a limited number of sales, marketing, customer service and support personnel and may need to increase our staff to generate a greater volume of sales and to support any new customers or the expanding needs of existing customers. The employment market for sales, marketing, customer service and support personnel in our industry is very competitive, and we may not be able to hire the kind and number of sales, marketing, customer service and support personnel we are targeting. Our inability to hire qualified sales, marketing, customer service and support personnel may harm our business, operating results and financial condition. While we have entered into a limited number of agreements with distributors, we may not be able to sufficiently build out a distribution network or enter into arrangements with qualified distributors on acceptable terms or at all. If we are not able to develop greater distribution capacity, we may not be able to generate sufficient revenue to support our operations.

If we are unable to continue to retain the services of Dr. Hayward, we may not be able to continue our operations.

Our success depends to a significant extent upon the continued service of Dr. James A. Hayward, our CEO. On July 28, 2016, we entered into an employment agreement with Dr. Hayward. The initial term was from July 1, 2016 through June 30, 2017, with automatic one-year renewal periods. As of June 30, 2019, the employment contract automatically renewed for an additional year. Loss of the services of Dr. Hayward could significantly harm our business, results of operations and financial condition. We do not maintain key-person insurance on the life of Dr. Hayward.

We may have conflicts of interest with our affiliates and related parties, and in the past we have engaged in transactions and entered into agreements with affiliates that were not negotiated at arms' length.

We have engaged, and may in the future engage, in transactions with affiliates and other related parties. These transactions may not have been, and may not be, on terms as favorable to us as they could have been if obtained from non-affiliated persons. While an effort has been made, and will continue to be made, to enter into transactions with affiliated persons and other related parties at rates and on terms as favorable as would be charged by others, there will always be an inherent conflict of interest between our interests and those of our affiliates and related parties. In August 2018 and November 2018, we issued an aggregate of $2.2 million in principal amount of secured convertible notes, a majority of which were owned by Dr. James A. Hayward, our CEO. Dr. Hayward and other directors, officers, and affiliates of the Company converted substantial portions of such August 2018 Notes and November 2018 Notes into common stock of the Company in September 2019. The Company may be adversely impacted if any related party agreement or transaction is made on unfavorable terms.

The markets for our supply chain security and product authentication solutions are very competitive, and we may be unable to continue to compete effectively in these industries in the future.

The principal markets for our offerings are intensely competitive. We compete with many existing suppliers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing products that are more effective than the products that we have or may develop and may be more successful than us in producing and marketing their existing products. Some of our competitors that operate in the anti-counterfeiting and fraud prevention markets include: 3DTL Inc., AlpVision Sa, Authentix Inc., Brandwatch Technologies, Chromologic LLC, Collectors Universe Inc., DataDot Technology, De La Rue Plc., Digimarc Corp., DNA Technologies, Inc., FractureCode Corporation, Haelixa, ICA Bremen GmbH, Ipsidy Inc., IEHCorporationInformium AG, Eastman Kodak Company, IDEMIA, opSec Security Group plc., MicroTag Temed Ltd., Nanotech Security Corp., Nokomis, Inc., Oritain Global Limited, Prooftag SAS, SafeTraces Inc., Selectamark Security Systems plc, Spectra Systems Corp., SmartWater Technology, Inc., Sun Chemical Corp, TraceTag International, TruTag Technologies Inc., Tailorlux gmbH and YottaMark Inc.

We expect this competition to continue and intensify in the future. Competition in our markets is primarily driven by:

- product performance, features and liability;
- price;
- timing of product introductions;
- ability to develop, maintain and protect proprietary products and technologies;
- sales and distribution capabilities;
- technical support and service;
- brand loyalty;
- applications support; and
- breadth of product line.

If a competitor develops superior technology or cost-effective alternatives to our products, our business, financial condition and results of operations could be significantly harmed.

Revenues from our customer contracts with respect to cotton will be seasonal and may also be subject to weather conditions and other factors beyond our control, which may cause our operating results to fluctuate significantly quarterly and annually.

A significant proportion of our revenues is expected to be derived from customer contracts for tagging, authentications and other services related to cotton. The cotton ginning season in the United States takes place between September and March each year. Therefore, revenues from our customer contracts relating to cotton may be seasonal and recognized primarily during our first and fourth fiscal quarters, which may cause our operating results to fluctuate significantly quarterly and annually. Additionally, weather and climatic conditions, natural disasters and other factors beyond our control also affect the production and sale of cotton and other agricultural commodities to which our customer contracts may relate, as well as our customers' or prospective customers' decisions regarding purchases of our products and services, and may cause our operating results to fluctuate significantly quarterly and annually. The seasonal fluctuations in operating results described above may cause a decline in the price of our common stock.

Fluctuations in quarterly results may cause a decline in the price of our common stock.

Our revenues and profitability are difficult to predict due to the nature of the markets in which we compete, fluctuating user demand, the uncertainty of current and future global economic conditions, and for many other reasons, including that our operating results are highly dependent on the volume and timing of orders received during a quarter, which are difficult to forecast. Customers generally order on an as-needed basis and we typically do not obtain firm, long-term purchase commitments from our customers. The quarterly fluctuations in operating results described above may cause a decline in the price of our common stock.

Shifting enforcement priorities of U.S. federal laws relating to cannabis may create uncertainties for our business.

The Company is currently developing supply chain solutions for the cannabis industry. These solutions are intended to verify the authenticity, origin and provenance of cannabis. Cannabis is a Schedule I substance as defined under U.S. federal law, and its possession and use is generally not permitted under U.S. federal law, although a number of individual states have enacted state laws to authorize possession, sale and use of cannabis for medical purposes, and in some states for recreational purposes. Our solutions will be utilized in those U.S. states where cannabis possession, sale and/or use is legal under state law. While our cannabis supply chain solutions are distinct from cannabis itself, our cannabis supply chain business and related revenue may nevertheless be adversely impacted by such laws at the federal and/or state level in the United States, or potentially in foreign jurisdictions. It is possible that such laws may result in our cannabis supply chain business having no revenues or may subject the Company to increased risk of litigation.

Pharmaceutical and biologic-related revenue is generally dependent on regulatory approval, oversight and compliance.

All of our pharmaceutical and biologic product candidates will require significant preclinical and clinical development before we can seek regulatory approval for them and launch a product commercially. The sale and use of our products and services in the pharmaceutical and biologic markets will generally be subject to regulatory approval and oversight, potentially including approval and/or oversight in various foreign jurisdictions. In addition, our pharmaceutical and biologic products and services may be incorporated into products that cannot be marketed in the United States or in many other jurisdictions without approval by the Food and Drug Administration ("FDA") or comparable agencies of other countries or regions. Obtaining such regulatory approvals is costly, time-consuming, uncertain, and subject to unanticipated delays. When, if ever, such approvals will be obtained is unknown. Our revenue in the pharmaceutical and biologic markets is highly dependent upon obtaining such approval.

Federal agencies, including the FDA and Federal Trade Commission ("FTC"), as well as state, local, and foreign authorities, also exercise ongoing review and control of the manufacturing, packaging, labeling, advertising, sale, distribution, and monitoring of pharmaceutical and biologic products. If our pharmaceutical or biologic product candidates or pharmaceutical or biologic products incorporating our products are ever approved, failure to comply with any of these regulations or other requirements could also have an adverse effect on our revenue in the pharmaceutical and biologic markets.

Pharmaceutical and biologic-related revenue will be highly dependent on our collaborators' and customers' success in obtaining regulatory approval and commercializing their products.

Some of our products in the pharmaceutical and biologic market will be incorporated into products that are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. In the United States, to obtain approval from the FDA to market any future pharmaceutical or biologic product that incorporates our technology, our collaborators or customers will be required to submit a New Drug Application ("NDA") or Biologics Licensing Application ("BLA"). Ordinarily, the FDA requires a company to support an NDA or BLA with substantial evidence of the product candidate's safety and efficacy in treating the targeted indication based on data derived from adequate and well-controlled clinical trials, including Phase III safety and efficacy trials conducted in patients with the disease or condition being targeted. The process of obtaining such regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process may cause delays in the approval or rejection of an application. There is no guarantee that our collaborators and customers will ever be successful in obtaining regulatory approval for any product that incorporates our products or technology. Even if regulatory approval is received, the manufacturing processes, post approval clinical data, labeling, advertising and promotional activities for any such product will be subject to continual requirements of and review by the FDA and other regulatory bodies. Our business may be materially harmed by our collaborators' and customers' inability to obtain or maintain regulatory approvals for their products.

In addition, we will be dependent on, and have no control over, consumer demand for the products into which our products are incorporated. Consumer demand for our collaborators' and customers' products could be adversely affected by, among other things, delays in health regulatory approval, the loss of patent and other intellectual property rights protection, the emergence of competing products, including generic drugs or biosimilars, the degree to which private and government drug plans subsidize payment for a particular product and changes in the marketing strategies for such products. The healthcare industry has changed significantly over time, and we expect the industry to continue to evolve. Some of these changes may have a material adverse effect on our collaborators and customers and thus may have a material adverse effect on our business. If the products into which our products are incorporated do not gain market acceptance, our revenues and profitability may be adversely affected.

Pharmaceutical and biologic products are highly complex, and if we or our collaborators and customers are unable to provide quality and timely offerings to our respective customers, our business could suffer.

The process of manufacturing pharmaceutical and biologics and their components is complex, highly-regulated and subject to multiple risks.

Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions.

Our ability to generate revenue in the pharmaceutical and biologic market depends on our ability to manufacture products that meet exacting quality and safety standards. If we are unable to manufacture these products to the required levels, it could have an adverse effect on our business, financial condition, and results of operations and may subject us to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture or distribution, restrictions on our operations, or civil sanctions, including monetary sanctions and criminal actions. In addition, we could be subject to costly litigation, including claims from our collaborators and customers for reimbursement for the cost of our products or other related losses, the cost of which could be significant.

Our business also depends on the ability of our collaborators and customers to manufacture the pharmaceutical or biologic products that incorporate our products. If the FDA determines that our collaborators and customers are not in compliance with FDA laws and regulations, including those governing Current Good Manufacturing Practice ("cGMP") regulations, the FDA may deny NDA or BLA approval until the deficiencies are corrected. Even if our collaborators or customers obtain regulatory approval for any of their product candidates, there is no assurance that they will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our collaborators or customers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Pharmaceutical and biologic-related revenue will be dependent on our collaborators' and customers' demand for our manufacturing services.

The amount of customer spending on biologic development and manufacturing will have an impact on our sales and profitability in the pharmaceutical and biologic market. Our collaborators and customers determine the amounts that they will spend based upon, among other things, available resources, access to capital, and their need to develop new products, which, in turn, are dependent upon a number of factors, including their competitors' research, development and product initiatives and the anticipated market uptake, and clinical and reimbursement scenarios for specific products and therapeutic areas. Consolidation in the pharmaceutical and biologic industry may impact such spending as customers integrate acquired operations, including R&D departments and manufacturing operations. Any reduction in spending on pharmaceutical and biotechnology development and related services as a result of these and other factors could have a material adverse effect on our business, results of operations and financial condition.

The markets for our drug and biologic candidates and linear DNA are very competitive, and we may be unable to continue to compete effectively in these industries in the future.

The principal markets for our drug and biologic candidates and linear DNA are intensely competitive. We compete with many existing suppliers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing products that are more effective than the product candidates that we have or may develop and may be more successful than us in producing and marketing their existing products. Some of our competitors that operate in the drugs, biologics and DNA manufacturing markets include: Intrexon Corp., Aldervron, LLC, Cobra Biologics, Limited, Integrated DNA Technologies, Inc., Ziopharm Oncology, Inc., MaxCyte Inc., Touchlight Genetics Ltd., Novartis AG, Kite Pharma, Inc. and Juno Therapeutics, Inc.

We expect this competition to continue and intensify in the future. Our competitors also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize drug and biologic candidates or linear DNA that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drug and biologic candidates and linear DNA that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, drug and biologic candidates and linear DNA developed by our competitors may render our potential drug and biologic candidates and linear DNA uneconomical or obsolete, and we may not be successful in marketing any drug and biologic candidates and linear DNA we may develop against competitors.

If any of these risks occur, our business, financial condition and results of operations could be significantly harmed.

Our research and development efforts for new products may be unsuccessful.

We incur research and development expenses to develop new products and technologies in an effort to maintain our competitive position in a market characterized by rapid rates of technological advancement. Our research and development efforts are subject to unanticipated delays, expenses and technical problems. There can be no assurance that any of these products or technologies will be successfully developed or that, if developed, will be commercially successful. In the event that we are unable to develop commercialized products from our research and development efforts or we are unable or unwilling to allocate amounts beyond our currently anticipated research and development investment, we could lose our entire investment in these new products and technologies. Any failure to translate research and development expenditures into successful new product introduction could have an adverse effect on our business.

In addition, research, development, and commercialization of pharmaceutical and biologic products is inherently risky. We cannot give any assurance that any of our pharmaceutical and biologic product candidates will receive regulatory approval, which is necessary before they can be commercialized.

Other risks include:

- Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.
- We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.
- If the FDA rejects an Investigational New Drug Application ("IND") submitted by us or places us on clinical hold, we will not be able to commence a Phase 1 clinical trial in the U.S., which would likely have a material adverse effect on us.
- We have never dosed any of our product candidates in humans. Our clinical trials may reveal significant adverse events, toxicities or other side effects not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- Positive results from early preclinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any future clinical trials of our product candidates. If we cannot show positive results or replicate any positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.
- We may not be successful in our efforts to create a pipeline of product candidates or to develop commercially successful products. If we fail to successfully identify and develop additional product candidates, our commercial opportunity may be limited.
- If we receive authorization to conduct our clinical trials, we may encounter substantial delays in our clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.
- We may encounter difficulties enrolling patients in our clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.
- Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay or limit the scope of regulatory approval and commercialization.
- Clinical development is a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development. If we are unable to design, conduct and complete our clinical trials successfully, our product candidates will not be able to receive regulatory approval.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced or more effective than ours, which may negatively impact our ability to successfully market or commercialize any product candidates we may develop and ultimately harm our financial condition.
- The manufacture of our product candidates is complex and difficulties may be encountered in production. If such difficulties are encountered or failure to meet regulatory standards occurs, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.
- Even if any product candidates we develop receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors, and others in the medical community necessary for commercial success.
- Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third party reimbursement practices, or healthcare reform initiatives, which would harm our business.

Failure to license new technologies could impair sales of our existing products or any new product development we undertake in the future.

To generate broad product lines, it is advantageous to sometimes license technologies from third parties rather than depend exclusively on the development efforts of our own employees. As a result, we believe our ability to license new technologies from third parties may be important to our ability to offer new products. In addition, from time to time we are notified of, or become aware of patents held by third parties that are related to technologies we are selling or may sell in the future. After a review of these patents, we may decide to seek a license for these technologies from these third parties. There can be no assurance that we will be able to successfully identify new technologies developed by others. Even if we are able to identify new technologies of interest, we may not be able to negotiate a license on favorable terms, or at all.

Our failure to manage our growth in operations and acquisitions of new product lines and new businesses could harm our business.

The recent growth in our operations could place a significant strain on our current management resources. To manage such growth, we may need to improve our:

- operations and financial systems;
- procedures and controls; and
- training and management of our employees.

If we explore or engage in future business combinations or other transactions, we may be subject to various uncertainties and risks.

From time-to-time, unrelated third-parties may approach the Company about potential transactions, including business combinations. As such, to date, we have not entered into any agreements related to any business combination. While we may explore such opportunities when they arise, we could not pursue any proposed business combination or other transaction unless our board of directors first has determined that doing so would be in our and our stockholders' interest. There can be no assurance that we will negotiate acceptable terms, enter into binding agreements or successfully consummate any business combination or other transaction with any third party.

We cannot currently predict the effects a future, potential business combination or other transaction would have on holders of our common stock, or warrants, or any of our other securities. There are various uncertainties and risks relating to our evaluation and negotiation of possible business combination or other transactions, our ability to consummate such transactions and the consummation of such transactions, including:

- evaluation and negotiation of a proposed transaction may distract management from focusing our time and resources on execution of our operating plan, which could have a material adverse effect on our operating results and business;
- the process of evaluating proposed transactions may be time consuming and expensive and may result in the loss of business opportunities;
- perceived uncertainties as to our future direction may result in increased difficulties in retaining key employees and recruiting new employees, particularly senior management;
- even if our board of directors negotiates a definitive agreement, successful integration or execution of a business combination or other transaction will be subject to additional risks;
- during the period in which we are considering a transaction, the market price of our common stock could be highly volatile;
- a failure to complete a transaction could result in a negative perception by our investors generally and could cause a decline in the market price of our common stock, as well as lead to greater volatility in the market price of our common stock, all of which could adversely affect our ability to access the equity and financial markets, as well as our ability to explore and enter into different strategic alternatives;
- expected benefits may not be successfully achieved;
- such transactions may increase our operating expenses and cash requirements, cause us to assume or incur indebtedness or contingent liabilities, make it difficult to retain management and key personnel; and
- dilution of our existing stockholders if such transaction involves our issuing dilutive securities.

A percentage of our sales occur outside of the U.S. As a result, we are subject to the economic, political, regulatory, legal, operational and other risks of international operations, which could adversely impact our businesses in many ways.

For fiscal 2019 and 2018, 23% and 45%, respectively, of our revenue was from customers located outside of the U.S. We believe that the revenue from the sale of our products and services outside the U.S. will grow in the near future. We intend to expand our international operations to the extent that suitable opportunities become available. Our foreign operations and sales could be adversely affected as a result of:

- nationalization of private enterprises and assets;
- political or economic instability in certain countries and regions;
- differences in foreign laws, including increased difficulties in protecting intellectual property and uncertainty in enforcement of contract rights;
- the possibility that foreign governments may adopt regulations or take other actions that could directly or indirectly harm our business and growth strategy;
- credit risks;
- currency fluctuations;
- tariff and tax increases;
- export and import restrictions and restrictive regulations of foreign governments;
- shipping products during times of crisis or wars; and
- other risks inherent in foreign operations.

In addition, as a U.S. company, we are required to comply with the economic sanctions and embargo programs administered by Office of Foreign Assets Control and similar multi-national bodies and governmental agencies worldwide, and the Foreign Corrupt Practices Act ("FCPA"). A violation of a sanction or embargo program or of the FCPA or similar laws prohibiting certain payments to governmental officials, such as the U.K. Bribery Act, could subject us, and individual employees, to a regulatory enforcement action as well as significant civil and criminal penalties which could adversely impact our business and operations.

Failure to attract and retain qualified scientific, production and managerial personnel could harm our business.

Recruiting and retaining qualified scientific and production personnel to perform and manage prototype, sample, and product manufacturing and business development personnel to conduct business development are critical to our success. In addition, our desired growth and expansion into areas and activities requiring additional expertise, such as clinical testing, government approvals, production, sales and marketing will require the addition of new management personnel and the development of additional expertise by existing management personnel. Because our industry is very competitive, we face significant challenges in attracting and retaining a qualified personnel base. Although we believe we have been, and will continue to be, able to attract and retain these personnel, we cannot assure you that we will continue to be able to successfully attract qualified personnel in the future. The failure to attract and retain these personnel or, alternatively, to develop this expertise internally would harm our business since our ability to conduct business development and manufacturing would be reduced or eliminated, resulting in lower revenues. We generally do not enter into employment agreements requiring our employees to continue in our employment for any period of time, with the exception of Dr. James A. Hayward, our CEO. See "If we are unable to continue to retain the services of Dr. James A. Hayward, we may not be able to continue our operations" above.

Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand.

Our patents, trademarks, trade secrets, copyrights and all of our other intellectual property rights are important assets for us. There are events that are outside of our control that pose a threat to our intellectual property rights as well as to our products and services. For example, effective intellectual property protection may not be available in every country in which our products and services are distributed. The efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights could harm our business or our ability to compete. Protecting our intellectual property rights is costly and time consuming. Any increase in the unauthorized use of our intellectual property could make it more expensive to do business and harm our operating results. Although we seek to obtain patent protection for our innovations, it is possible we may not be able to protect some of these innovations. Given the costs of obtaining patent protection, we may choose not to protect certain innovations that later turn out to be important. There is always the possibility that the scope of the protection gained from one of our issued patents will be insufficient or deemed invalid or unenforceable. We also seek to maintain certain intellectual property as trade secrets. The secrecy could be compromised by third parties, or intentionally or accidentally by our employees, which would cause us to lose the competitive advantage resulting from these trade secrets.

Intellectual property litigation could harm our business, financial condition and results of operations.

Litigation regarding patents and other intellectual property rights is extensive in the drug and biotechnology industry. In the event of an intellectual property dispute, we may be forced to litigate. This litigation could involve proceedings instituted by the U.S. Patent and Trademark Office or the International Trade Commission, as well as proceedings brought directly by affected third parties. Intellectual property litigation can be extremely expensive, and these expenses, as well as the consequences should we not prevail, could seriously harm our business.

If a third party claims an intellectual property right to technology we use, we might need to discontinue an important product or product line, alter our products and processes, pay license fees or cease our affected business activities. Although we might under these circumstances attempt to obtain a license to this intellectual property, we may not be able to do so on favorable terms, or at all. Furthermore, a third party may claim that we are using inventions covered by 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. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. A court may decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, a court may order us to pay the other party damages for having violated the other party's patents. The drug and 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 patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our or our licensor's issued patents or pending applications or that we or our licensors were the first to invent the technology. During the ordinary course of our business, we do not conduct "prior art" searches before filing a patent application. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our or our licensors' patent applications and could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Accidents related to hazardous materials could adversely affect our business.

Some of our operations require the controlled use of hazardous materials for chemical reactions and synthesis. These materials are common to molecular/biological/chemical laboratories and require no special handling or regulation. Although we believe our safety procedures comply with the standards prescribed by federal, state, local and foreign regulations, the risk of accidental contamination of property or injury to individuals from these materials cannot be completely eliminated. In the event of an accident, we could be liable for any damages that result, which could seriously damage our business and results of operations.

Potential product liability claims could affect our earnings and financial condition.

We face a potential risk of liability claims based on our products and services. Though we have product liability insurance coverage which we believe is adequate, we may not be able to maintain this insurance at reasonable cost and on reasonable terms. We also cannot assure that this insurance will be adequate to protect us against a product liability claim, should one arise. In the event that a product liability claim is successfully brought against us, it could result in a significant decrease in our liquidity or assets, which could result in the reduction or termination of our business. A successful product liability claim or series of claims brought against us could cause our stock price to decline, and, if judgments exceed our insurance coverage, could adversely affect our results of operations, prospects, and business. Product liability claims may result in impairment of our business reputation and other losses.

Litigation generally could affect our financial condition and results of operations.

We generally may be subject to claims made by and required to respond to litigation brought by customers, former employees, former officers and directors, former distributors and sales representatives, former consultants and vendors and service providers. We have faced such claims and litigation in the past and we cannot assure you that we will not be subject to claims in the future. In the event that a claim is successfully brought against us, considering our lack of material revenue and the losses our business has incurred for the period from our inception to June 30, 2019, this could result in a significant decrease in our liquidity or assets, which could result in the reduction or termination of our business.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, cyber-attacks or other vulnerabilities in our computer systems, terrorism, water shortages, tsunamis, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, political or economic instability, and other natural or manmade disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our revenue and financial condition and increase our costs and expenses.

General economic conditions may adversely affect our business, operating results and financial condition.

A general weakening or decline in the global economy or a period of economic slowdown may have serious negative consequences for our business and operating results. Since many of our customers incorporate our products into a variety of consumer goods, the demand for our products is subject to worldwide economic conditions and their impact on levels of consumer spending. Some of the factors affecting consumer spending include general economic conditions, unemployment, consumer debt, reductions in net worth, residential real estate and mortgage markets, taxation, energy prices, interest rates, consumer confidence and other macroeconomic factors. During periods of economic weakness or uncertainty, demand for consumer goods incorporating our products may weaken, and current or potential customers may defer purchases of our products.

A cybersecurity incident and other technology disruptions could negatively affect our business and our relationships with customers.

We use technology in substantially all aspects of our business operations. The widespread use of technology, including mobile devices, cloud computing, and the internet, give rise to cybersecurity risks, including security breach, espionage, system disruption, theft and inadvertent release of information. Our business involves the storage and transmission of numerous classes of sensitive and/or confidential information and intellectual property, including information relating to customers and suppliers, private information about employees, and financial and strategic information about us and our business partners. If we fail to effectively assess and identify cybersecurity risks associated with the use of technology in our business operations, we may become increasingly vulnerable to such risks. Additionally, while we have implemented measures to prevent security breaches and cyber incidents, our preventative measures and incident response efforts may not be entirely effective. The theft, destruction, loss, misappropriation, or release of sensitive and/or confidential information or intellectual property, or interference with our information technology systems or the technology systems of third parties on which we rely, could result in business disruption, negative publicity, brand damage, violation of privacy laws, loss of customers, potential liability and competitive disadvantage.

Risks Related to Our Reverse Stock Split:

We effected a reverse stock split on Friday, November 1, 2019 which may adversely impact the market price of our common stock.

On October 31, 2019, our stockholders approved a reverse stock split of our outstanding common stock at a ratio in the range from one-for-fifteen to one-for-fifty shares. Subsequently, on October 31, 2019, our board of directors approved a ratio of one-for-forty shares, which was effected on November 1, 2019. The effect of the reverse stock split upon the market price of our common stock cannot be predicted with certainty and there is no assurance that our common stock will trade at a price consistent with such reverse stock split. Accordingly, it is possible that the market price of our common stock following the reverse stock split will decline, possibly more than would occur in the absence of a reverse stock split.

The reverse stock split may decrease the liquidity of the shares of our common stock and the resulting market price of our common stock may not attract or satisfy the investing requirements of new investors, including institutional investors.

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares outstanding following the reverse stock split. Additionally, the reverse stock split may increase the number of shareholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such shareholders to experience an increase in the cost of selling their shares and greater difficulty affecting such sales. Moreover, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors, and there can be no assurance that the market price of our common stock will satisfy the investing requirements of these investors. Consequently, the trading liquidity of our common stock may not necessarily improve as a result of the reverse stock split.

The effective increase in the number of shares of our common stock available for issuance as a result of our reverse stock split could result in further dilution to our existing stockholders and have anti-takeover implications.

The reverse stock split alone had no effect on our authorized capital stock, and the total number of authorized shares remains the same as before the reverse stock split. The reverse stock split of our issued and outstanding shares was effected, increasing the number of shares of our common stock (or securities convertible or exchangeable for our common stock) available for issuance. The additional available shares are available for issuance from time to time at the discretion of the Company's board of directors when opportunities arise, without further stockholder action or the related delays and expenses, except as may be required for a particular transaction by law, the rules of any exchange on which our securities may then be listed, or other agreements or restrictions (including rights of first refusal, pursuant to the terms of certain of our outstanding secured convertible notes). Any issuance of additional shares of our common stock would increase the number of outstanding shares of our common stock and (unless such issuance was pro-rata among existing stockholders) the percentage ownership of existing stockholders would be diluted accordingly. In addition, any such issuance of additional shares of our common stock could have the effect of diluting the earnings per share and book value per share of outstanding shares of our common stock.

Additionally, the effective increase in the number of authorized shares could, under certain circumstances, have anti-takeover implications. For example, the additional shares of common stock that have become available for issuance could be used by us to oppose a hostile takeover attempt or to delay or prevent changes in control or our management. Although our reverse stock split is prompted by other considerations and not by the threat of any hostile takeover attempt, stockholders should be aware that our reverse stock split could facilitate future efforts by us to deter or prevent changes in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices.

Risks Related to Regulatory Approval of Our Pharmaceutical and Biotherapeutic Product Candidates and Other Legal Compliance Matters

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for, or obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Applications for our product candidates could fail to receive regulatory approval for a variety of reasons. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects.

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences.

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by regulatory authorities. Side effects related to a drug or biologic could affect patient recruitment, the ability of enrolled patients to complete the study, and/or result in potential product liability claims.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result. Regulatory authorities may withdraw approvals of such product or impose restrictions on distribution. They may require additional warnings or contraindications on the product label that could diminish the usage or otherwise limit the commercial success of the product. We may be required to change the way the product is administered, conduct additional clinical trials or post-approval studies. We may be forced to suspend marketing of the product or required to create a Risk Evaluation and Mitigation Strategy ("REMS"). In addition, our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. There could be significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Failure to comply with the regulatory requirements in international markets or failure to receive applicable marketing approvals could reduce our target market and harm our ability to realize the full market potential of our product candidates.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to extensive regulatory scrutiny.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Ongoing regulatory requirements include ensuring that quality control and manufacturing and production procedures conform to cGMP regulations, and we will be subject to continual review and inspections to assess compliance with cGMP regulations and adherence to commitments made in any regulatory filings. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a REMS), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug or biologic safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including, but not limited to, requiring withdrawal or recall of the product from the market, imposing civil or criminal penalties, and imposing restrictions on our operations. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

If the U.S. Food and Drug Administration were to begin to enforce regulation of Laboratory Developed Tests, we could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.

As a LDT, our iCTC capture assay is currently subject to enforcement discretion by the FDA. In October 2014, the FDA issued two draft guidance documents: "Framework for Regulatory Oversight of Laboratory Developed Tests," which provides an overview of how the FDA would regulate LDTs through a risk-based approach, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests", which provides guidance on how the FDA intends to collect information on existing LDTs, including adverse event reports. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers will be subject to medical device registration, listing, and adverse event reporting requirements. LDT manufacturers will be required to either submit a pre-market application and receive the FDA's approval before an LDT may be marketed or submit a pre-market notification in advance of marketing. The Framework for Regulatory Oversight draft guidance states that within six months after the guidance documents are finalized, all laboratories will be required to give notice to the FDA and provide basic information concerning the nature of the LDTs offered.

On November 18, 2016, however, the FDA announced that it would not release final versions of these guidance documents and would instead continue to work with stakeholders, the new administration and Congress to determine the right approach. On January 13, 2017, the FDA released a discussion paper on LDTs outlining a possible risk-based approach for FDA and CMS oversight of LDTs. According to the 2017 discussion paper, previously marketed LDTs would not be expected to comply with most or all FDA oversight requirements (grandfathering), except for adverse event and malfunction reporting. In addition, certain new and significantly modified LDTs would not be expected to comply with pre-market review unless the agency determines certain tests could lead to patient harm. Since LDTs currently on the market would be grandfathered in, pre-market review of new and significantly modified LDTs could be phased-in over a four-year period, as opposed to the nine years proposed in the Framework for Regulatory Oversight draft guidance. In addition, tests introduced after the effective date, but before their phase-in date, could continue to be offered during pre-market review.

The discussion paper notes that the FDA will focus on analytical and clinical validity as the basis for marketing authorization. The FDA anticipates laboratories that already conduct proper validation should not be expected to experience new costs for validating their tests to support marketing authorization and laboratories that conduct appropriate evaluations would not have to collect additional data to demonstrate analytical validity for FDA clearance or approval. This goal would be achieved through a precertification process. The evidence of the analytical and clinical validity of all LDTs will be made publically available. LDTs are encouraged to submit prospective change protocols in their pre-market submission that outline specific types of anticipated changes, the procedures that will be followed to implement them, and the criteria that will be met prior to implementation.

In March 2017, a draft bill "The Diagnostics Accuracy and Innovation Act" ("DAIA") was introduced in Congress. The bill would establish a new regulatory framework for the oversight of in vitro clinical tests ("IVCTs") which include LDTs. Following review and comment from FDA on the provisions of DAIA, a revised version of the bill, now called "The Verifying Accurate, Leading-edge IVCT Development Act" (VALID) was introduced in Congress in December 2018. Under the bill, a risk-based approach will be used to regulate IVCTs. Each test will be classified as high-risk or low-risk. Pre-market review will be required for high-risk tests. To market a high-risk IVCT, reasonable assurance of analytical and clinical validity for the intended use must be established. Under VALID, a precertification process would be established which will allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre-certified, low-risk IVCTs it develops will not be subject to pre-market review. The new regulatory framework will include quality control and post-market reporting requirements. The FDA will have the authority to withdraw from the market IVCTs that present an unreasonable and substantial risk of illness or injury when used as intended. We cannot predict whether this bill will become law. If the FDA were to require us to seek clearance or approval for our existing product or any of our future products for clinical use, we may not be able to obtain such approvals on a timely basis or at all. Our business could be negatively impacted as a result of commercial delay that may be caused by any new requirements. The cost of conducting clinical trials and otherwise developing data and information to support pre-market approval may be significant. If we are required to submit applications for our currently-marketed iCTC test, we may be required to conduct additional studies, which may be time-consuming and costly and could result in our currently-marketed test being withdrawn from the market. Continued compliance with the FDA's regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, such as fines, product suspensions, warning letters, recalls, injunctions and other civil and criminal sanctions. Any other regulatory or legislative proposals that would increase general FDA oversight of clinical laboratories and LDTs could negatively impact our business if additional requirements are imposed. We are monitoring developments and anticipate that our products will be able to comply with requirements that are ultimately imposed by the FDA.

If we fail to comply with laboratory licensing requirements, we could lose the ability to offer our clinical testing services or experience disruptions to our business.

The CLIA is a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Clinical laboratories must be certified under CLIA in order to perform testing on human specimens, unless they fall within an exception to CLIA certification, such as research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients. CLIA certification is also required to be eligible to bill Federal and State healthcare programs, as well as many private third-party payers, for diagnostic testing and services. Currently, we are supplying our iCTC capture assay and associated testing services under the research exception to CLIA. If we expand our laboratory testing services so that the research exception no longer applies, we will be required to obtain CLIA certification which can be time-consuming and costly. A delay in obtaining certification or a failure to do so could significantly harm our business, results of operations, and prospects.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

Third party payors are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in the United States in 2010, the Affordable Care Act, or ACA, was enacted. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The repeal of or changes in some or all of the ACA and complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business. Until the ACA is fully implemented or there is more certainty concerning the future of the ACA, it will be difficult to predict its full impact and influence on our business.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our product candidates, if we obtain regulatory approval, including: our ability to receive or set a price that we believe is fair for our products; our ability to generate revenue and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us.

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. In particular, research, sales, marketing, education and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our future arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal, state and foreign healthcare laws and regulations which may affect our ability to operate and expose us to areas of risk include: federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009; the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations; federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and analogous state and foreign laws and regulations.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or any suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any suppliers we currently or may in the future engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our preclinical trials, future clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, prospects, financial condition, results of operations, and prospects.

Risks Relating to Our Common Stock and Other Securities:

There are a large number of shares of common stock underlying our outstanding options and warrants and the sale of these shares may depress the market price of our common stock and cause immediate and substantial dilution to our existing stockholders.

As of December 6, 2019, we had 3,485,399 shares of common stock issued and outstanding, outstanding options to purchase 199,261 shares of common stock, outstanding warrants to purchase 2,350,048 shares of common stock, 84,798 shares of common stock issuable upon conversion of secured convertible notes and 139,146 shares available for grant under our 2005 Incentive Stock Plan. The issuance of shares upon exercise of our outstanding options and warrants will cause immediate and substantial dilution to our stockholders. Under our warrants sold privately that have registration rights, in the event of a "Fundamental Transaction" (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50% of our common stock), each warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the warrant for a purchase price in cash equal to the Black Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and/or results of operations and may prevent or deter a third party from acquiring us.

We may require additional financing which may in turn require the issuance of additional shares of common stock, preferred stock or other debt or equity securities (including convertible securities) and which would dilute the ownership held by our stockholders.

We may need to raise funds through either debt or the sale of our shares of our common stock in order to achieve our business goals. Any additional shares issued would further dilute the percentage ownership held by the stockholders. Furthermore, if we raise funds in equity transactions through the issuance of convertible securities which are convertible at the time of conversion at a discount to the prevailing market price, substantial dilution is likely to occur resulting in a material decline in the price of your shares. Our public offerings completed in November 2014, April 2015, December 2018 and November 2019, our registered direct public offering and concurrent private placement during November 2015, our private placements completed in November 2016, June 2017, and August 2019, and our registered direct offering in December 2017 resulted in dilution to investors and future offerings of securities could result in further dilution to investors. Our private placements of secured convertible notes in August 2018, November 2018 and July 2019 could result in dilution to investors if the holders convert their notes into shares of our common stock. In particular, holders of such secured convertible notes, including Dr. Hayward and other directors, officers, and affiliates of the Company, converted substantial portions of such August 2018 Notes and November 2018 Notes into our common stock in September 2019.

Conversion of our secured convertible notes into common stock will result in additional dilution to our stockholders.

Upon satisfaction of certain conversion conditions (including conditions outside of our control, such as market price or trading price) and proper conversion of secured convertible notes by a holder, we may be required to deliver shares of our common stock to a converting holder. If additional shares of our common stock are issued due to conversion of some or all of the outstanding secured convertible notes, the ownership interests of existing stockholders will be diluted. Further, any sales in the public market of any shares of common stock issued upon conversion or hedging or arbitrage trading activity that develops due to the potential conversion of the secured convertible notes could adversely affect prevailing market prices of our common stock.

Substantially all of our assets are encumbered. If we should fail to make timely payments on our secured convertible notes, holders of the notes may choose to enforce their remedies and ultimately realize on the collateral securing the notes, which includes substantially all of our intellectual property.

The Company issued and sold an aggregate of $1,650,000 in principal amount of August 2018 Notes, of which $53,264 remain outstanding and $550,000 in principal amount of November 2018 Notes of which $51,733 remain outstanding. The Company issued and sold $1.5 million in principal amount of July 2019 Notes, bearing interest at a rate of 6% per annum, and simultaneously amended the terms of the August 2018 and November 2018 Notes. The outstanding secured convertible notes are due and payable in full on November 28, 2021 and are convertible, in whole or in part, at any time, at the option of the purchasers, into shares of our common stock in an amount determined by dividing the principal amount of each secured convertible note, together with any and all accrued and unpaid interest, by the related Conversion Price. A majority of the August 2018 and November 2018 Notes were owned by Dr. James A. Hayward, our CEO. Dr. Hayward and other directors, officers, and affiliates of the Company converted the outstanding principal and unpaid interest of their notes, which represented more than 96% of the August 2018 and November 2018 Notes, into common stock of the Company in September 2019.

Until the principal and accrued but unpaid interest under the secured convertible notes outstanding is paid in full, or the secured convertible notes are converted into shares of common stock, our obligations under the secured convertible notes are secured by a lien on substantially all of our assets (excluding certain cash accounts) and the assets of APDN (B.V.I.) Inc., our wholly-owned subsidiary, in favor of Delaware Trust Company, as collateral agent for the purchasers of the secured convertible notes. The secured assets also include substantially all of our intellectual property. In addition, on July 19, 2019, the Company also amended the security agreements dated as of October 19, 2018, to among other amendments, exclude 20% of the Company's equity interest in LRx from the assets securing the secured convertible notes. The existence of such lien may substantially limit our ability to obtain additional secured financing and force us to attempt to incur additional unsecured indebtedness, which may be unavailable to us. If we should fail to make timely payments on the secured convertible notes, holders of the secured convertible notes may choose to enforce their remedies and ultimately realize on the collateral securing the secured convertible notes, which may have a material adverse effect on our business, including the inability for us to continue our operations.

We may require additional financing in the future, which may not be available or, if available, may be on terms that cause a decline in the value of the shares of our common stock held by stockholders.

If we raise capital in the future by issuing additional securities, our stockholders may experience a decline in the value of the shares of our common stock they currently hold or may acquire prior to any such financing. In addition, such securities may have rights senior to the rights of holders of our shares of common stock.

If we fail to comply with the continuing listing standards of The Nasdaq Capital Market, our securities could be delisted.

Our common stock is listed on The Nasdaq Capital Market under the symbol "APDN". For our common stock to continue to be listed on The Nasdaq Capital Market ("Nasdaq"), we must meet the current continued listing requirements. If we were unable to meet these requirements, our common stock could be delisted from Nasdaq. If our common stock were to be delisted from Nasdaq, our common stock could begin to trade on one of the markets operated by OTC Markets Group, including OTCQX, OTCQB or OTC Pink (formerly known as the "pink sheets"), as the case may be. In such event, our common stock could be subject to the "penny stock" rules which among other things require brokers or dealers to approve investors' accounts, receive written agreements and determine investor suitability for transactions and disclose risks relating to investing in the penny stock market. Any such delisting of our common stock could have an adverse effect on the market price of, and the efficiency of the trading market for our common stock, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and less coverage of us by securities analysts, if any. Also, if in the future we were to determine that we need to seek additional equity capital, it could have an adverse effect on our ability to raise capital in the public or private equity markets. As of November 21, 2019, we received written notice from the Listing Qualifications department of Nasdaq notifying us that we had regained compliance with the minimum bid price and stockholder's equity rules and had met the requirements of a Nasdaq Listing Panel decision dated October 1, 2019.

Any material weaknesses in our internal control over financial reporting in the future could adversely affect investor confidence, impair the value of our common stock and increase our cost of raising capital.

Any failure to remedy deficiencies in our internal control over financial reporting that may be discovered or our failure to implement new or improved controls, or difficulties encountered in the implementation of such controls, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure could, in turn, affect the future ability of our management to certify that internal control over our financial reporting is effective. Inferior internal control over financial reporting could also subject us to the scrutiny of the SEC and other regulatory bodies which could cause investors to lose confidence in our reported financial information and could subject us to civil or criminal penalties or stockholder litigation, which could have an adverse effect on our results of operations and the market price of our common stock.

In addition, if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting, the disclosure of that fact, even if quickly remedied, could reduce the market's confidence in our financial statements and harm our share price. Furthermore, deficiencies could result in future non-compliance with Section 404 of the Sarbanes-Oxley Act of 2002. Such non-compliance could subject us to a variety of administrative sanctions, including review by the SEC or other regulatory authorities.

Short sellers of our stock may be manipulative and may drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own but rather has borrowed or intends to borrow from a third party with the intention of buying identical securities at a later date to return to the lender. A short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is therefore in the short seller's interest for the price of the stock to decline, some short sellers publish, or arrange for the publication of, opinions or characterizations regarding the relevant issuer, its business prospects and similar matters calculated to or which may create negative market momentum, which may permit them to obtain profits for themselves as a result of selling the stock short. Issuers whose securities have historically had limited trading volumes and/or have been susceptible to relatively high volatility levels can be particularly vulnerable to such short seller attacks. The publication of any such commentary regarding us in the future may bring about a temporary, or possibly long term, decline in the market price of our common stock. In the past, the publication of commentary regarding us by a disclosed short seller has been associated with the selling of shares of our common stock in the market on a large scale, resulting in a precipitous decline in the market price per share of our common stock. No assurances can be made that similar declines in the market price of our common stock will not occur in the future, in connection with such commentary by short sellers or otherwise.

The price of our common stock may be volatile or may decline, and the trading volume of our common stock may fluctuate, which may make it more difficult to realize a profit on your investment in our shares of common stock.

Our common stock is listed on The Nasdaq Capital Market. The trading price of our common stock has been and may continue to be volatile. In addition, the trading volume of our common stock may fluctuate and cause significant price variations to occur. Volatility in the market price of our common stock may prevent you from being able to sell your shares of common stock at or above the price you paid for your shares of common stock, which may make it more difficult to realize a profit on your investment. A number of factors may affect the market price of our common stock, including, but not limited to, the following:

- our operating and financial performance and prospects;
- our quarterly or annual earnings or those of other companies in our industry or those that investors deem comparable to us;
- conditions that impact demand for our products and services;
- public reactions to our press releases, other public announcements and filings with the SEC;
- market and industry perception of our success, or lack thereof, in pursuing our growth strategy;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- changes in accounting standards, policies, guidance, interpretations or principles;
- arrival and departure of key personnel, including management personnel;
- changes in our capital structure;
- changes in the price of our warrants or other securities we may issue from time to time;
- sales of common stock by us, our directors, officers or large stockholders;
- the expiration of any applicable contractual lock-up agreements;
- changes in general market, economic and political conditions in the United States and global economies or financial markets, including those resulting from natural disasters, terrorist attacks, acts of war and responses to such events;
- announcements of new products or innovations by us or our competitors and announcements concerning our competitors or our industry in general;
- difficulties in commercialization and distribution of our products or lower than expected sales volume or revenues;
- changes in our relationships with manufacturers, suppliers or collaborators, or our inability to supply enough product to meet demand;
- our ability to obtain additional funding;
- changes or developments in applicable laws or regulations;
- any intellectual property infringement actions or other litigation or legal proceeding in which we may become involved;
- changes in financial estimates or recommendations by securities analysts, or their ceasing to publish research or reports about our business;
- the trading volume of our common stock; and
- the appeal and current level of investor interest in the biotechnology/biopharmaceutical capital market sector and in companies in general with business, research strategies and product development pipelines which are similar to us.

In addition, Nasdaq and other securities markets have, from time to time, experienced extreme price and trading volume fluctuations. The market prices of securities of biotechnology and other life sciences companies in a comparable stage to ours historically have been particularly volatile, and trading volume in such securities and our common stock has often been relatively low. Moreover, the securities and financial markets in general have experienced substantial volatility that has often been unrelated or disproportionate to the operating results of any individual company. During certain periods, specific industry sectors, such as the biotechnology segment, may experience greater volatility than other sectors or the securities markets as a whole. These broad market fluctuations, during which our industry and companies at our stage may experience a stronger degree of market sensitivity, will adversely affect the market price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters is located at the Long Island High Technology Incubator ("LIHTI"), which is located on the campus of Stony Brook University at 50 Health Sciences Drive, Stony Brook, NY 11790. The lease is for a 30,000 square foot building. The term of the lease commenced on June 15, 2013 and expired on May 31, 2016, with the option to extend the lease for two additional three-year periods. We have exercised our option to extend the lease for one additional three-year period, ending May 31, 2019. The base rent during the additional three-year period was $458,098 per annum. We have currently extended this lease until January 15, 2020. In addition to the office space, we also have 1,500 square feet of laboratory space. The term of the lease commenced on November 1, 2015, expired on October 31, 2016 and was renewed through October 31, 2017. Effective November 20, 2017, we have renewed this lease for one additional year ending October 31, 2018, with a month to month agreement thereafter. This lease has also been extended until January 15, 2020. We also have a satellite testing facility in Ahmedabad, India, which was established during fiscal 2018. On November 17, 2017, we leased 1,108 square feet for a three-year term beginning November 1, 2017. The base rent is approximately $6,500 per annum.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

Our common stock is listed on The NASDAQ Capital Market under the symbol "APDN". Our warrants were listed on The NASDAQ Capital Market under the symbol "APDNW". These warrants expired during November 2019. There is no certainty that the common stock will continue to be listed or that any liquidity exists for our stockholders.

The following table sets forth the quarterly quotes of high and low prices for our common stock and warrants on The NASDAQ Capital Market, during the fiscal years ended September 30, 2019 and 2018. The following high and low sales prices of our common stock and warrants have been adjusted retroactively to reflect a one-for-40 reverse stock split that was effective on November 1, 2019

	Fiscal 2019		Fiscal 2018	
	High	Low	High	Low
Common Stock:				
First Quarter	$ 65.20	$ 12.00	$ 138.00	$ 60.80
Second Quarter	$ 36.80	$ 14.00	$ 70.00	$ 54.40
Third Quarter	$ 33.60	$ 20.00	$ 63.60	$ 48.40
Fourth Quarter	$ 8.80	$ 23.20	$ 73.60	$ 44.00

	Fiscal 2019		Fiscal 2018	
	High	Low	High	Low
Warrants:				
First Quarter	$ 10.40	$ 0.04	$ 34.00	$ 8.40
Second Quarter	$ 1.24	$ 0.16	$ 17.60	$ 10.00
Third Quarter	$ 0.80	$ 0.16	$ 14.40	$ 4.80
Fourth Quarter	$ 0.72	$ 0.04	$ 12.00	$ 5.20

Holders

As of December 6, 2019, we had approximately 351 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The transfer agent of our common stock is American Stock Transfer & Trust Company, 6201 15th Avenue, Brooklyn, New York 11219.

Dividends

We have never declared or paid any cash dividends on our common stock. We do not anticipate paying any cash dividends to stockholders in the foreseeable future. In addition, any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements, and such other factors as the Board of Directors deem relevant.

ITEM 6. SELECTED FINANCIAL DATA.

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and analysis includes certain forward-looking statements that involve risks, uncertainties and assumptions. You should review the Risk Factors section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by such forward-looking statements. See "Forward-Looking Information" at the beginning of this Form 10-K.

All warrants, option, share and per share information in this report gives retroactive effect to a one-for-forty reverse stock split that was effective on November 1, 2019.

Introduction

Using our large scale PCR based manufacturing platform, we manufacture large quantities of linear DNA for various markets. Whether for supply chain security, brand protection, law enforcement or drug or biologic applications, it is our goal to help establish secure flourishing environments that foster quality, integrity and success. With secure taggants, high-resolution DNA authentication, and comprehensive reporting, our SigNature® molecular tag technologies are designed to deliver what we believe to be the greatest levels of security, deterrence and legal recourse strength. Under our 98% owned subsidiary, LineaRx, Inc. ("LRx"), we supply DNA for use in the *in vitro* medical diagnostics, preclinical biotechnology and preclinical drug and biologic development and manufacturing markets. We are also engaged in preclinical and animal drug candidate development, directly and with collaborators, focusing on therapeutically relevant DNA constructs manufactured via our PCR-based DNA production platform.

General

To date, the substantial portion of our revenues has been generated from sales of our SigNature® and SigNature® T molecular tags, our principal supply chain security and product authentication solutions. We expect to grow revenues from sales of our SigNature® molecular tags, SigNature® T molecular tags, SigNify® and CertainT® offerings as we work with companies and governments to secure supply chains for various types of products and product labeling throughout the world. In addition, we expect to continue to grow revenues from PCR-produced linear DNA products and services using our patented Triathlon™ and other proprietary PCR production and post-processing systems. We have continued to incur expenses in expanding our business to meet current and anticipated future demand. We have limited sources of liquidity. Our products and services are offered in the United States, Europe and Asia. At the present time, we are focusing our efforts on textile and apparel, pharmaceuticals and nutraceuticals, microcircuits and other electronics, legal cannabis and PCR-produced linear DNA products for use in biotherapeutic applications, as well as services for *in vitro* medical diagnostics, preclinical biotechnology research and preclinical biotherapeutic manufacturing. Currently, approximately 35% of our annual revenue comes from the textile market. The basic technology we use in various markets is very similar, and we believe our solutions are adaptable for many types of products and markets. In the future, we plan to expand our focus to include additional consumer products, food and beverage and industrial materials. The cotton ginning season in the United States takes place between September and March each year; therefore, revenues from our cotton customer contracts may be seasonal and recognized primarily during our first and fourth fiscal quarters, which may cause operating results to fluctuate significantly quarterly and annually.

In addition, we seek to develop, acquire and commercialize, ourselves or with partners, a diverse portfolio of nucleic acid-based drugs and biologics based on PCR-produced linear DNA to improve existing nucleic acid-based therapeutics or to create new nucleic acid-based therapeutics that address unmet medical needs. We are also engaged in preclinical and animal drug candidate development activities focusing on therapeutically relevant DNA constructs manufactured through our large scale PCR production systems. LRx uses its PCR systems to rapidly produce customized DNA for use by our contract research organization/contract manufacturing organization clients, our preclinical drug and biologic clients and partners, and for our own nucleic acid-based preclinical drugs and biologics under development in the field of CAR T-cell immunotherapy. LRx's proprietary processes enables large, gram-scale production of DNA through PCR for bio-based therapeutics, adoptive cell therapies, vaccines (including cancer), clustered regularly interspaced short palindromic repeats, or CRISPR and other nucleic acid-based therapies. Linear DNA does not require recombination, therefore, there is no need for a virus or for plasmids. This reduces the risk of unwanted DNA or other contaminants that would need to be removed.

Critical Accounting Policies

Financial Reporting Release No. 60, published by the SEC, recommends that all companies include a discussion of critical accounting policies used in the preparation of their financial statements. While all these significant accounting policies impact our financial condition and results of operations, we view certain of these policies as critical. Policies determined to be critical are those policies that have the most significant impact on our consolidated financial statements and require management to use a greater degree of judgment and estimates. Actual results may differ from those estimates.

We believe that given current facts and circumstances, it is unlikely that applying any other reasonable judgments or estimate methodologies would cause a material effect on our consolidated results of operations, financial position or liquidity for the periods presented in this report.

The accounting policies identified as critical are as follows:

- Revenue recognition; and
- Equity based compensation.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board ("FASB") issued accounting standard updates which clarified principles for recognizing revenue arising from contracts with customers ("ASC 606" or "Topic 606") and superseded most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue standard is that an entity recognizes revenue to depict the transfer of promised goods or services to clients in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance applies a five-step model for revenue measurement and recognition and also requires increased disclosures including the nature, amount, timing, and uncertainty of revenue and cash flows related to contracts with clients.

The Company adopted the new revenue standard at the beginning of the first quarter of fiscal 2019, using the modified retrospective method of adoption and applied the guidance to those contracts that were not completed as of September 30, 2018. Comparative financial information for reporting periods beginning prior to October 1, 2018, has not been restated and continues to be reported under the previous reporting guidance. Under the modified retrospective method of adoption, the cumulative effect of applying the new standard is recorded at the date of initial application, with no restatement of the comparative prior periods presented. Based on the evaluation, the Company has identified certain customer contracts, which will require different recognition under the new guidance. The Company has determined that the revenue under certain of its research and development contracts should be recognized on an over time basis using the input method as compared to ratably over the contract term. Also, the shipment to the Company's cotton customer during fiscal 2018 that included extended payment terms and was included in deferred revenue as of September 30, 2018, would have met the criteria under the new guidance to be recognized as revenue upon shipment. The Company has determined that the cumulative adjustment to opening retained earnings in fiscal 2019 was approximately $493,000.

The Company measures revenue at the amounts that reflect the consideration to which it is expected to be entitled in exchange for transferring control of goods and services to customers. The Company recognizes revenue either at the point in time or over the period of time that performance obligations to customers are satisfied. The Company's contracts with customers may include multiple performance obligations (e.g. taggants, maintenance, authentication services, research and development services, etc.). For such arrangements, the Company allocates revenues to each performance obligation based on their relative standalone selling price.

Under the new accounting guidance, the Company recognizes revenue upon transfer of control of promised goods or services to customers in an amount that reflects the consideration it expects to receive for those goods or services, including any variable consideration.

Due to the short-term nature of the Company's contracts with customers, it has elected to apply the practical expedients under Topic 606 to: (1) expense as incurred, incremental costs of obtaining a contract and (2) not adjust the consideration for the effects of a significant financing component for contracts with an original expected duration of one year or less.

Equity Based Compensation

We account for stock-based compensation for employees, directors, and nonemployees in accordance with ASC 718, Compensation ("ASC 718"). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Under the provisions of ASC 718, stock-based compensation costs are measured at the grant date, based on the fair value of the award, and are recognized as expense over the employee's requisite service period (generally the vesting period of the equity grant). The fair value of the Company's common stock options are estimated using the Black Scholes option-pricing model with the following assumptions: expected volatility, dividend rate, risk free interest rate and the expected life. The Company expenses stock-based compensation by using the straight-line method. In accordance with ASC 718, excess tax benefits realized from the exercise of stock-based awards are classified as cash flows from operating activities. All excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) are recognized as income tax expense or benefit in the condensed consolidated statements of operations.

Use of Estimates

The preparation of the financial statements in conformity with Accounting Principles Generally Accepted in the U.S. ("GAAP") requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The most complex and subjective estimates include revenue recognition, recoverability of long-lived assets, including the values assigned to goodwill, intangible assets and property and equipment, fair value calculations for stock based compensation and convertible promissory notes, contingencies, allowance for doubtful accounts and management's anticipated liquidity. Management reviews its estimates on a regular basis and the effects of any material revisions are reflected in the consolidated financial statements in the period they are deemed necessary. Accordingly, actual results could differ from those estimates.

Comparison of the Fiscal Year Ended September 30, 2019 to the Fiscal Year Ended September 30, 2018

Revenues

Product revenues

For the twelve month periods ended September 30, 2019 and 2018, we generated $2,136,055 and $1,827,626 in revenues from product sales, respectively. Product revenue increased by $308,429 or 17% for the twelve month period ended September 30, 2019 as compared to the prior fiscal year. Revenues increased by $889,230 in textiles relating to shipments of DNA concentrate to protect the cotton supply chain. The increase was offset by decreases of $393,063 in Consumer Asset Marking due to a decrease in demand for automobile marking in Scandinavia and $139,957 in biopharmaceuticals due to a customer having decreased demand and therefore delaying the issuance of its annual purchase order. The purchase order for such customer for the current fiscal year was received during the twelve month period ended September 30, 2019 and shipments commenced in May 2019.

Service revenues

For the twelve month periods ended September 30, 2019 and 2018, we generated $3,253,034 and $2,075,717 in revenues from sales of services, respectively. Service revenues include our feasibility projects and any research and/or development contracts as well as fiberTyping and authentication services. The increase in service revenues of $1,177,317 or 57% for the twelve month period ended September 30, 2019 as compared to the prior fiscal year is attributable to an increase in revenue from a cannabis licensing agreement (now terminated) of $1,000,000, as well as an additional increase of $122,832 for a cannabis pre-commercial feasibility project.

Costs and Expenses

Cost of Revenues

Cost of revenues for the twelve month period ended September 30, 2019 decreased by $329,201 or 27% from $1,206,814 for the twelve month period ended September 30, 2018 to $877,613 for the twelve month period ended September 30, 2019. Cost of revenues as a percentage of product revenues was 41% and 66% for the twelve month periods ended September 30, 2019 and 2018, respectively. This decrease in cost of revenues as a percentage of product revenues is due to product sales mix, as sales during the twelve month period ended September 30, 2018 were primarily comprised of biopharmaceutical and consumer asset marking sales, which are at a lower gross margin.

Selling, General and Administrative

Selling, general and administrative expenses for the fiscal year ended September 30, 2019 decreased by $765,418 or 7% to $10,278,045 from $11,043,463 in fiscal year 2018. The decrease is primarily attributable to a decrease in payroll of $862,395 due to headcount reductions and salesforce realignment as well as a decrease in stock based compensation expense of $227,353. These decreases were offset by an increase in legal expenses of $463,967.

Research and Development

Research and development expenses increased to $2,967,278 for the twelve month period ended September 30, 2019 from $2,751,578 for the twelve month period ended September 30, 2018, an increase of $215,700 or 8%. This increase is primarily due to approximately $345,000 for the in-process research and development purchased as part of the Vitatex asset acquisition. This increase was offset by decreases relating to the completion of the government contract award of approximately $100,000.

Depreciation and Amortization

In the twelve month period ended September 30, 2019, depreciation and amortization decreased by $157,372 or 29% from $547,796 for the twelve month period ended September 30, 2018 to $390,424 for the twelve month period ended September 30, 2019. This decrease is related primarily to items becoming fully depreciated during fiscal 2019 and therefore not having a full 12 months of expense in the current fiscal year.

***Interest (expense)* income**

Interest (expense) income for the fiscal year ended September 30, 2019, increased to expense of $162,432 from expense of $9,615 in the same period of 2018. The increase in interest expense was due to interest incurred on the secured convertible notes payable for the fiscal year ended September 30, 2019.

Other (expense) income

Other expense for the fiscal year ended September 30, 2019, increased to $43,299 from $37,005 in fiscal 2018.

Loss on extinguishment of debt

Loss on extinguishment of debt increased to $1,260,399 for the fiscal year ended September 30, 2019 and relates to the August 2018 and November 2018 secured convertible notes amendment during July 2019 resulting in accounting for such notes as an extinguishment of debt and issuance of new debt. The majority of these notes were subsequently converted into equity during September 2019.

Gain on change in fair value of secured convertible notes payable

Gain on change in fair value of secured convertible notes payables increased to $1,972,955 for the fiscal year ended September 30, 2019 and relates to fair value adjustments relating to the August 2018 and November 2018 secured convertible notes as amended in July 2019. Due to the amendment, the Company elected the fair value option and adjusts the remaining secured convertible notes to fair value upon conversion as well as at every quarter-end.

Net Loss

Net loss decreased $3,069,805, or 26% to $8,623,123 for the fiscal year ended September 30, 2019 compared to $11,692,928 for the fiscal year ended September 30, 2018 due to the factors noted above.

Recently Issued Accounting Pronouncements

See Note B, "Recent Accounting Principles," to the accompanying consolidated financial statements for a description of accounting standards which may impact our consolidated financial statements in future reporting periods.

Liquidity and Capital Resources

Our liquidity needs consist of our working capital requirements and research and development expenditure funding. As of September 30, 2019, we had a working capital deficit of $99,682. For the fiscal year ended September 30, 2019, we used cash in operating activities of $6,861,772 consisting primarily of our loss of $8,623,123 net with non-cash adjustments of $390,424 in depreciation and amortization charges, $1,260,399 for loss on extinguishment of debt, $1,972,955 for gain on change in fair value of secured convertible notes payable, $1,129,110 in stock-based compensation expense, $251,420 for the Vitatex asset acquisition, $9,323 for the net loss attributable to noncontrolling interest, $7,624 of bad debt expense and $23,828 in amortization of debt issuance costs. Additionally, we had a net decrease in operating assets of $740,846 and a net decrease in operating liabilities of $60,022. Cash used in investing activities was $67,438, for the purchase of property and equipment. Cash provided by financing activities was $5,828,634, which included net proceeds from the sale of common stock and warrants of $2,463,591, net proceeds from the sale of common stock to a private placement in August 2019 of $402,381, net proceeds from the exercise of warrants of $987,501 and the proceeds from the sale of secured convertible promissory notes during November 2018 and July 2019 of $1,985,392. In addition, on November 15, 2019, we closed on an underwritten public offering of common stock and warrants which resulted in aggregate gross proceeds of approximately $12.0 million, exclusive of warrant proceeds. After deducting underwriting discounts and commissions and other estimated offering expenses total expected net proceeds are approximately $10.8 million.

We have recurring net losses, which have resulted in an accumulated deficit of $256,805,589 as of September 30, 2019. We have incurred a net loss of $8,632,446 for the fiscal year ended September 30, 2019. At September 30, 2019, we had cash and cash equivalents of $558,988.

Our current capital resources include cash and cash equivalents, accounts receivable and inventories. We expect to finance our operations primarily through cash received from the November 2019 public offering, as well as collection of our accounts receivable. We estimate that we will have sufficient cash and cash equivalents to fund operations for the next twelve months from the date of filing of this annual report. Historically, we have financed our operations principally from the sale of equity and equity-linked securities.

We may require additional funds to complete the continued development of our products, product manufacturing, and to fund expected additional losses from operations until revenues are sufficient to cover our operating expenses. If revenues are not sufficient to cover our operating expenses, and if we are not successful in obtaining the necessary additional financing, we will most likely be forced to reduce operations.

We expect capital expenditures to be less than $250,000 in fiscal 2019. Our primary investments will be in laboratory equipment related to our biotherapeutic research and development activities.

Substantially all of the real property used in our business is leased under operating lease agreements.

Recent Debt and Equity Financing Transactions

Fiscal 2019

Private Placement of Secured Convertible Notes. On November 29, 2018, we closed a securities purchase agreement with our chairman, president and chief executive officer and one member of the management team, pursuant to which we issued and sold an aggregate of $550,000 in principal amount of secured convertible notes bearing interest at a rate of 6% per annum (the "November 2018 Notes"). The November 2018 Notes are substantially similar to our August 2018 Notes (as defined below) except with respect to maturity date. The November 29th Notes are secured on a pari passu basis with the same Company assets as the August 2018 Notes.

Underwritten Public Offering. On December 21, 2018, the Company entered into an underwriting agreement (the "Agreement") with Maxim Group LLC ("Maxim"), as the sole underwriter and book running manager, with respect to the issuance and sale of an aggregate of 137,500 shares (the "Shares") of common stock, together with warrants to purchase an aggregate of 137,500 shares of common stock (the "Warrants") at an exercise price equal to $20.00 per share of common stock (the "Exercise Price") in an underwritten public offering. The public offering price for each Share together with the accompanying Warrant was $20.00. Pursuant to the Agreement, the Company also granted Maxim a 45-day option to purchase an additional 20,625 Shares and/or additional Warrants to purchase 20,625 Shares to cover any over-allotments made by the underwriters in the sale and distribution of the Shares and Warrants. The gross proceeds of the offering, before deducting underwriter discounts and commissions and other offering expenses, were approximately $2,750,000 The offering closed on December 26, 2018. On December 26, 2018, Maxim partially exercised its overallotment option and purchased an additional 20,000 Warrants at a price of $0.0000004 per Warrant.

After deducting underwriting fees and other expenses related to the offering, the aggregate net proceeds were approximately $2,262,000.

On January 25, 2019, the Company closed on the underwriters' partial exercise of its over-allotment option for 12,500 shares of common stock for gross proceeds of $250,000. After deducting underwriting fees and other expenses related to the over-allotment option, the aggregate net proceeds were approximately $201,000.

The total number of common stock and Warrants issued under this offering, including the exercise of the over-allotment option was 150,000 and 157,500, respectively. The gross proceeds to us were $3.0 million and net proceeds after deducting underwriting expenses and other estimated offering expenses was approximately $2.5 million.

The Warrants are immediately exercisable beginning on the date of issuance (the "Initial Exercise Date"). The Warrants will be exercisable for five years from the Initial Exercise Date, but not thereafter.

The Warrants include an adjustment provision that, subject to certain exceptions, reduces their exercise price if the Company issues common stock or common stock equivalents at a price lower than the then-current exercise price of the Warrants, subject to a minimum exercise price of $5.60 per share. The exercise price and number of the shares of the Company's common stock issuable upon the exercise of the Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. In addition, on or after any trading day 75 days after the closing date of the offering, if the daily volume weighted average price of the Company's common stock fails to exceed the Exercise Price, the aggregate number of warrant shares issuable in a cashless exercise shall equal the product of (i) the aggregate number of warrant shares that would be issuable upon exercise of the Warrants if such exercise were by means of a cash exercise and (ii) 0.70.

As a result of the November 2019 underwritten public offering (detailed below under "Subsequent Events"), the exercise price of the Warrants was reduced to an exercise price of $5.60 per share in accordance with the adjustment provision contained in the warrant agreement.

As a result of this financing, the exercise price of the 68,375 warrants issued during December 2017 was reduced to an exercise price of $17.60 per share in accordance with the adjustment provision contained in the warrant agreement. The incremental change in fair value of these warrants as a result of the triggering event was insignificant.

Private Placement of Secured Convertible Notes. On July 16, 2019, we issued $1.5 million of secured convertible notes (the "July 2019 Notes"), bearing interest at a rate of 6% per annum, in a non-brokered private placement with an accredited investor, Dillon Hill Capital, LLC ("Dillon Hill") and simultaneously amended the terms of certain outstanding August 2018 secured convertible notes (as amended, the "August 2018 Notes") and November 2018 secured convertible notes (as amended, the "November 2018 Notes", and together with the August 2018 Notes, the "Existing Notes", and together with the August 2018 Notes and July 2019 Notes, the "Company Notes"), to, among other amendments, (i) reduce the conversion price of the Existing Notes to $21.60 to facilitate their conversion into equity and (ii) change the maturity date of the August 2018 Notes to be November 28, 2021. Dillon Hill was granted a right to participate in certain of our future financing transactions, (each a "Subsequent Financing") until July 16, 2020 equal to the amount required for Dillon Hill to maintain its pro rata ownership of us as if the July 2019 Notes had been fully converted into our common stock.

The Company Notes contain certain events of default that are customarily included in financings of this nature. If an event of default occurs, the holders of the Company Notes (by an affirmative vote of the holders of the Company Notes representing at least 30% of the aggregate principal amount of the Company Notes then outstanding) may require us to redeem the Company Notes, in whole or in part, at a redemption price equal to the greater of (i) their outstanding principal balance, plus all accrued and unpaid interest, divided by the Conversion Price (as defined below), multiplied by the volume-weighted average price ("VWAP") on the date the redemption price is either (x) demanded or otherwise due or (y) paid in full, whichever has a higher VWAP, or (ii) 130% of the outstanding principal, plus all accrued and unpaid interest.

After giving effect to the amendments to the Existing Notes, the July 2019 Notes are substantially similar to the Existing Notes. The July 2019 Notes are secured on a pari passu basis with the same Company assets as the Existing Notes. In addition, on July 19, 2019, we also amended the security agreements dated as of October 19, 2018, to among other amendments, exclude 20% of our equity interest in LRx from the assets securing the Company Notes. The Company Notes are convertible, in whole or in part, at any time, at the option of the purchasers, into shares of our common stock, in an amount determined by dividing the principal amount of the Company Notes, together with any and all accrued and unpaid interest, by the conversion price of $21.60 (the "Conversion Price"). The Company Notes are due and payable in full on November 28, 2021. We have reserved sufficient shares of our common stock for the potential conversion of the Company Notes.

The July Company Notes, contain certain negative covenants that restrict us, including prohibitions or limitations, among other things, on the incurrence of additional indebtedness, subsidiary asset sales, intercompany loans, liens, amendments to our organization documents, dividends, and redemptions without consent of the Required Holders (as defined in the Company Notes).

Private Placement of Common Stock. On August 22, 2019, the Company issued and sold 38,704 shares of common stock at a price of $10.80 per share for total gross proceeds of $418,000 to a group of accredited investors, including its chief executive officer, president and chairman of the board of directors, our chief information officer, and a 5% or greater stockholder.

Conversion of Notes. During September 2019, approximately $2.2 million of the Existing Notes were converted into 102,893 shares of our common stock. Included in the conversion, Dr. James A. Hayward, our CEO, converted approximately $1.59 million of the Existing Notes, into approximately 72,500 shares of our common stock. In addition, other directors, officers, and affiliates of the Company converted approximately $409,000 of such Existing Notes in September 2019 into 18,929 shares of our common stock.

Fiscal 2018

Registered Direct Offering. On December 22, 2017, we closed a securities purchase agreement with certain institutional investors for the purchase and sale of 68,375 shares of our common stock and warrants to purchase an aggregate of 68.375 shares of common stock in a registered direct offering with aggregate gross proceeds of $4,786,250, at a combined purchase price of $70.00 per share. The warrants will be immediately exercisable at a price of $80.00 per share of common stock and will expire five years from the date of issuance.

After deducting placement agent fees and other estimated expenses related to the registered direct offering, the aggregate net proceeds were approximately $4,200,000.

The warrants include an adjustment provision that, subject to certain exceptions, reduces their exercise price if we issue common stock or common stock equivalents at a price lower than the then-current exercise price of the warrants, subject to a minimum exercise price of $17.60. The exercise price and number of the shares of our common stock issuable upon the exercise of the warrants will be subject to adjustment as set forth therein (including for stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction). The warrants are subject to a call provision whereby we may, subject to certain provisions, including that the weighted average price of our common stock has exceeded $200.00 for twenty consecutive trading days, call for cancellation of all or any portion of the warrants not yet exercised.

In addition, if and only if there is no effective registration statement registering, or no current prospectus available for, the resale of the warrants, the investors may exercise the warrants by means of a "cashless exercise."

Private Placement of Secured Convertible Notes. On August 31, 2018, we entered into a securities purchase agreement with accredited investors and certain members of our management team and Board of Directors (the "Purchaser"), pursuant to which we issued and sold an aggregate of $1,650,000 in principal amount of secured convertible notes (the "August 2018 Notes") bearing interest at a rate of 6% per annum (the "Private Placement"). As part of the August 2018 Notes, certain members of our management and Board of Directors purchased Notes with a principal amount of $1,185,000. As described above under Fiscal 2019, $1,707,700 of the August 2018 Notes have been converted into our common stock.

The August 2018 Notes are convertible, in whole or in part, at any time, at the option of the Purchasers, into shares of our common stock, in an amount determined by dividing the principal amount of each Note, together with any and all accrued and unpaid interest, by the conversion price of $100.00. We have the right to require the Purchasers to convert all or any part of their Notes into shares of our common stock at a conversion price of $100.00 if the price of the common stock remains at a closing price of $140.00 or more for a period of twenty consecutive trading days.

Upon any Change in Control (as defined in the August 2018 Notes), the Purchasers have the right to require us to redeem the Notes, in whole or in part, at a redemption price equal to such Notes' outstanding principal balance plus accrued interest.

The August 2018 Notes contain certain events of default that are customarily included in financing of this nature. If an event of default occurs, the Purchasers may require us to redeem the August 31st Notes, in whole or in part, at a redemption price equal to such notes' outstanding principal balance plus accrued interest.

The August 2018 Notes bear interest at the rate of 6% per annum, payable semi-annually in cash or in kind, at our option, and are due and payable in full on August 30, 2021. Until the principal and accrued but unpaid interest under the August 2018Notes is paid in full, or converted into shares of common stock pursuant to their terms, our obligations under the Notes will be secured by a lien on substantially all assets of the Company (excluding certain cash accounts) and the assets of APDN (B.V.I.) Inc., the Company's wholly-owned subsidiary ("APDN BVI"), in favor of Delaware Trust Company, as Collateral Agent for the Purchasers pursuant to security agreements dated as of the date of the Purchase Agreement (the "Security Agreements").

We have also entered into a registration rights agreement, dated as of the date of the Purchase Agreement (the "Registration Rights Agreement"), with the Purchasers, pursuant to which we have agreed to prepare and file a registration statement with the SEC to register under the Securities Act of 1933, as amended (the "Securities Act") resales from time to time of the common stock issued or issuable upon conversion or redemption of the Notes. We are required to file a registration statement within 60 days of receiving a demand registration request from holders of a majority of the outstanding principal balance of the Notes, and to cause the registration statement to be declared effective within 45 days (or 90 days if the registration statement is reviewed by the SEC).

Subsequent Events

On October 31, 2019, we filed a Certificate of Amendment of our Certificate of Incorporation with the Secretary of State of the State of Delaware that effected a one-for-forty (1:40) reverse stock split of our common stock, effective November 1, 2019.

On November 15, 2019, we closed an underwritten public offering where we issued and sold 2,285,000 shares of the Company's common stock and 2,285,000 accompanying warrants each with the right to purchase one share of Common Stock at an exercise price of $5.25 per share. The shares of Common Stock and accompanying Common Warrants were sold at a combined offering price of $5.25 before underwriting discounts. The Common Warrants have an exercise price of $5.25 per share.

After deducting underwriter fees and other estimated expenses related to the registered direct offering, we estimate the aggregate net proceeds to be approximately $10.8 million.

The Company also granted Maxim an option to purchase an additional 342,750 shares of Common Stock and/or additional Common Warrants to purchase 342,750 shares of Common Stock (the "***Option Warrants***") to cover any over-allotments made by the Underwriters in the sale and distribution of the Securities.

The Common Warrant includes an adjustment provision that, subject to certain exceptions, reduces its exercise price if the Company issues Common Stock or Common Stock equivalents at a price lower than the then-current exercise price of the Common Warrant, subject to a minimum exercise price of $1.47 per share.

Subject to limited exceptions, a holder of a Common Warrant will not have the right to exercise any portion of its Common Warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise (the "***Beneficial Ownership Limitation***"); provided, however, that upon 61 days' prior notice to us, the holder may increase the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99%.

The exercise price and number of the shares of Common Stock issuable upon the exercise of the Common Warrant will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrant Agreement.

Product Research and Development

We anticipate spending approximately $2,500,000 for product research and development activities during the next twelve months.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Inflation

The effect of inflation on our revenue and operating results was not significant during the fiscal years ended September 30, 2019 and 2018.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Information requested by this Item is not applicable as we are electing scaled disclosure requirements available to Smaller Reporting Companies with respect to this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

See pages F-1 through F-30 following the Exhibit Index.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Management Report on Internal Control over Financial Reporting

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including, our Chief Executive Officer, along with the Chief Financial Officer, on September 30, 2019, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) under the Exchange Act, as of September 30, 2019. Disclosure controls and procedures are those controls and procedures designed to provide reasonable assurance that the information required to be disclosed in our Exchange Act filings is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (2) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2019, our disclosure controls and procedures were effective.

Management Report on Internal Control 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). Our internal control over financial reporting was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published consolidated financial statements. Internal control over financial reporting is promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers 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, no matter how well designed, has inherent limitations and may not prevent or detect misstatements. Therefore, even effective internal control over financial reporting can only provide reasonable assurance with respect to the financial statement preparation and presentation.

Our management has conducted, with the participation of our CEO and CFO, an assessment, including testing of the effectiveness, of our internal control over financial reporting as of September 30, 2019. Management's assessment of internal control over financial reporting was based on assessment criteria established in the *2013 Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on such evaluation, management concluded that our internal control over financial reporting was effective as of September 30, 2019.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

On December 9, 2019, we entered into a consulting agreement, effective December 12, 2019 with one of the members of our board of directors, Scott L. Anchin. As part of the consulting agreement, Mr. Anchin will assist the Company with respect to the Company's business strategy as well as the Company's capital allocation, operating budget, and cash management. The term of the agreement is for six months and may be renewed for an additional six-month term at the option of the Company. The compensation granted pursuant to such consultant agreement includes both cash and stock options. The total cash compensation during the initial six-month term is $125,000. The Company will grant options with a total value of $175,000 for the initial six month term.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

ITEM 11. EXECUTIVE COMPENSATION

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

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by Items 10, 11, 12, 13 and 14 will be included in our definitive proxy statement for the 2019 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after September 30, 2019. The relevant portions of such definitive proxy statement are incorporated herein by reference.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) We have filed the following documents as part of this Form 10-K:

1. Consolidated Financial Statements

Our consolidated financial statements at September 30, 2019 and 2018 and for the years ended September 30, 2019 and 2018, and the notes thereto, together with the report of our independent registered public accounting firm on those consolidated financial statements, are hereby filed as part of this report beginning on page F-1.

2. Financial Statement Schedules

All financial statement schedules have been omitted since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and notes thereto.

3. Exhibits

The information required by this item is set forth on the exhibit index that follows the signature page of this report.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

APPLIED DNA SCIENCES, INC.

Date: December 12, 2019

/s/ James A. Hayward
James A. Hayward
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ **JAMES A. HAYWARD** James A. Hayward	Chief Executive Officer (*Principal Executive Officer*), President, Chairman of the Board of Directors and Director	December 12, 2019
/s/ **BETH M. JANTZEN** Beth M. Jantzen	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	December 12, 2019
/s/ **JOHN BITZER, III** John Bitzer, III	Director	December 12, 2019
/s/ **ROBERT CATELL** Robert Catell	Director	December 12, 2019
/s/ **JOSEPH D. CECCOLI** Joseph D. Ceccoli	Director	December 12, 2019
/s/ **SCOTT L. ANCHIN** Scott L. Anchin	Director	December 12, 2019
/s/ **YACOV A. SHAMASH** Yacov A. Shamash	Director	December 12, 2019
/s/ **SANFORD R. SIMON** Sanford R. Simon	Director	December 12, 2019
/s/ **ELIZABETH M. SCHMALZ FERGUSON** Betsy M. Schmalz Ferguson	Director	December 12, 2019

EXHIBIT INDEX

The following exhibits are included as part of this Form 10-K. References to "the Company" in this Exhibit List mean Applied DNA Sciences, Inc., a Delaware corporation.

Exhibit Number	Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	Exhibit	File No.	Date Filed	
3.1	Certificate of Incorporation	8-K	3.1	002-90539	1/16/2009	
3.2	Certificate of Amendment of Certificate of Incorporation	8-K	3.1	002-90539	6/30/2010	
3.3	Second Certificate of Amendment of Certificate of Incorporation	8-K	3.1	002-90539	1/30/2012	
3.4	Third Certificate of Amendment of Certificate of Incorporation	8-K	3.1	002-90539	10/29/2014	
3.5	Fourth Certificate of Amendment of Certificate of Incorporation	8-K	3.1	001-36745	10/31/2019	
3.6	Form of Certificate of Designations of the Series A Convertible Preferred Stock	8-K	3.1	002-90539	11/29/2012	
3.7	Form of Certificate of Designations of the Series B Convertible Preferred Stock	8-K	3.1	002-90539	7/22/2013	
3.8	By-Laws	8-K	3.2	002-90539	1/16/2009	
4.1	Form of Underwriter's Warrant to be issued to Maxim Group LLC	S-1/A	10.26	333-199121	10/30/2014	
4.2	Form of Senior Indenture, to be entered into between Applied DNA Sciences, Inc. and the Trustee designated therein	S-3	4.1	333-202432	3/2/2015	
4.3	Form of Subordinated Indenture, to be entered into between Applied DNA Sciences, Inc. and the Trustee designated therein	S-3	4.3	333-202432	3/2/2015	
4.4	Form of Underwriter's Warrant	8-K	4.1	001-36745	3/27/2015	
4.5	Form of Purchase Warrant	8-K	4.1	001-36745	11/23/2015	
4.6	Form of Placement Agent Warrant issued to Maxim Group LLC	8-K	4.2	001-36745	11/23/2015	
4.7	Form of Placement Agent Warrant issued to Maxim Group LLC and Imperial Capital, LLC	8-K	4.1	001-36745	11/2/2016	
4.8	Form of Purchase Warrant	8-K	4.1	001-36745	12/20/2017	
10.1†	Applied DNA Sciences, Inc. 2005 Incentive Stock Plan and form of employee stock option agreement thereunder, as amended and restated as of January 21, 2015	10-K	10.1	001-36745	12/14/2015	
10.2*	Joint Development and Marketing Agreement, dated April 18, 2007 by and between Applied DNA Sciences and International Imaging Materials, Inc.	8-K	10.1	002-90539	4/24/2007	
10.3	Form of Subscription Agreement, dated July 15, 2011, by and among Applied DNA Sciences, Inc. and the investors named on the signature pages thereto	10-K	10.28	002-90539	12/9/2011	
10.4†	Employment Agreement, dated July 1, 2017, between James A. Hayward and Applied DNA Sciences, Inc.	8-K	10.1	001-36745	8/2/2016	
10.5*	Exclusive Sales Agreement dated November 1, 2011 by and between Applied DNA Sciences, Inc. and Nissha Printing Co., Ltd.	10-Q	10.1	002-90539	2/14/2012	
10.6	Software Distribution Agreement, dated as of January 25, 2012, by and between Applied DNA Sciences, Inc. and DivineRune, Inc.	10-Q	10.1	002-90539	5/15/2012	
10.7	Form of Subscription Agreement dated June 21, 2012, by and among Applied DNA Sciences, Inc. and the investor named on the signature page thereto	10-K	10.37	002-90539	12/20/2012	
10.8†	Form of Indemnification Agreement dated as of September 7, 2012, by and between Applied DNA Sciences, Inc. and each of its directors and executive officers	8-K	10.1	002-90539	9/13/2012	
10.9	Asset Purchase Agreement dated May 10, 2013, between Applied DNA Sciences, Inc. and RedWeb Technologies Limited	10-Q	10.1	002-90539	8/13/2013	

Exhibit Number	Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	Exhibit	File No.	Date Filed	
10.10	Agreement of Lease dated June 14, 2013, between Applied DNA Sciences, Inc. and Long Island High Technology Incubator, Inc.	10-Q	10.2	002-90539	8/13/2013	
10.11*	Term sheet for Mutual Cooperation with Borealis AG dated March 31, 2014	8-K/A	10.1	002-90539	7/22/2014	
10.12	Form of Subscription Agreement dated June 3, 2014	8-K	10.1	002-90539	6/6/2014	
10.13	Form of Warrant dated June 3, 2014	8-K	10.2	002-90539	6/6/2014	
10.14	Form of Award/Contract issued by U.S. Missile Defense Agency dated July 14, 2014	8-K	10.1	002-90539	7/18/2014	
10.15	Form of Award/Contract awarded by Office of Secretary of Defense on behalf of Defense Logistics Agency dated August 28, 2014	8-K/A	10.1	002-90539	9/8/2014	
10.16	Underwriting agreement between Applied DNA Sciences, Inc. and Maxim Group LLC dated November 17, 2014	S-1/A	1.1	333-199121	11/12/2014	
10.17	Form of Warrant Agreement between Applied DNA Sciences, Inc. and American Stock Transfer & Trust Company, LLC, as warrant agent	S-1/A	10.25	002-90539	11/12/2014	
10.18	First Amendment to Warrant Agreement dated April 1, 2015 between Applied DNA Sciences, Inc. and American Stock Transfer & Trust Company, LLC as warrant agent	8-K	4.1	001-36745	4/1/2015	
10.19	Underwriting Agreement dated March 27, 2015, between Applied DNA Sciences, Inc. and Maxim Group LLC, as representative of the underwriters named on Schedule A thereto.	8-K	1.1	001-36745	3/27/2015	
10.20**	Asset Purchase Agreement dated September 11, 2015 between Applied DNA Sciences, Inc. and Vandalia Research, Inc.	8-K	2.1	001-36745	9/17/2015	
10.21	Placement Agency Agreement by and between Applied DNA Sciences, Inc. and Maxim Group LLC, dated November 23, 2015	8-K/A	10.1	001-36745	11/23/2015	
10.22	Form of Securities Purchase Agreement	8-K/A	10.2	001-36745	11/23/2015	
10.23	Placement Agency Agreement between Maxim Group LLC, Imperial Capital, LLC and Applied DNA Sciences, Inc. dated November 2, 2016	8-K	10.1	001-36745	11/2/2016	
10.24	Securities Purchase Agreement dated November 2, 2016	8-K	10.2	001-36745	11/2/2016	
10.25	Registration Rights Agreement dated November 2, 2016	8-K	10.3	001-36745	11/2/2016	
10.26	Second Amendment to Warrant Agreement dated November 2, 2016	8-K	10.4	001-36745	11/2/2016	
10.27	License Agreement with Himatsingka America, Inc. dated June 23, 2017	10-Q	10.1	001-36745	8/10/2017	
10.28	Securities Purchase Agreement dated as of December 20, 2017, by and between Applied DNA Sciences, Inc. and the Purchasers named therein.	8-K	10.2	001-36745	12/20/2017	
10.29	Form of Subscription Agreement	8-K	10.1	001-36745	6/28/2017	
10.30	Form of Convertible Note	8-K	10.1	001-36745	12/6/2018	
10.31	Registration Rights Agreement, dated November 29, 2018	8-K	10.2	001-36745	12/6/2018	
10.32	Securities Purchase Agreement, dated November 29, 2018	8-K	10.3	001-36745	12/6/2018	
10.33	Form of Convertible Note	8-K/A	10.1	001-36745	12/10/2018	
10.34	Registration Rights Agreement, dated August 31, 2018	8-K/A	10.2	001-36745	12/10/2018	
10.35	Securities Purchase Agreement, dated August 31, 2018	8-K/A	10.3	001-36745	12/10/2018	
10.36	Collateral Agency Agreement dated October 19, 2018	10-K	10.39	001-36745	12/18/2018	Filed
10.37	Security Agreement dated October 19, 2018	10-K	10.40	001-36745	12/18/2018	Filed

Exhibit Number	Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	Exhibit	File No.	Date Filed	
10.38	First Amendment to Security Agreement dated November 26, 2018	10-K	10.41	001-36745	12/18/2018	Filed
10.39	Guaranty and Security Agreement dated October 19, 2018	10-K	10.42	001-36745	12/18/2018	Filed
10.40	Intellectual Property Security Agreement dated October 19, 2018	10-K	10.43	001-36745	12/18/2018	Filed
10.41	Intellectual Property Security Agreement dated October 19, 2018	10-K	10.44	001-36745	12/18/2018	Filed
10.42	Securities Purchase Agreement, dated August 31, 2018	10-K	10.45	001-36745	12/18/2018	Filed
10.43	Underwriting Agreement entered into by and between Applied DNA Sciences, Inc. and Maxim Group LLC, as sole underwriter, dated December 21, 2018	8-K	1.1	001-36745	12/21/2019	Filed
10.44	Form of Common Stock Purchase Warrant	8-K	4.1	001-36745	12/21/2019	Filed
10.45	First Amendment to Intellectual Property Security Agreement, Dated February 26, 2019, between the Company and Delaware Trust Company as collateral agent for the benefit of the investors listed thereto	10-Q	10.8	001-36745	5/9/2019	Filed
10.46	First Amendment to Intellectual Property Security Agreement, dated February 26, 2019, between APDN (B.V.I.), Inc. and Delaware Trust Company as collateral agent for the benefit of the investors listed thereto.	10-Q	10.9	001-36745	5/9/2019	Filed
10.47	Second Amendment to Intellectual Property Security Agreement, dated July 19, 2019 by the Company in favor of Delaware Trust Company as collateral agent for the secured parties defined therein.	10-Q	10.8	001-36745	8/13/2019	Filed
10.48	Second Amendment to Intellectual Property Security Agreement, dated July 19, 2019 by APDN (B.V.I.) Inc. in favor of Delaware Trust Company as collateral agent for the secured parties defined therein.	10-Q	10.9	001-36745	8/13/2019	Filed
10.49+	Patent and Know-How License and Cooperation Agreement, dated March 28, 2019, between the Company, APDN (B.V.I.), Inc., and ETCH BioTrace S.A.	10-Q	10.10	001-36745	5/9/2019	Filed
10.50	Omnibus Amendment Agreement, dated February 26, 2019, among the Company, APDN (B.V.I.), Inc., and Delaware Trust Company as collateral agent for the benefit of the buyers listed on Schedule I thereto.	10-Q	10.7	001-36745	5/9/2019	Filed
10.51	Form of Secured Convertible Note	8-K	10.1	001-36745	7/17/2019	Filed
10.52	Registration Rights Agreement, dated July 16, 2019 by and among Applied DNA Sciences, Inc. and the investor named on the signature page thereof.	8-K	10.2	001-36745	7/17/2019	Filed
10.53	Securities Purchase Agreement, dated July 16, 2019 by and among Applied DNA Sciences, Inc. and the investor named on the signature page thereof.	8-K	10.3	001-36745	7/17/2019	Filed
10.54	Amendment to Secured Convertible Notes, dated July 16, 2019 by and among Applied DNA Sciences, Inc. and the investors named on the signature page thereof.	8-K	10.4	001-36745	7/17/2019	Filed
10.55	Omnibus Amendment Agreement, dated July 16, 2019 by and among Applied DNA Sciences, Inc. and the parties named on the signature page thereof.	8-K	10.5	001-36745	7/17/2019	Filed
10.56	Second Omnibus Amendment Agreement, dated July 19, 2019 by and among the Company, APDN (B.V.I.) Inc., and Delaware Trust Company, as collateral agent for the benefit of the buyers listed on Schedule I thereto.	10-Q	10.7	001-36745	8/13/2019	Filed
10.57	Asset Purchase Agreement, dated July 29, 2019 by and between LineaRX, Inc. and Vitatex Inc.	8-K	10.1	001-36745	8/12/2019	Filed
10.58	Form of Subscription Agreement between investors and Applied DNA Sciences, Inc., dated August 22, 2019.	8-K	10.1	001-36745	8/26/2019	Filed
21.1	Subsidiaries of Applied DNA Sciences, Inc.	S-1/A	21.1	333-199121	10/30/2014	
23.1	Consent of Marcum LLP					Filed
31.1	Certification of Chief Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					Filed
31.2	Certification of Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					Filed
32.1	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					Filed
32.2	Certification of Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					Filed
101 INS	XBRL Instance Document					Filed
101 SCH	XBRL Taxonomy Extension Schema Document					Filed
101 CAL	XBRL Taxonomy Extension Calculation Linkbase Document					Filed
101 DEF	XBRL Taxonomy Extension Definitions Linkbase Document					Filed
101 LAB	XBRL Taxonomy Extension Labels Linkbase Document					Filed
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document					Filed

† Indicates a management contract or any compensatory plan, contract or arrangement.

* A request for confidentiality has been granted for certain portions of the indicated document. Confidential portions have been omitted and filed separately with the SEC as required by Rule 24b-2 promulgated under the Exchange Act.

+ Portions of this exhibit have been omitted because the information is both not material and would likely cause competitive harm to the registrant if publicly disclosed. The omissions have been indicated by bracketed asterisks ("[***]").

** Schedules (or similar attachments) have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Applied DNA Sciences, Inc. agrees to furnish supplementally a copy of any such omitted schedule or attachment to the U.S. Securities and Exchange Commission upon request; provided, however, that Applied DNA Sciences, Inc. may request confidential treatment pursuant to Rule 24b-2 under the Exchange Act for any schedule or attachment so furnished.

APPLIED DNA SCIENCES, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Applied DNA Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Applied DNA Sciences, Inc. (the "Company") as of September 30, 2019 and 2018, the related consolidated statements of operations, (deficit) equity and cash flows for each of the two years in the period ended September 30, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2019, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Marcum llp

Marcum llp

We have served as the Company's auditor since 2014.

Melville, NY
December 12, 2019

APPLIED DNA SCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2019 AND 2018

	September 30,	
	2019	**2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 558,988	$ 1,659,564
Accounts receivable, net of allowance of $4,500 and $13,133 at September 30, 2019 and 2018, respectively	839,951	1,485,938
Inventories	142,629	221,369
Prepaid expenses and other current assets	604,740	635,174
Total current assets	2,146,308	4,002,045
Property and equipment, net	226,221	419,774
Other assets:		
Deferred offering costs	109,698	-
Deposits	62,351	62,325
Goodwill	285,386	285,386
Intangible assets, net	734,771	864,203
Total Assets	$ 3,564,735	$ 5,633,733
LIABILITIES AND (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities (including related party of $5,844 at September 30, 2018)	$ 1,616,997	$ 965,167
Deferred revenue	628,993	1,856,693
Total current liabilities	2,245,990	2,821,860
Long term accrued liabilities	621,970	470,739
Secured convertible notes payable, net of debt issuance costs (including related party of $1,139,490 at September 30, 2018	1,442,497	1,586,631
Secured convertible notes payable, recorded at fair value	102,777	-
Total liabilities	4,413,234	4,879,230
Commitments and contingencies		
Applied DNA Sciences, Inc. Stockholders' (Deficit) Equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- shares issued and outstanding as of September 30, 2019 and 2018	-	-
Series A Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2019 and 2018	-	-
Series B Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2019 and 2018	-	-
Common stock, par value $0.001 per share; 500,000,000 shares authorized; 1,200,399 and 752,802 shares issued and outstanding as of September 30, 2019 and 2018, respectively	1,200	753
Additional paid in capital	255,962,930	249,119,833
Accumulated deficit	(256,805,589)	(248,366,083)
Applied DNA Sciences, Inc.'s stockholders' (deficit) equity	(841,459)	754,503
Noncontolling interest	(7,040)	-
Total (deficit) equity	(848,499)	754,503
Total Liabilities and (Deficit) Equity	$ 3,564,735	$ 5,633,733

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2019 AND 2018

	2019	2018
Revenues:		
Product revenues	$ 2,136,055	$ 1,827,626
Service revenues	3,253,034	2,075,717
Total revenues	5,389,089	3,903,343
Cost of revenues	877,613	1,206,814
Operating expenses:		
Selling, general and administrative	10,278,045	11,043,463
Research and development	2,967,278	2,751,578
Depreciation and amortization	390,424	547,796
Total operating expenses	13,635,747	14,342,837
LOSS FROM OPERATIONS	(9,124,271)	(11,646,308)
Other (expense) income:		
Interest (expense) income, net (including related party interest of $46,586 and $5,844 for the years ended September 30, 2019 and 2018, respectively)	(162,432)	(9,615)
Other expense, net	(43,299)	(37,005)
Loss on extinguishment of debt	(1,260,399)	-
Unrealized gain on change in fair value of secured convertible notes payable	1,972,955	-
Loss before provision for income taxes	(8,617,446)	(11,692,928)
Provision for income taxes	15,000	-
NET LOSS	$ (8,632,446)	$ (11,692,928)
Less: Net loss attributable to noncontrolling interest	9,323	-
NET LOSS attributable to Applied DNA Sciences, Inc.	$ (8,623,123)	$ (11,692,928)
Deemed dividend related to warrant modifications	(309,607)	-
NET LOSS applicable to common stockholders	$ (8,932,730)	$ (11,692,928)
Net loss per share applicable to common stockholders-basic and diluted	$ (9.69)	$ (15.86)
Weighted average shares outstanding-basic and diluted	921,809	737,441

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC.
CONSOLIDATED STATEMENTS OF (DEFICIT) EQUITY
YEARS ENDED SEPTEMBER 30, 2019 and 2018

	Common Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Total
Balance, October 1, 2017	684,427	$ 684	$ 243,530,551	$ (236,673,155)	$ -	$ 6,858,080
Common stock issued in private placement, net of offering costs	68,375	69	4,232,931	-	-	4,233,000
Stock based compensation expense	-	-	1,356,351	-	-	1,356,351
Net loss	-	-	-	(11,692,928)	-	(11,692,928)
Balance, September 30, 2018	752,802	$ 753	$ 249,119,833	$ (248,366,083)	$ -	$ 754,503
Common stock issued in public offering, net of offering costs	150,000	150	2,463,441	-	-	2,463,591
Common stock issued in private placement, net of offering costs	38,704	39	402,342	-	-	402,381
Impact of adoption of new accounting pronouncements included in accumulated deficit	-	-	-	493,224	-	493,224
Exercise of warrants	55,376	55	987,446	-	-	987,501
Exercise of warrants cashlessly	100,617	100	(100)	-	-	-
Common stock issued in secured convertible note conversion	102,900	103	1,440,402	-	-	1,440,505
Deemed dividend - warrant repricing	-	-	309,607	(309,607)	-	-
Investment in LineaRx, Inc.	-	-	110,849	-	2,283	113,132
Stock based compensation expense	-	-	1,129,110	-	-	1,129,110
Net Loss	-	-	-	(8,623,123)	(9,323)	(8,632,446)
Balance, September 30, 2019	1,200,399	$ 1,200	$ 255,962,930	$ (256,805,589)	$ (7,040)	$ (848,499)

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC.
CONSOLIDATED STATEMENT OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2019 AND 2018

	2019	2018
Cash flows from operating activities:		
Net loss	$ (8,632,446)	$ (11,692,928)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	390,424	547,796
Loss on extinguishment of debt	1,260,399	-
Unrealized gain on change in fair value of senior secured convertible notes	(1,972,955)	-
Stock based compensation expense	1,129,110	1,356,351
Non-cash in process research and development	251,420	-
Amortization of debt issuance costs	23,828	1,479
Provision for bad debts	7,624	20,552
Change in operating assets and liabilities:		
Accounts receivable	638,339	1,081,480
Inventories	78,740	105,099
Prepaid expenses, other current assets and deposits	23,767	(268,920)
Accounts payable and accrued liabilities	667,898	426,924
Deferred revenue	(727,920)	1,504,958
Net cash used in operating activities	(6,861,772)	(6,917,209)
Cash flows from investing activities:		
Purchases of property and equipment	(67,438)	(266,008)
Net cash used in investing activities	(67,438)	(266,008)
Cash flows from financing activities:		
Proceeds from secured convertible notes payable (including related parties of $550,000 and $1,185,000 for the years ended September 30, 2019 and 2018, respectively)	1,985,392	1,650,000
Net proceeds from sale of common stock and warrants	2,463,591	4,233,000
Net proceeds from private placement	402,381	-
Proceeds from exercise of warrants	987,501	-
Capitalized offering costs	(10,231)	-
Net cash provided by financing activities	5,828,634	5,883,000
Net decrease in cash and cash equivalents	(1,100,576)	(1,300,217)
Cash and cash equivalents at beginning of year	1,659,564	2,959,781
Cash and cash equivalents at end of year	$ 558,988	$ 1,659,564
Supplemental Disclosures of Cash Flow Information:		
Cash paid during year for interest	$ -	$ -
Cash paid during year for income taxes	$ -	$ -
Non-cash investing and financing transactions:		
Public offering costs included in accounts payable and accrued liabilities	$ 99,468	$ 64,848
Deemed dividend-warrant repricing	$ 309,607	$ -
Interest paid in kind (related party of $98,752)	$ 126,980	$ -
Impact of adoption of new accounting pronouncements included in accumulated deficit	$ 493,223	-
Warrants exercised cashlessly	$ 100	$ -
Conversion of notes payable	$ 1,440,505	$ -

See the accompanying notes to the consolidated financial statements

NOTE A – LIQUIDITY AND MANAGEMENT'S PLAN

Applied DNA Sciences, Inc. (the "Company") has recurring net losses, which have resulted in an accumulated deficit of $256,805,589 as of September 30, 2019. The Company incurred a net loss of $8,632,446 and generated negative operating cash flow of $6,861,772 for the fiscal year ended September 30, 2019. At September 30, 2019 the Company had cash and cash equivalents of $558,988 and working capital deficit of $99,682.

The Company's current capital resources include cash and cash equivalents, accounts receivable and inventories. The Company expects to finance its operations primarily through cash received from the November 2019 underwritten public offering, discussed below, as well as collection of its accounts receivable. The Company estimates that it will have sufficient cash and cash equivalents to fund operations for the next twelve months from the date of filing of this annual report. Historically, the Company has financed its operations principally from the sale of equity and equity-linked securities.

As discussed in Note H, on November 15, 2019 the Company closed on an underwritten public offering of 2,285,000 shares of common stock and warrants to purchase up to an aggregate of 2,285,000 shares of common stock. Each share of common stock was sold together with one warrant to purchase one share of common stock at a combined effective price to the public of $5.25 per share and accompanying warrant. Gross proceeds, before underwriting discounts and commissions and estimated offering expenses, were approximately $12.0 million. After deducting underwriting discounts and commissions and other estimated offering expenses total expected net proceeds are $10.8 million.

The Company has granted the underwriters a 45-day option to purchase up to an additional 342,750 shares of common stock and/or warrants to purchase up to 342,750 shares of common stock, at the public offering price less discounts and commissions.

The Company may require additional funds to complete the continued development of its products, product manufacturing, and to fund expected additional losses from operations until revenues are sufficient to cover its operating expenses. If revenues are not sufficient to cover the Company's operating expenses, and if it is not successful in obtaining the necessary additional financing, the Company will most likely be forced to reduce operations.

NOTE B – SUMMARY OF ACCOUNTING POLICIES

Business and Basis of Presentation

On September 16, 2002, the Company was incorporated under the laws of the State of Nevada. Effective December 2008, the Company reincorporated from the State of Nevada to the State of Delaware. The Company is principally devoted to developing and marketing linear DNA technology solutions in the United States, Europe and Asia. To date, the Company has produced limited recurring revenues from its products and services; it has incurred expenses and has sustained losses. Consequently, its operations are subject to all the risks inherent in the establishment and development of a biotechnology company.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, APDN (B.V.I.) Inc., Applied DNA Sciences Europe Limited, Applied DNA Sciences India Private Limited and its majority-owned subsidiary, LineaRx, Inc. ("LRx"). Applied DNA Sciences India Private Limited was incorporated in India on June 22, 2018 and LineaRx, Inc. was incorporated in Delaware on September 11, 2018. Significant inter-company transactions and balances have been eliminated in consolidation. To facilitate comparison of information across periods, certain reclassifications have been made to prior year amounts to conform to the current year's presentation.

On October 31, 2019, the Company filed a Certificate of Amendment of its Certificate of Incorporation with the Secretary of State of the State of Delaware that effected a one-for-forty (1:40) reverse stock split of its common stock, par value $.001 per share, effective November 1, 2019. All warrant, option, share, and per share information in the consolidated financial statements gives retroactive effect to a one-for-forty reverse stock split that was affected on November 1, 2019.

Use of Estimates

The preparation of the financial statements in conformity with Accounting Principles Generally Accepted in the U.S. ("GAAP") requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The most complex and subjective estimates include revenue recognition, recoverability of long-lived assets, including the values assigned to goodwill, intangible assets and property and equipment, fair value calculations for stock based compensation and convertible promissory notes, contingencies, allowance for doubtful accounts and management's anticipated liquidity. Management reviews its estimates on a regular basis and the effects of any material revisions are reflected in the consolidated financial statements in the period they are deemed necessary. Accordingly, actual results could differ from those estimates.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Revenue Recognition

In May 2014, the Financial Accounting Standards Board ("FASB") issued accounting standard updates which clarified principles for recognizing revenue arising from contracts with customers ("ASC 606" or "Topic 606") and superseded most current revenue recognition guidance, including industry-specific guidance. The core principle of the revenue standard is that an entity recognizes revenue to depict the transfer of promised goods or services to clients in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The new guidance applies a five-step model for revenue measurement and recognition and also requires increased disclosures including the nature, amount, timing, and uncertainty of revenue and cash flows related to contracts with clients.

The Company adopted the new revenue standard at the beginning of the first quarter of fiscal 2019, using the modified retrospective method of adoption and applied the guidance to those contracts that were not completed as of September 30, 2018. Comparative financial information for reporting periods beginning prior to October 1, 2018, has not been restated and continues to be reported under the previous reporting guidance. Under the modified retrospective method of adoption, the cumulative effect of applying the new standard is recorded at the date of initial application, with no restatement of the comparative prior periods presented. Based on the evaluation, the Company has identified certain customer contracts, which required different recognition under the new guidance. The Company has determined that the revenue under certain of its research and development contracts should be recognized on an over time basis using the input method as compared to ratably over the contract term. Also, the shipment to the Company's cotton customer during fiscal 2018 that included extended payment terms and was included in deferred revenue as of September 30, 2018, would have met the criteria under the new guidance to be recognized as revenue upon shipment. The Company has determined that the cumulative adjustment to opening retained earnings in fiscal 2019 was approximately $493,000.

The Company measures revenue at the amounts that reflect the consideration to which it is expected to be entitled in exchange for transferring control of goods and services to customers. The Company recognizes revenue either at the point in time or over the period of time that performance obligations to customers are satisfied. The Company's contracts with customers may include multiple performance obligations (e.g. taggants, maintenance, authentication services, research and development services, etc.). For such arrangements, the Company allocates revenues to each performance obligation based on their relative standalone selling price.

Under the new accounting guidance, the Company recognizes revenue upon transfer of control of promised goods or services to customers in an amount that reflects the consideration it expects to receive for those goods or services, including any variable consideration.

Due to the short-term nature of the Company's contracts with customers, it has elected to apply the practical expedients under Topic 606 to: (1) expense as incurred, incremental costs of obtaining a contract and (2) not adjust the consideration for the effects of a significant financing component for contracts with an original expected duration of one year or less.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Impact of Adoption

A summary and discussion of such cumulative effect adjustment and the impact on current period financial statements of adopting Topic 606 is as follows:

	Fiscal Year ended September 30, 2019		
	Prior U.S. GAAP	Topic 606 impact	As reported
Statement of Operations			
Revenues			
Product	$ 2,902,247	$ (766,192)	$ 2,136,055
Service	3,402,138	(149,104)	3,253,034
Total revenues	6,304,385	(915,296)	5,389,089
Cost of revenues	884,281	(6,668)	877,613
Loss from operations	(8,215,643)	(908,628)	(9,124,271)
Assets			
Prepaids and other current assets	$ 611,408	$ (6,668)	$ 604,740
Liabilities and (deficit) equity			
Deferred Revenue	$ 802,107	$ (173,114)	$ 628,993
Accumulated Deficit	(256,805,589)	-	(256,805,589)

Product Revenues and Authentication Services

The Company's PCR-produced linear DNA products, including molecular taggants are manufactured in accordance with contracts with customers. The Company recognizes revenue upon satisfying its promises to transfer goods or services to customers under the terms of its contracts. These performance obligations are satisfied at the point in time the Company transfers control of the goods to the customer, which in nearly all cases is when title to and risk of loss of the goods transfer to the customer. The timing of transfer of title and risk of loss is dictated by customary or explicitly stated contract terms. The Company does not consider payment terms a performance obligation for customers with contractual terms that are one year or less and has elected the practical expedient. Nearly all of the Company's sales contracts reflect market pricing at the time the contract is executed, are one year or less, and generally provide for shipment within 30 to 60 days after the price has been agreed upon with the customer. We invoice customers upon shipment, and our collection terms range, on average from 30-60 days

The cotton ginning season in the United States takes place between September and March each year; therefore, revenues from these customer contracts may be seasonal and recognized primarily during the first and fourth quarters of the Company's fiscal year.

Authentication Services

The Company recognizes revenue for authentication services upon satisfying its promises to provide services to customers under the terms of its contracts. These performance obligations are satisfied at the point in time the Company services are complete, which in nearly all cases is when the authentication report is released to the customer.

Research and Development Services

The Company records revenue for its research and development contracts using the over-time revenue recognition model. Revenue is primarily measured using the cost-to-cost method, which the Company believes best depicts the transfer of control to the customer. Under the cost-to-cost method, the extent of progress towards completion is measured based on the ratio of actual costs incurred to the total estimated costs expected upon satisfying the identified performance obligation.

Revenues are recorded proportionally as costs are incurred. For contracts where the total costs cannot be estimated, revenues are recognized for the actual costs incurred during a period until the remaining costs to complete a contract can be estimated. The Company has elected to not disclose the value of unsatisfied performance obligations for contracts with an original expected duration of one year or less.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Disaggregation of Revenue

The following table presents revenues disaggregated by our business operations and timing of revenue recognition:

	Fiscal Years Ended: September 30,	
	2019	2018
Research and development services (over-time)	$ 2,975,961	$ 1,766,202
Product and authentication services (point-in-time):		
Supply chain	1,438,106	674,224
Asset marking	587,012	1,002,934
Large scale DNA production	388,010	459,983
Total	$ 5,389,089	$ 3,903,343

Contract balances

As of September 30, 2019, the Company has entered into contracts with customers for which revenue has not yet been recognized. Consideration received from a customer prior to revenue recognition is recorded to a contract liability and is recognized as revenue when the Company satisfies the related performance obligations under the terms of the contract. The Company's contract liabilities, which are reported as deferred revenue on the consolidated balance sheet, consist almost entirely of research and development contracts where consideration has been received and the development services have not yet been fully performed.

The opening and closing balances of the Company's contract balances are as follows:

	Balance sheet classification	October 1, 2018	September 30, 2019	$ change
Contract liabilities	Deferred revenue	$ 1,356,502	$ 628,993	$ (727,509)

For the fiscal year ended September 30, 2019, the Company recognized $1,224,331 of revenue that was included in Contract liabilities as of October 1, 2018.

Cash Equivalents

For the purpose of the accompanying consolidated financial statements, all highly liquid investments with a maturity of three months or less are considered to be cash equivalents.

Accounts Receivable

The Company provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. The Company's estimate is based on historical collection experience and a review of the current status of trade accounts receivable. It is reasonably possible that the Company's estimate of the allowance for doubtful accounts may change.

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company classifies receivable amounts as current or long-term based on expected payment and records long-term accounts receivable when the collection period is expected to be greater than one year.

At September 30, 2019 and 2018, the Company has an allowance for doubtful accounts of $4,500 and $13,133, respectively. The Company writes-off receivables that are deemed uncollectible.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Inventories

Inventories, which consist primarily of raw materials and finished goods, is stated at the lower of cost or net realizable value, with cost determined by using the first-in, first-out (FIFO) method.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, Income Taxes ("ASC 740-10") which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statement or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Temporary differences between taxable income reported for financial reporting purposes and income tax purposes include, but not limited to, accounting for intangibles, equity based compensation and depreciation and amortization. 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 of the deferred tax asset will not be realized. During the fiscal years ended September 30, 2019 and 2018, the Company incurred losses from operations. Based upon these results and the trends in the Company's performance projected for fiscal year 2019, it is more likely than not that the Company will not realize any benefit from the deferred tax assets recorded by the Company in previous periods. Management makes judgments as to the interpretation of 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 for all years. If actual taxable income by tax jurisdiction varies from estimates, additional allowances or reversals of reserves may be necessary. The Company has identified its federal tax return and its state tax return in New York as "major" tax jurisdictions. Based on the Company's evaluation, it has been concluded that there are no significant uncertain tax positions requiring recognition in the Company's consolidated financial statements.

The Company believes that its income tax positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. It is the Company's policy to accrue interest and penalties on unrecognized tax benefits as components of income tax provision. The Company did not have any accrued interest or penalties as of September 30, 2019 and 2018. Tax years 2015 through 2018 remain subject to future examination by the applicable taxing authorities.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight line method over their estimated useful lives. The estimated useful life for computer equipment, lab equipment and furniture is 3 years and leasehold improvements are amortized over the shorter of their useful life or the remaining lease terms. Property and equipment consist of:

	September 30,	
	2019	2018
Computer equipment	$ 265,542	$ 135,621
Lab equipment	1,885,487	1,951,955
Furniture	74,781	74,781
Leasehold improvements	293,672	293,672
Total	2,519,482	2,456,029
Accumulated depreciation	2,293,261	2,036,255
Property and equipment, net	$ 226,221	$ 419,774

Depreciation expense for the fiscal years ended September 30, 2019 and 2018 were $260,992 and $369,924, respectively.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Impairment of Long-Lived Assets

The Company evaluates its long lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Events relating to recoverability may include significant unfavorable changes in business conditions, recurring losses, or a forecasted inability to achieve break-even operating results over an extended period. The Company evaluates the recoverability of long-lived assets based upon forecasted undiscounted cash flows. Should impairment in value be indicated, the carrying value of long-lived assets will be adjusted, based on estimates of future discounted cash flows resulting from the use and ultimate disposition of the asset.

Net Loss per Share

The Company presents loss per share utilizing a dual presentation of basic and diluted loss per share. Basic loss per share includes no dilution and has been calculated based upon the weighted average number of common shares outstanding during the period. Dilutive common stock equivalents consist of shares issuable upon the exercise of the Company's stock options and warrants.

For the fiscal years ended September 30, 2019 and 2018, common stock equivalent shares are excluded from the computation of the diluted loss per share as their effect would be anti-dilutive.

Securities that could potentially dilute basic net income per share in the future that were not included in the computation of diluted net loss per share because to do so would have been antidilutive for the fiscal years ended September 30, 2019 and 2018 are as follows:

	2019	2018
Warrants	263,592	305,217
Options	199,395	154,581
Secured convertible note	74,282	16,500
	573,269	476,298

Stock-Based Compensation

The Company accounts for stock-based compensation for employees, directors and nonemployees in accordance with ASC 718, Compensation ("ASC 718"). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Under the provisions of ASC 718, stock-based compensation costs are measured at the grant date, based on the fair value of the award, and are recognized as expense over the employee's requisite service period (generally the vesting period of the equity grant). The fair value of the Company's common stock options are estimated using the Black Scholes option-pricing model with the following assumptions: expected volatility, dividend rate, risk free interest rate and the expected life. The Company expenses stock-based compensation by using the straight-line method. In accordance with ASC 718 and, excess tax benefits realized from the exercise of stock-based awards are classified as cash flows from operating activities. All excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) are recognized as income tax expense or benefit in the condensed consolidated statements of operations.

Concentrations

Financial instruments and related items, which potentially subject the Company to concentrations of credit risk, consist primarily of cash, cash equivalents and trade receivables. The Company places its cash and cash equivalents with high credit quality institutions. At times, such investments may be in excess of the FDIC insurance limit.

The Company's revenues earned from sale of products and services for the fiscal year ended September 30, 2019 included an aggregate of 27%, 26% and 15%, respectively from three customers.

The Company's revenues earned from sale of products and services for the fiscal year ended September 30, 2018 included an aggregate of 24%, 16%, 14% and 11%, respectively from four customers.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

One customer accounted for 77% of the Company's accounts receivable at September 30, 2019 and one customer accounted for an aggregate of 80% of the Company's total accounts receivable at September 30, 2018.

Research and Development

The Company accounts for research and development costs in accordance with the ASC 730, Research and Development ("ASC 730"). Under ASC 730, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and development costs are expensed when the contracted work has been performed or as milestone results have been achieved. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred. During the fiscal years ended September 30, 2019 and 2018, the Company incurred research and development expenses of $2,967,278 and $2,751,578, respectively.

Advertising

The Company follows the policy of charging the costs of advertising to expense as incurred. The Company charged to operations approximately $133,000 and $287,156, as advertising costs for the fiscal years ended September 30, 2019 and 2018, respectively.

Goodwill and Other Intangible Assets

The Company amortizes its intangible assets using the straight-line method over their estimated period of benefit. All of the Company's intangible assets, except for goodwill are subject to amortization.

Goodwill arises as a result of business acquisitions. Goodwill consists of the excess of the cost of the acquisitions over the tangible and intangible assets acquired and liabilities assumed.

The Company evaluates goodwill for impairment at least annually. The Company qualitatively and quantitatively determines whether, more likely than not, the fair value exceeds the carrying amount of a reporting unit. There are numerous assumptions and estimates underlying the quantitative assessments including future earnings, long-term strategies, and the Company's annual planning and forecasts. If these planned initiatives do not accomplish the targeted objectives, the assumptions and estimates underlying the quantitative assessments could be adversely affected and have a material effect upon the Company's financial condition and results of operations. As of September 30, 2019 and 2018, the Company performed its qualitative assessment of goodwill and indicated that there was no impairment.

Internally Developed Software

Internally developed software products, consist of capitalized costs associated with the development of computer software to be sold, leased or otherwise marketed. Software development costs associated with new products are expensed as incurred until technological feasibility, as defined in FASB ASC Topic 985-20, has been established. Costs incurred thereafter are capitalized until the product is made generally available. The stage during the Company's development process for a new product or new release at which technological feasibility requirements are established affects the amount of costs capitalized. Annual amortization of internally developed software products is the greater of the amount computed using the ratio that current gross revenues for a product bear to the total of current and anticipated future gross revenues for that product or the straight-line method over the remaining estimated economic life of the software product, generally estimated to be 3 years from the date the product became available for general release to customers. The Company generally recognizes amortization expense for capitalized software costs using the straight-line method. Internally developed software products are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and its carrying amount exceeds its fair value.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Convertible Instruments

The Company accounts for convertible instruments (when it has determined that the embedded conversion options should not be bifurcated from their host instruments) in accordance with ASC 470-20, Debt with Conversion and Other Options. Accordingly, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their earliest date of redemption.

Fair Value of Financial Instruments

The valuation techniques utilized are based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect internal market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Level 2 — Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related asset or liabilities.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of assets or liabilities.

The Company utilizes observable market inputs (quoted market prices) when measuring fair value whenever possible.

For fair value measurements categorized within Level 3 of the fair value hierarchy, the Company's accounting and finance department, who report to the Chief Financial Officer, determine its valuation policies and procedures. The development and determination of the unobservable inputs for Level 3 fair value measurements and fair value calculations are the responsibility of the Company's accounting and finance department and are approved by the Chief Financial Officer.

As of September 30, 2019, there were no transfers between Levels 1, 2 and 3 of the fair value hierarchy.

Summary of Significant Valuation Techniques

Level 3 Measurements:

Secured convertible notes payable: For the Existing Notes (as defined in Note G), the Company has elected to record them at fair value. The fair value for the Existing Notes is estimated using the Monte Carlo simulation model. Significant observable and unobservable inputs include stock price, conversion price, annual risk free rate, term, likelihood of an event of default, and expected volatility. An increase or decrease in these inputs could significantly increase or decrease the fair value of the secured convertible notes payable. See Note G.

Recently Issued Accounting Standards

In November 2018, the FASB issued ASU 2018-18," Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606" ("ASU 2018-18"). The amendments in this update clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606. ASU 2018-18 is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently assessing the impact of ASU 2018-18 on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation – "Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting", which addresses aspects of the accounting for nonemployee share-based payment transactions. This pronouncement is effective for annual reporting periods and interim periods within those annual periods beginning after December 15, 2019. The Company early adopted ASU 2018-07 on October 1, 2018 using the modified retrospective transition approach. The cumulative -effect adjustment to opening retained earnings was not material.

In July 2017, the FASB issued a two-part ASU No. 2017-11, I. Accounting for Certain Financial Instruments With Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception ("ASU 2017-11"). ASU 2017-11 amends guidance in FASB ASC 260, Earnings Per Share, FASB ASC 480, Distinguishing Liabilities from Equity, and FASB ASC 815, Derivatives and Hedging. The amendments in Part I of ASU 2017-11 change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. The amendments in Part II of ASU 2017-11 re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. ASU 2017-11 is effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted. The Company adopted ASU 2017-11 during the fiscal year ended September 30, 2019. The effect of adoption was $0.34 per share to basic and diluted earnings per share.

In May 2017, FASB issued ASU No. 2017-09, Compensation – "Stock Compensation (Topic 718): Scope of Modification Accounting" ("ASU 2017-09"), which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This pronouncement is effective for annual reporting periods and interim periods within those annual periods beginning after December 15, 2017. Early adoption is permitted. The Company adopted ASU 2017-09 during the fiscal year ended September 30, 2019 and it did not have a material impact on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-04, "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment" ("ASU 2017-04"). The purpose of the amendment is to simplify how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. For public entities, the amendments in ASU 2017-04 are effective for interim and annual reporting periods beginning after December 15, 2019. The Company is currently assessing the impact of ASU 2017-04 on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)." The objective of this update is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. This ASU is effective for fiscal years beginning after December 15, 2018, including interim periods within those annual periods and is to be applied utilizing a modified retrospective approach. The Company is currently evaluating the new guidance and does not expect the adoption to have a significant impact on its consolidated financial statements, as the Company does not currently have any long-term lease obligations.

NOTE C – INVENTORIES

Inventories consist of the following at September 30, 2019 and 2018:

	2019	2018
Raw materials	$ 87,886	$ 147,984
Finished goods	54,743	73,385
Total	$ 142,629	$ 221,369

NOTE D – ASSET PURCHASE AGREEMENT

During August 2019, LRx entered into an Asset Purchase Agreement (the "Vitatex Agreement") with Vitatex, Inc. ("Vitatex"), providing for the purchase of substantially all of the assets of Vitatex ("Vitatex Assets"). The Vitatex assets relate to the business of an early stage private biotechnology company focused on advancing personalized medicine with a potential solution that isolates Invasive Circulating Tumor Cells ("iCTCs") from standard patient blood samples. The acquisition of the Vitatex Assets was completed in August 2019. The Vitatex Assets include physical assets, such as laboratory equipment, as well as registered trademarks and other intellectual property. The Vitatex Assets also include Vitatex's rights under an exclusive patent license agreement between The Research Foundation for the State University of New York (the "Research Foundation") and Vitatex. The Company did not assume any liabilities of Vitatex. In connection with the acquisition of the Vitatex Assets, the Company entered into the Amended and Restated Exclusive License Agreement with the Research Foundation and Vitatex on August 7, 2019, pursuant to which the Company assumed the rights to a global patent portfolio covering the iCTC technology.

The purchase price for the Vitatex Assets consisted of $500,000 in cash and common stock of LRx and up to an additional $500,000 of LRx common stock as performance-based contingent consideration. Of this amount, (i) an initial payment comprised of $300,000 in shares of common stock of LRx made to the shareholders of Vitatex, (ii) $100,000 in cash must be paid to Vitatex on or before September 30, 2019, subject to adjustment as provided below, and (iii) $100,000 in cash must be paid to Vitatex on or before December 31, 2019. The purchase price was reduced by an amount equal to any payment required to be made by LRx to pay off and satisfy Vitatex's outstanding cash and/or equity obligations owed to the Research Foundation under the License Agreement as delineated in the Restated License Agreement. Pursuant to the Restated License Agreement, LRx paid $11,710 in cash to the Research Foundation, thereby reducing the cash payment due to Vitatex before September 30, 2019 to $88,290. In addition, the shareholders of Vitatex are also entitled to additional performance-based equity distributions of up to $500,000 in shares of common stock of LRx with (i) $250,000 of LRx common stock that was paid upon the occurrence of LRx completing certain National Cancer Institute Small Business Innovation Research program filings, (ii) $100,000 of LRx common stock that will become due if the Vitatex Assets yield more than $100,000 in gross revenue by July 29, 2020 and (iii) $150,000 of LRx common stock that will become due if the Vitatex Assets yield an additional $200,000 in gross revenue. The Research Foundation will receive cash instead of shares of LRx upon the completion of any such performance-based events. As part of this transaction, the Company issued 2% of LRx's common stock, valued at $113,132.

This transaction was accounted for as an asset acquisition in accordance with ASC 805. The Company concluded that since the assets acquired were considered in process research and development assets, the value of $345,332 that was assigned to the "know-how" was expensed to research and development expenses in the consolidated statement of operations for the fiscal year ended September 30, 2019. For the remaining contingent consideration, the Company has determined that it is not probable that the milestones will be met and therefore, no liability is recorded as of September 30, 2019.

NOTE E – INTANGIBLE ASSETS

Intangible assets at September 30, 2019 and 2018 are as follows:

	2019	2018
Internally developed software (5-year useful life)	$ 157,221	$ 157,221
Customer relationships (10-year useful life)	621,000	621,000
Intellectual property (5-15 years)	917,350	917,350
	1,695,571	1,695,571
Less:		
Accumulated amortization	960,800	831,368
Intangible assets, net	$ 734,771	$ 864,203

Total amortization expense charged to operations for the fiscal years ended September 30, 2019 and 2018 were $129,432 and $177,872, respectively.

The following table presents the estimated amortization expense of the intangible assets for each of the five succeeding years as of September 30, 2019:

	Amount
2020	$ 129,432
2021	91,967
2022	91,967
2023	91,967
2024	91,967
Thereafter	237,471
Total	$ 734,771

NOTE F – ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities at September 30, 2019 and 2018 are as follows:

	2019	2018
Accounts payable	$ 1,152,103	$ 500,849
Accrued salaries payable	319,260	401,130
Income taxes payable	15,000	-
Other accrued expenses	130,634	63,188
Total	$ 1,616,997	$ 965,167

NOTE G – SECURED CONVERTIBLE NOTES PAYABLE

On August 31, 2018, the Company entered into a securities purchase agreement (the "Purchase Agreement") with accredited investors and certain members of its management team and Board of Directors (the "Purchasers"), pursuant to which the Company issued and sold an aggregate of $1,650,000 in principal amount of secured convertible notes (the "August 2018 Notes") bearing interest at a rate of 6% per annum. As part of the August 2018 Notes, the Company's management and Board of Directors purchased August 2018 Notes with a principal amount of $1,185,000.

The August 2018 Notes are convertible, in whole or in part, at any time, at the option of the Purchasers, into shares of the Company's Common Stock, in an amount determined by dividing the principal amount of each August 2018 Note, together with any and all accrued and unpaid interest, by the conversion price of $100.00. The Company has the right to require the Purchasers to convert all or any part of their August 2018 Notes into shares of its Common Stock at a conversion price of $100.00 if the price of the Common Stock remains at a closing price of $140.00 or more for a period of twenty consecutive trading days.

Upon any Change in Control (as defined in the August 2018 Notes), the Purchasers have the right to require the Company to redeem the August 2018 Notes, in whole or in part, at a redemption price equal to such August 2018 Notes' outstanding principal balance plus accrued interest.

The August 2018 Notes contain certain events of default that are customarily included in financing of this nature. If an event of default occurs, the Purchasers may require the Company to redeem the August 2018 Notes, in whole or in part, at a redemption price equal to such notes' outstanding principal balance plus accrued interest.

NOTE G – SECURED CONVERTIBLE NOTES PAYABLE, continued

The August 2018 Notes bear interest at the rate of 6% per annum, payable semi-annually in cash or in kind, at the Company's option, and are due and payable in full on August 30, 2021. Until the principal and accrued but unpaid interest under the August 2018 Notes is paid in full, or converted into shares of Common Stock pursuant to their terms, the Company's obligations under the August 2018 Notes will be secured by a lien on substantially all assets of the Company (excluding certain cash accounts) and the assets of APDN (B.V.I.) Inc.

The Company has also entered into a registration rights agreement, dated as of the date of the Purchase Agreement, with the Purchasers, pursuant to which it has agreed to prepare and file a registration statement with the SEC to register under the Securities Act of 1933, as amended (the "Securities Act") resales from time to time of the Common Stock issued or issuable upon conversion or redemption of the August 2018 Notes. The Company is required to file a registration statement within 60 days of receiving a demand registration request from holders of a majority of the outstanding principal balance of the August 2018 Notes, and to cause the registration statement to be declared effective within 45 days (or 90 days if the registration statement is reviewed by the SEC).

On November 29, 2018, the Company closed a securities purchase agreement with its chairman, president and chief executive officer and one member of the management team, pursuant to which the Company issued and sold an aggregate of $550,000 in principal amount of secured convertible notes bearing interest at a rate of 6% per annum (the "November 2018 Notes"). The November 2018 Notes are substantially similar to the Company's August 2018 Notes except with respect to maturity date, which is November 29, 2021 The November 2018 Notes are secured on a *pari passu* basis with the same Company assets as the August 2018 Notes.

On July 17, 2019, the Company closed $1.5 million in gross proceeds in July 2019 Notes, bearing interest at a rate of 6% per annum, in a non-brokered private placement with an accredited investor, Dillon Hill Capital, LLC ("Dillon Hill") and simultaneously amended the terms of the Existing Notes and, (together with the July 2019 Notes, the "Company Notes") to, among other amendments, (i) reduce the conversion price of the Existing Notes to $21.60 to facilitate their conversion into equity and (ii) change the maturity date of the August 2018 Notes to be November 28, 2021. Under the terms of the July 2019 Notes, until October 13, 2019, Dillon Hill had the right to purchase on the same terms as the July 16, 2019 sale up to an additional $500,000 in principal amount of the July 2019 Notes, and up to an additional $1 million in principal amount of the July 2019 Notes if approved by the Company. This right was not exercised. In addition, Dillon Hill was granted a right to participate in certain future financing transactions of the Company (each a "Subsequent Financing") until July 16, 2020 equal to the amount required for Dillon Hill to maintain its pro rata ownership of the Company as if the July 2019 Notes had been fully converted into Common Stock. Until July 16, 2020, Dillon Hill shall have the right to participate in full for the first $1 million of such Subsequent Financing. This right was exercised and Dillon Hill participated in the November 2019 underwritten public offering.

After giving effect to the amendments to the Existing Notes, the July 2019 Notes are substantially similar to the Existing Notes. The July 2019 Notes are secured on a *pari passu* basis with the same Company assets as the Existing Notes. In addition, on July 19, 2019, the Company also amended the security agreements dated as of October 19, 2018, to among other amendments, exclude 20% of the Company's equity interest in LRx from the assets securing the Company Notes. The July 2019 Notes are convertible, in whole or in part, at any time, at the option of Dillon Hill, into shares of Common Stock, in an amount determined by dividing the principal amount of the July 2019 Notes, together with any and all accrued and unpaid interest, by the conversion price of $21.60 (the "Conversion Price"). The July 2019 Notes are due and payable in full on November 28, 2021.

On or before September 30, 2019, the Company had the right to prepay all or a portion of the July 2019 Notes. If the Company exercised such option, Dillon Hill had the option to (i) convert all or any part of the July 2019 Notes into shares of Common Stock at the Conversion Price or (ii) redeem the July 2019 Notes at a redemption price equal to the outstanding principal balance plus accrued interest of the July 2019 Notes and be issued warrants equal in amount to 40% of the shares of Common Stock that Dillon Hill would have received had it elected to convert its July 2019 Note into shares of Common Stock. Such warrants, if any, would have an exercise price equal to 105% of the Conversion Price. Further, the Company has the right to require Dillon Hill to convert all or any part of their Notes into shares of the Company's Common Stock at the Conversion Price if the price of the Common Stock remains at a closing price of $140.00 or more for a period of twenty consecutive trading days. The prepayment option expired on September 30, 2019.

The July 2019 Notes and the Existing Notes, after giving effect to the amendments to the Existing Notes, contain certain negative covenants that restrict the Company, including prohibitions or limitations, among other things, on the incurrence of additional indebtedness, subsidiary asset sales, intercompany loans, liens, amendments to the Company's organization documents, dividends, and redemptions without consent of the Required Holders (as defined in the Company Notes).

NOTE G – SECURED CONVERTIBLE NOTES PAYABLE, continued

The July 2019 Notes contain certain events of default that are customarily included in financings of this nature. If an event of default occurs, Dillon Hill (by an affirmative vote of the holders of the Company Notes representing at least 30% of the aggregate principal amount of the Company Notes then outstanding) may require the Company to redeem the July 2019 Notes, in whole or in part, at a redemption price equal to the greater of (i) their outstanding principal balance, plus all accrued and unpaid interest, divided by the Conversion Price, multiplied by the volume-weighted average price (VWAP) on the date the redemption price is either (x) demanded or otherwise due or (y) paid in full, whichever has a higher VWAP, or (ii) 130% of the outstanding principal, plus all accrued and unpaid interest.

The amendments to the Existing Notes resulted in a change in fair value of the conversion option that exceeded ten percent of the carrying amount of the Existing Notes. Accordingly, the amendment was treated as an extinguishment of the Existing Notes and a corresponding loss on extinguishment of debt of $1,260,399. The fair value of the Existing Notes immediately after the amendments ("Amended Existing Notes") was $3,498,457. Going forward, the Company has elected to record the Amended Existing Notes at fair value in accordance with ASC 825. As a result, the Company recorded a gain on the change in fair value of $65,576 for the year ended September 30, 2019. The July 2019 Notes are recorded at carrying value.

During September 2019, a total of $2.2 million of the Amended Existing Notes was converted into 102,893 shares of the Company's common stock. As part of the total amount converted, Dr. James A. Hayward, our Chairman, Chief Executive Officer and President ("CEO"), converted approximately $1.59 million of the Amended Existing Notes, into approximately 73,400 shares of the Company's common stock, and other directors, officers, and affiliates of the Company converted approximately $409,000 of such Existing Notes in September 2019 into 18,929 shares of the Company's common stock. The fair value of the Amended Existing Notes was calculated immediately prior to conversion and resulted in a gain on the change in fair value of the Amended Existing Notes of approximately $1,907,379.

During the fiscal year ended September 30, 2019, the Company reclassified $126,980 from accrued liabilities to senior secured notes payable to represent interest due to noteholders that was paid in kind and therefore increasing the convertible note balance outstanding at September 30, 2019.

The Company incurred $64,848 to debt issuance costs based on the cost incurred to complete the Existing Notes financing, which was written off as part of the extinguishment accounting discussed above. The Company incurred $64,608 to debt issuance costs based on the cost incurred to complete the July 2019 Notes. During the fiscal years ended September 30, 2019 and 2018 the Company amortized $23,828 and $1,479, respectively, of debt issuance costs resulting in unamortized debt issuance costs of $59,698 and the secured notes payable of $1,602,777 at September 30, 2019. The debt issuance cost will be amortized over the life of the Company Notes. During the fiscal years ended September 30, 2019 and 2018, the Company incurred $138,604 and $8,136 of interest expense. The effective interest rate for the fiscal years ended September 30, 2019 and 2018 was 7.5% and 7.4%, respectively.

NOTE H – CAPITAL STOCK

On October 31, 2019, the Company filed a Certificate of Amendment of its Certificate of Incorporation with the Secretary of State of the State of Delaware that effected a one-for-forty (1:40) reverse stock split of its common stock, par value $.001 per share, effective November 1, 2019. All warrant, option, share, and per share information in the consolidated financial statements gives retroactive effect to the one-for-forty reverse stock split that was effected on November 1, 2019.
Common Stock Transactions subsequent to the Fiscal Year Ended September 30, 2019:

On November 15, 2019, the Company closed an underwritten public offering (the "Offering") in which, pursuant to the Underwriting Agreement dated November 13, 2019 by and between the Company and Maxim Group LLC ("Maxim"), as Representative of the Underwriters, the Company issued and sold 2,285,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock") and 2,285,000 accompanying warrants each with the right to purchase one share of Common Stock at an exercise price of $5.25 per share (the "Common Warrants"). The shares of Common Stock and accompanying Common Warrants were sold at a combined offering price of $5.25 before underwriting discounts. The Common Stock and the Common Warrants are collectively referred to herein as the "Securities."

As part of the Offering, the Company granted Maxim an option to purchase an additional 342,750 shares of Common Stock and/or additional Common Warrants to purchase 342,750 shares of Common Stock (the "Option Warrants") at the public offering price, less discounts and commissions, to cover any over-allotments made by the Underwriters in the sale and distribution of the Securities. The option to purchase additional shares of Common Stock and/or Option Warrants has not yet been exercised and may be exercised from time to time within 45 days after November 13, 2019.

The gross proceeds of the offering, before deducting Underwriter discounts and commissions and other offering expenses, are approximately $12.0 million, or approximately $13.8 million if the Underwriters exercise in full their overallotment option. After deducting Underwriter fees and other estimated expenses related to the underwritten public offering, we estimate the aggregate net proceeds to be approximately $10.8 million, assuming the overallotment option is not exercised.

Pursuant to the Warrant Agreement, each Common Warrant will be exercisable beginning on the date of issuance thereof and ending on November 15, 2024.

The Common Warrant includes an adjustment provision that, subject to certain exceptions, reduces its exercise price if the Company issues Common Stock or Common Stock equivalents at a price lower than the then-current exercise price of the Common Warrant, subject to a minimum exercise price of $1.47 per share.

Subject to limited exceptions, a holder of a Common Warrant will not have the right to exercise any portion of its Common Warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that upon 61 days' prior notice to us, the holder may increase the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99%.

The exercise price and number of the shares of Common Stock issuable upon the exercise of the Common Warrant will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrant Agreement.

NOTE H – CAPITAL STOCK, continued

Common Stock Transactions during the Fiscal Year Ended September 30, 2019:

On August 22, 2019, the Company issued and sold 38,704 shares of common stock at a price of $10.80 per share for total gross proceeds of $418,000 to a group of accredited investors, including its chief executive officer, president and chairman of the board of directors, its chief information officer, and a 5% or greater stockholder.

On December 21, 2018, the Company entered into an underwriting agreement (the "Agreement") with Maxim, as the sole underwriter and book running manager, with respect to the issuance and sale of an aggregate of 137,500 shares (the "Shares") of Common Stock, together with warrants to purchase an aggregate of 137,500 shares of Common Stock (the "Warrants") at an exercise price equal to $20.00 per share of Common Stock (the "Exercise Price") in an underwritten public offering. The public offering price for each Share together with the accompanying Warrant was $20.00. Pursuant to the Agreement, the Company also granted Maxim a 45-day option to purchase an additional 20,625 Shares and/or additional Warrants to purchase 20,625 Shares to cover any over-allotments made by the underwriters in the sale and distribution of the Shares and Warrants. The gross proceeds of the offering, before deducting underwriter discounts and commissions and other offering expenses, were $2,750,000. The offering closed on December 26, 2018. On December 26, 2018, Maxim partially exercised its overallotment option and purchased an additional 20,000 Warrants at a price of $0.0000004 per Warrant.

After deducting underwriting fees and other expenses related to the offering, the aggregate net proceeds were approximately $2,262,000.

On January 25, 2019, the Company closed on the underwriters' partial exercise of its over-allotment option for 12,500 shares of Common Stock for gross proceeds of $250,000. After deducting underwriting fees and other expenses related to the over-allotment option, the aggregate net proceeds were approximately $201,000.

The total number of Common Stock and Warrants issued under this offering, including the exercise of the over-allotment option was 150,000 and 157,500, respectively. The gross proceeds to us were approximately $3.0 million and net proceeds after deducting underwriting expenses and other estimated offering expenses was approximately $2.5 million.

The Warrants are immediately exercisable beginning on the date of issuance (the "Initial Exercise Date"). The Warrants will be exercisable for five years from the Initial Exercise Date, but not thereafter.

The Warrants include an adjustment provision that, subject to certain exceptions, reduces their exercise price if the Company issues Common Stock or Common Stock equivalents at a price lower than the then-current exercise price of the Warrants, subject to a minimum exercise price of $5.60 per share. The exercise price and number of the shares of the Company's Common Stock issuable upon the exercise of the Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. In addition, on or after any trading day 75 days after the closing date of the offering, if the daily volume weighted average price of the Company's Common Stock fails to exceed the Exercise Price, the aggregate number of warrant shares issuable in a cashless exercise shall equal the product of (i) the aggregate number of warrant shares that would be issuable upon exercise of the Warrants if such exercise were by means of a cash exercise and (ii) 0.70.

As a result of the 2019 private placement offering of the Company's common stock, the exercise price of these warrants was reduced to $12.00 per share. The incremental change in fair value of these warrants as a result of the triggering event was $78,785. Subsequently, as a result of the underwritten public offering on November 15, 2019, the exercise price of these warrants was further reduced to $5.60 per share.

As a result of the Company's stock price falling below $20.00, 143,252 warrants have been cashlessly exercised. These exercises resulted in the issuance of 100,617 shares of the Company's Common Stock.

As a result of this financing, the exercise price of the 68,375 warrants issued during December 2017 was reduced to an exercise price of $17.60 per share in accordance with the adjustment provision contained in the warrant agreement. The incremental change in fair value of these warrants as a result of the triggering event was $281,042.

NOTE H – CAPITAL STOCK, continued

Common Stock Transactions during the Fiscal Year Ended September 30, 2018:

On December 22, 2017, the Company entered into a securities purchase agreement with certain institutional investors for the purchase and sale of 68,375 shares of its common stock and warrants to purchase an aggregate of 68,375 shares of common stock in a registered direct offering with aggregate gross proceeds of $4,786,250, at a combined purchase price of $70.00 per share. The warrants will be immediately exercisable at a price of $80.00 per share of common stock and will expire five years from the date of issuance.

After deducting placement agent fees and other estimated expenses related to the registered direct offering, the aggregate net proceeds were approximately $4,200,000.

The warrants will be exercisable for five years from the grant date, but not thereafter. The warrants include an adjustment provision that, subject to certain exceptions, reduces their exercise price if the Company issues Common Stock or Common Stock equivalents at a price lower than the then-current exercise price of the Purchase Warrants, subject to a minimum exercise price of $17.60. The exercise price and number of the shares of our Common Stock issuable upon the exercise of the warrants will be subject to adjustment as set forth therein (including for stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction).

In addition, if and only if there is no effective registration statement registering, or no current prospectus available for, the resale of the Purchase Warrants, the Purchasers may exercise the Purchase Warrants by means of a "cashless exercise."

NOTE I – STOCK OPTIONS AND WARRANTS

Warrants

Transactions involving warrants (see Note H) are summarized as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Balance at October 1, 2018	305,217	$ 129.60
Granted	258,502	18.36
Exercised	(199,127)	(18.42)
Cancelled or expired	(101,000)	(87.70)
Balance, September 30, 2019	263,592	$ 131.12

NOTE I – STOCK OPTIONS AND WARRANTS, continued

Stock Options

In 2005, the Board of Directors and the holders of a majority of the outstanding shares of Common Stock approved the 2005 Incentive Stock Plan, as amended and restated as of January 21, 2015 (the "Incentive Plan"). On March 27, 2019, the Board of Directors approved an amendment to the Incentive Plan, which was approved by shareholders on May 16, 2019. The amendment increases the number of shares of Common Stock that can be issued as stock awards and stock options thereunder from an aggregate of 208,334 to an aggregate of 358,334. The number of shares of Common Stock that can be covered by awards made to any participant in any calendar year is 20,834 shares. The Incentive Plan's expiration date is January 25, 2025.

The Incentive Plan is designed to retain directors, executives, and selected employees and consultants by rewarding them for making contributions to the Company's success with an award of options to purchase shares of Common Stock. As of September 30, 2019, a total of 6,894 shares have been issued and options to purchase 212,271 shares have been granted under the Incentive Plan.

NOTE I – STOCK OPTIONS AND WARRANTS, continued

Stock Options, continued

Transactions involving stock options issued are summarized as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value	Weighted Average Contractual Life (years)
Outstanding at October 1, 2018	154,676	$ 125.16		
Granted	86,349	100.65		
Exercised	-	-		
Cancelled or expired	(41,630)	195.96		
Outstanding at September 30, 2019	199,395	$ 99.68		
Vested at September 30, 2019	162,112	116.50	$ -	6.18
Non-vested at September 30, 2019	37,283	27.01	$ -	9.48

For the fiscal year ended September 30, 2019, the Company issued an aggregate of 86,349 (including award modifications of 35,040) options to employees, consultants, members of the strategic advisory board and non-employee board of director members.

For the fiscal year ended September 30, 2018, the Company issued an aggregate of 54,704 (including award modifications of 16,667) options to employees, consultants, members of the strategic advisory board and non-employee board of director members. Included in these grants was 12,500 options granted to executives.

The fair value of options granted during the fiscal years ended September 30, 2019 and 2018 was determined using the Black Scholes Option Pricing Model. For the purposes of the valuation model, the Company used the simplified method for determining the granted options expected lives. The simplified method is used since the Company does not have adequate historical data to utilize in calculating the expected term of options. The fair value for options granted was calculated using the following weighted average assumptions:

	2019	2018
Stock price	$ 32.82	$ 52.40
Exercise price	$ 100.65	$ 80.00
Expected term	4.40	4.42
Dividend yield	-	-
Volatility	89%	86%
Risk free rate	2.43%	2.70%

The Company recorded $1,129,110 and $1,356,351 as stock compensation expense within selling, general and administrative for fiscal years ended September 30, 2019 and 2018, respectively. Included in this amount is $221,046 and $145,053 for the fiscal years ended September 30, 2019 and 2018, respectively for employee stock option modifications. These modifications extended the terms of the options for employees in fiscal 2019 and extended the terms of the options for former employees in fiscal 2019 and 2018. As of September 30, 2019, unrecorded compensation cost related to non-vested awards was $434,553 which is expected to be recognized over a weighted average period of approximately 0.61 years. The weighted average grant date fair value per share for options granted during the fiscal years ended September 30, 2019 and 2018 was $11.51 and $30.00, respectively.

NOTE J – INCOME TAXES

The income tax provision (benefit) for the fiscal years ended September 30, 2019 and 2018 consists of the following:

	2019	2018
Federal:		
Current	$ -	-
Deferred	(1,658,000)	4,430,000
	(1,658,000)	4,430,000
State and local:		
Current	-	-
Deferred	308,000	(925,000)
	308,000	(925,000)
Foreign:		
Current	15,000	-
Deferred	-	-
	15,000	-
Change in valuation allowance	1,350,000	(3,505,000)
Income tax provision (benefit)	$ 15,000	-

The provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory rate to losses before income tax expense for the years ended September 30, 2019 and 2018 as follows:

	2019	2018
Statutory federal income tax rate	21.00 %	24.28 %
Statutory state and local income tax rate (1%, as of September 30, 2019 and 2018), net of federal benefit	0.52 %	2.50 %
Stock based compensation	(1.62)%	(2.29)%
Other permanent differences	(3.15)%	4.24 %
Change in deferred tax rate	(2.33)%	0.00 %
Impact of change in Federal statutory tax rate	0.00 %	(58.71)%
Change in valuation allowance	(14.42)%	29.98 %
Effective tax rate	0.00 %	0.00 %

Deferred income taxes result from temporary differences in the recognition of income and expenses for financial reporting purposes and for tax purposes. The tax effect of these temporary differences representing deferred tax asset and liabilities result principally from the following:

	September 30,	
	2019	2018
Deferred tax assets (liabilities):		
Stock based compensation	$ 1,960,000	$ 1,947,000
Depreciation and amortization	277,000	339,000
Net operating loss carry forward	14,091,000	13,248,000
Tax credits	1,171,000	944,000
Other	397,000	69,000
Less: valuation allowance	(17,896,000)	(16,547,000)
Net deferred tax asset	$ -	$ -

NOTE J– INCOME TAXES, continued

As of September 30, 2019, the Company has approximately $58,458,000 of Federal and $75,496,000 of State net operating loss "NOL" carryforwards available which begin to expire after 2022. The Federal and State carry forwards of $5,230,470 and $5,797,009, respectively for fiscal year end 2019 have indefinite lives. Pursuant to Internal Revenue Code Section 382, the Company's ability to utilize the NOLs is subject to certain limitations due to changes in stock ownership in prior years. The annual limitation ranges between $786,000 and $1,103,000 and any unused amounts can be carried forward to subsequent years.

The Company has provided a full valuation allowance against all of the net deferred tax assets based on management's determination that it is more likely than not that the net deferred tax assets will not be realized in the future. The valuation allowance increased by $1,350,000.

The Company has Federal research and development credits of approximately $762,000 that will begin to expire after 2034. The Company also has state investment tax credits of $392,000 that will begin to expire after 2029.

NOTE K – COMMITMENTS AND CONTINGENCIES

Operating leases

The Company leases office space under an operating lease in Stony Brook, New York for its corporate headquarters. The lease is for a 30,000 square foot building. The term of the lease commenced on June 15, 2013 and expired on May 31, 2017, with the option to extend the lease for two additional three-year periods. The Company has exercised its option to extend the lease for one additional three-year period ending May 31, 2019. The base rent during the additional three-year period is $458,098 per annum. During November 2019, the Company extended this lease until January 15, 2020. In addition to the office space, the Company also has 1,500 square feet of laboratory space. The term of the lease commenced on November 1, 2015 and expired on October 31, 2018, with a month to month agreement thereafter. Effective November 20, 2018, the Company renewed this lease for one additional year, ending October 31, 2018. This lease has also been extended until January 15, 2020. The Company set up a satellite testing facility in Ahmedabad, India during fiscal 2018. On November 17, 2017, it leased 1,108 square feet for a three-year term beginning November 1, 2017. The base rent is approximately $6,500 per annum.

Total rent expense for the fiscal years ended September 30, 2019 and 2018 were $516,988 and $528,234, respectively.

Future minimum rental payments (excluding real estate tax and maintenance costs) as of September 30, 2019 are as follows:

For the fiscal year ending September 30,	
2020	$ 7,104
2021	595
Total	$ 7,699

Employment and Consulting Agreements

Employment agreements

On July 11, 2011, the Company's Board of Directors approved the terms of employment for Dr. James A. Hayward, the Company's CEO.

The CEO's employment agreement provides that he will be the Company's CEO, and will continue to serve on the Company's Board of Directors. On July 28, 2017, a new employment agreement was entered into with the CEO effective July 1, 2017. The initial term was from July 1, 2017 through June 30, 2018, with automatic one-year renewal periods. As of June 30, 2019, the employment contract renewed for an additional year. Under the new agreement, the CEO will be eligible for a special cash incentive bonus of up to $800,000, $300,000 of which is payable if and when annual revenue reaches $8 million and $100,000 of which would be payable for each $2 million of annual revenue in excess of $8 million. Pursuant to the contract, the CEO's annual salary is $400,000. The Board of Directors, acting in its discretion, may grant annual bonuses to the CEO. The CEO will be entitled to certain benefits and perquisites and will be eligible to participate in retirement, welfare and incentive plans available to the Company's other employees.

NOTE K – COMMITMENTS AND CONTINGENCIES, continued

The agreement with the CEO also provides that if he is terminated before the end of the initial or a renewal term by the Company without cause or if the CEO terminates his employment for good reason, then, in addition to previously earned and unpaid salary, bonus and benefits, and subject to the delivery of a general release and continuing compliance with restrictive covenants, the CEO will be entitled to receive a pro rata portion of the greater of either (X) the annual bonus he would have received if employment had continued through the end of the year of termination or (Y) the prior year's bonus; salary continuation payments for two years following termination equal to the greater of (i) three times base salary or (ii) two times base salary plus bonus; company-paid COBRA continuation coverage for 18 months post-termination; continuing life insurance benefits (if any) for two years; and extended exercisability of outstanding vested options (for three years from termination date or, if earlier, the expiration of the fixed option term). If termination of employment as described above occurs within six months before or two years after a change in control of the Company, then, in addition to the above payments and benefits, all of the CEO's outstanding options and other equity incentive awards will become fully vested and the CEO will receive a lump sum payment of the amounts that would otherwise be paid as salary continuation. In general, a change in control will include a 30% or more change in ownership of the Company.

Upon termination due to death or disability, the CEO will generally be entitled to receive the same payments and benefits he would have received if his employment had been terminated by the Company without cause (as described in the preceding paragraph), other than salary continuation payments.

Effective March 15, 2018, the Compensation Committee of the Company's Board of Directors, approved a bonus of $121,125 that would be payable to the CEO when the Company reaches $3,000,000 in revenues for two consecutive quarters or $12,000,000 in revenues for a fiscal year, provided that the CEO is still employed by the Company on such date (the "Revenue Bonus").

Effective May 2, 2018, the Compensation Committee of the Company's Board of Directors, increased the amount of the Revenue Bonus to $403,623. Effective December 27, 2018, the compensation committee approved an additional bonus opportunity of $150,000 for the calendar year-ended December 31, 2019 that would be payable to the CEO under the same terms as described above.

As of September 4, 2019, the CEO voluntarily reduced his salary to $50,000.

The accrual for the Revenue Bonus of $590,502 is recorded to long term accrued liabilities on the balance sheet as of September 30, 2019.

Litigation

From time to time, the Company may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. When the Company is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, the Company will record a liability for the loss. In addition to the estimated loss, the recorded liability includes probable and estimable legal costs associated with the claim or potential claim. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm the Company's business. There is no pending litigation involving the Company at this time.

NOTE L – GEOGRAPHIC AREA INFORMATION

Net revenues by geographic location of customers are as follows:

	Year Ended September 30,	
	2019	**2018**
Americas	$ 4,166,315	$ 2,141,169
Europe	600,374	1,004,452
Asia and other	622,400	757,722
Total	$ 5,389,089	$ 3,903,343

Note M – FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company's financial instruments at fair value are measured on a recurring basis. Related unrealized gains or losses are recognized in unrealized gain on change in fair value of secured convertible notes payable in the consolidated statements of operations. For additional disclosures regarding methods and assumptions used in estimating fair values of these financial instruments, see Note B.

The following table presents carrying amounts and fair values of the Company's financial instruments as of September 30, 2019 and summarizes the significant unobservable inputs in fair value measurement of Level 3 financial assets and liabilities as of September 30, 2019. The Company did not have any assets or liabilities categorized as Level 1 or 2 as of September 30, 2019.

	Fair value at September 30, 2019	Carrying value at September 30, 2019	Valuation Technique	Unobservable Input	Range	Weighted Average
Liabilities:						
Secured Convertible Notes ("Existing Notes")	$ 102,777	$ 104,482	Monte Carlo simulation	Annualized volatility	87.22% - 92.66%	87.39%

The following table presents a summary of changes in fair value of the secured convertible notes (Level 3 financial liabilities) which are marked to market on a periodic basis:

	2019
Beginning balance	$ 3,516,237
Change in fair value included in earnings	(1,972,955)
Change in fair value for conversion of notes payable	(1,440,505)
Ending balance	$ 102,777

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Applied DNA Sciences, Inc. on Form S-3 (File No. 333-202432, File No. 333-220481, File No. 333-218158, File No. 333-214920 and File No. 333-208162) and Form S-8 (File No. 333-182350, 333-205123 and 333-231944) of our report dated December 12, 2019 with respect to our audits of the consolidated financial statements of Applied DNA Sciences, Inc. as of September 30, 2019 and 2018, and for each of the two years in the period ended September 30, 2019, which report is included in this Annual Report on Form 10-K of Applied DNA Sciences, Inc. for the year ended September 30, 2019.

/s/ Marcum LLP

Marcum LLP
Melville, NY
December 12, 2019

Exhibit 31.1

CERTIFICATION

I, James A. Hayward, certify that:

1. I have reviewed this Annual Report on Form 10-K of Applied DNA Sciences, Inc.;

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

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

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

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

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

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

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

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

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

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 12, 2019

/s/ James A. Hayward
James A. Hayward
President, Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Beth Jantzen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Applied DNA Sciences, Inc.;

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

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

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

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

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

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

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

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

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

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: December 12, 2019

/s/ Beth Jantzen
Beth Jantzen, CPA
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Applied DNA Sciences, Inc. (the "Company") for the fiscal year ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James A. Hayward, President, Chief Executive Officer and Chairman of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James A. Hayward
James A. Hayward
President, Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: December 12, 2019

* A signed original of this written statement required by Section 906 has been provided to Applied DNA Sciences, Inc. and will be retained by Applied DNA Sciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Applied DNA Sciences, Inc. (the "Company") for the fiscal year ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Beth Jantzen, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Beth Jantzen
Beth Jantzen, CPA
Chief Financial Officer
(Principal Financial Officer)

Date: December 12, 2019

* A signed original of this written statement required by Section 906 has been provided to Applied DNA Sciences, Inc. and will be retained by Applied DNA Sciences, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.