APPLIED DNA SCIENCES INC
Form 10-K
December 18, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended September 30, 2018

¨ 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	(I.R.S. Employer

incorporation or organization) 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	**Name of each Exchange on Which Registered**
Common Stock, $0.001 par value	The NASDAQ Capital Market
Warrants to purchase Common Stock	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 x 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 x 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.

x 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).

x 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 x Smaller reporting company x

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 x 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, 2018), was approximately $38 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, 2018 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 14, 2018, the Registrant had outstanding 30,112,057 shares of common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement for the 2019 Annual Meeting of Shareholders, to be filed within 120 days after the end of the fiscal year ended September 30, 2018 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 "plan", "anticipate", "estimate", "potential", "position", "predicts", "strategy", "guidance", "intend", "seek", "budget", "projec 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:

Our ability to continue as a going concern;

our lack of significant revenues;

our limited experience in marketing our large-scale PCR based manufacturing platform;

our history of net losses, which may continue, and our potential inability to achieve profitability;

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;

difficulty in obtaining or inability to obtain, additional financing if such financing becomes necessary;

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;

volatility in the price and/or trading volume of our common stock;

future short selling and/or manipulation of the price of our common stock;

our inability to implement our short and long-term strategies;

competition from products and services provided by other companies, including competition in the principal markets for our drug and biologic candidates and linear DNA;

potential difficulties and failures in manufacturing our products;

loss of strategic relationships;

dependence on a limited number of key customers;

lack of acceptance of our products and services by potential customers;

potential failure to introduce new products and services;

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;

seasonality in revenues related to our cotton customer contracts;

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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;

inability to attract and retain qualified scientific, production and managerial personnel, including of Dr. Hayward, our Chief Executive Officer;

failure to maintain the listing on, or the delisting of our securities from, The NASDAQ Capital Market;

conflicts of interest with affiliates and related parties with whom we have engaged or entered into transactions;

inability to compete effectively in the industries in which we operate;

lack of success in our research and development efforts for new products;

failure to manage our growth in operations and acquisitions of new technologies and businesses;

inability to protect our intellectual property rights;

intellectual property litigation against us or other legal actions or proceedings in which we may become involved;

unauthorized disclosure of sensitive or confidential data (including customer data) and cybersecurity breaches; and

adverse changes in worldwide or domestic economic, political or business conditions.

All forward-looking statements and risk factors included in this Annual Report on Form 10-K are made as of the date hereof, 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® 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 our large scale polymerase chain reaction (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 wholly 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.

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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 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 and services for use in vitro medical diagnostics, preclinical biotechnology research and preclinical drug and biologic development and manufacturing receive 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, along 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 to 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.

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 these techniques are effective but have generally been reverse-engineered and replicated which limit their usefulness as forensic methods for authentication of the sources of products and other items.

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.

Law Enforcement Applications

Burglaries, car theft, and cash-in-transit robberies are worldwide problems begging for a solution. The United States leads the world in the occurrence of home burglaries, with a burglary occurring about every 18 seconds in the U.S. (The SafeWise Report - September 13, 2017). Interpol reported that for the year ending December 31, 2017, they had received 7.2 million records of reported stolen motor vehicles from 126 different countries (Interpol — Database Statistics). According to the FBI, there were an estimated 765,484 motor vehicles stolen in the United States in 2016 and the value of the stolen motor vehicles was approximately $5.9 billion. These crimes have wide-ranging impacts, affecting law enforcement agencies, insurance companies, legislative bodies, and justice departments.

Asset identification, management, protection and authentication solutions that deliver value to the customer are critical components of any successful theft deterrent program. In addition to tagging assets with a unique mark to prevent theft and facilitate return of stolen goods, it is imperative that would-be thieves know that the items are marked and that law enforcement is trained to properly identify recovered property. Forensic marking of home assets, including automobiles, uses technology to code valuables at risk of theft to identify burglars, linking them directly with a crime scene. Over the years, authorities have found it difficult to obtain convictions of thieves in possession of suspected stolen property unless the true owner can be identified.

Nucleic Acid-Based Therapeutics

Nucleic acid-based therapeutics have emerged as a new class of drugs and biologics for treating unmet medical needs. Gene therapy, which includes adoptive cell therapy, DNA vaccines and RNA-based therapies, is the foundation for the current fast-paced medical revolution. All gene therapies are driven by DNA, which is required in large scale. As of January 2018, almost 2600 gene therapy 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 gene therapies 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 gene therapy. Through the use of our PCR-based manufacturing platforms, we feel we are well situated to supply DNA to the growing nucleic acid-based drug and biologic markets. 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.

Products and Services

SigNature® molecular tags, SigNature® T molecular tags, fiberTyping®, DNAnet®, SigNify® BackTrac®, Beacon® and CertainT® comprise our principal security technology platform. The large-scale production of specific DNA sequences is used in the diagnostics and reagent industries. Contract research and drug development and commercialization relating to PCR-produced DNA constructs forms the basis of LRx.

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 spot test, or the molecular tags can be forensically analyzed 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,” described below, 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 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. The use of endogenous DNA to identify the cotton fiber content in textile supply chains, along with the SigNature T molecular tag system 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 SigNatureT molecular tags and fiberTyping solutions cover the forensic authentication market for textiles and that the related protocols we have developed may be applicable to multiple industry verticals (such as ingredients in nutraceuticals and cannabis) and can mark and authenticate products at every stage of their life cycle, from beginning to end.

DNAnet, Smart DNA and Backtrac

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 commercial 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.

The SigNify IF portable DNA reader provides 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. The 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, and other third party devices and is designed to share data with third party applications through standard interfaces.

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DNA Transfer Systems and Cannabis Tracking System. Our DNA Transfer Systems and 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. They are being used to mark cotton at six U.S. cotton gins in the 2018-2019 ginning season and one location in Australia.

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.

Large-scale production of specific DNA sequences using PCR.

Our patented Triathlon™ PCR 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 being used by customers as components of diagnostic tests and reagents, which provide us the opportunity to cross-sell our DNA-based supply chain security solutions to this installed base and others. We believe we have the ability to manufacture longer DNA sequences valuable in gene therapies, adoptive cell therapies (such as CAR T), DNA vaccines, RNA therapies and 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 security markers and represent a potential new entry into medical markets, where we believe there are opportunities for our broader platform. 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 manufacturing receive DNA product that we believe is made cleaner and faster than historical manufacturing methods, thereby offering the opportunity for increased efficiency and turnaround times in their processes.

Contract Research

Under LRx, we act as a contract research organization for the nucleic acid-based medical and biologic markets. 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.

Therapeutics

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 CRO/CMO clients, our preclinical drug and biologic clients and partners, and for our own preclinical nucleic acid-based drugs and biologics under development in the field of CAR T-cell immunotherapy.

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, 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 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 and services for in vitro medical diagnostics, preclinical biotechnology research and preclinical drug and biologic manufacturing receive DNA product made we believe 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 focusing on therapeutically relevant DNA constructs manufactured via our PCR-based production platform. We seek to develop, acquire and commercialize, 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 create new nucleic acid-based therapeutics that address unmet medical needs.

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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, as well as and services for in vitro medical diagnostics, preclinical biotechnology research and preclinical biotherapeutic manufacturing. Currently, approximately twenty percent of our annual revenue comes from the textile market. 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. 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. 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 Triathlon™ PCR systems.

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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, DNA technology.

Present 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. Installed in October 2017, our updated fully automated, secure DNA Transfer Systems allow for traceability and monitoring of all molecularly-tagged cotton at multiple gins in Arkansas, Texas and California. During fiscal 2018, a DNA Transfer System was installed in a gin in Australia. The DNA Transfer Systems allow for expansion of tagging at other gins to support increased demand for tagging in future years.

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 beginning to be used to mark Upland cotton, under the HomeGrown™ LoneStar™ and HomeGrown Acala™ trademarks. 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 are 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 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 15 million pounds of fiber have been initially 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 October 2018, GHCL launched CIRKULARITY™, a new brand of eight lines of bedding supporting the circular economy. These lines center on "reduce, reuse and recycle". REKOOP®, the inspiration behind CIRKULARITY, is a brand of bedding products made from recycled plastic (rPET) and is the first bedding product to use our CertainT platform. REKOOP uses our CertainT platform to trace and authenticate the post-consumer recycled polyester plastic in its bed sheets, pillowcases, and shams throughout the entire supply chain.

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.

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

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The problem is not limited to the defense industry. According to an April 2016 report by OECD and the EU Intellectual Property Office, fake products are worth nearly $461 billion per year, or roughly 2.5% of all global trade.

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, runs from June 1, 2017 to May 31 2019, and was granted via a Rapid Innovation Fund (RIF) that provides DLA with innovative technologies that can be rapidly inserted into acquisition programs to meet specific defense needs. Management oversight for this RIF contract is from DLA HQ located in Fort Belvoir, Virginia. This firm-fixed price contract follows 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 will extend our authentication platform to facilitate broader use in protecting high-risk or mission-critical material purchased by DLA.

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.

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.

Under the terms of the CRADA, a cooperative effort under the DLA RIF award secured by us in June 2017, ECBC's subject matter experts and our science team will cooperatively study the feasibility of commercializing ECBC's in-field DNA detection technology in varied supply chains. ECBC's hand-held in-field DNA microarray technology allows for detection of a DNA taggant within a few minutes. The project goal is to demonstrate the system with our taggants introduced into standard inks or varnishes or onto other surfaces, without the need for DNA amplification or other sample preparation, thus greatly simplifying in-field DNA detection.

Cash-in-Transit

Cash-in-transit businesses transport and store cash and ATM cassettes. In the U.K. alone, there is an estimated £500 billion being transported each year (approximately $755 billion as of December 2015) or £1.4 billion per day (approximately $2.2 billion) (British Security Industry Association: "Combating Cash Delivery Crime"). The nature of this business makes cash-in-transit an attractive target for criminals and as a result the industry invests in excess of £100 million (approximately $151.1 million) per year in security equipment and devices. Since 2009, the number of CViT (Cash and Valuables in Transit) convictions attributed to the use of SigNature DNA in cash boxes has risen to more than 125, with prison sentences of over 610 years. SigNature DNA forensic tags are helping Police across Europe to identify stolen cash and to link the evidence directly to the perpetrators. According to the FBI, in 2016, over 40 people were killed or injured in over 4,000 robberies of financial institutions across the nation (Bank Crime Statistics 2016 - FBI).

Our Market Response

We incorporate our SigNature DNA molecular tags in cash degradation inks that are used in the cash-in-transit industry in countries throughout the United Kingdom and other countries within Europe. This solvent-based ink marks bank notes if the cash box is compromised and has the ability to penetrate the bank notes rapidly and permanently. We believe our SigNature DNA molecular tags are more resilient and detectable than other competing technologies.

To date, the use of SigNature DNA in the cash handling industry has allowed our products to facilitate the convictions of more than 125 criminals across Europe involved in cash-in-transit crime with aggregate prison sentences of over 610 years. SigNature DNA has been used since 2008 in Europe within the ink and / or smoke systems of Intelligent Bank Note Neutralisation Systems ("IBNS"), more commonly known as cash boxes and ATM cassettes. Unique, SigNature DNA molecular tags are incorporated into each IBNS during manufacture.

Consumer Asset Marking

Car crime is a very large and profitable business, costing billions of dollars per year and representing approximately one-third of all reported crime. It is estimated that approximately 70 percent of stolen cars are broken up and sold for spare parts, while the rest are given a false identity and sold, with many of those being exported to the Middle and Far East.

Everyone has assets they want to look after - from household goods such as TVs, jewelry and antiques to office equipment including computers and laptops. There are a wide variety of valuable items that need to be uniquely identified and protected from theft. Forensic marking of home assets uses technology to code valuables at risk of theft to mark burglars, linking them directly with a crime scene.

Over the years, authorities have found it difficult to obtain convictions of thieves in possession of suspected stolen property unless the true owner can be identified. If marked items are stolen and later found, police can link them directly with the crime scene, not only allowing the property to be returned to its owner, but also increasing the chance of convicting the thieves.

Our Market Response

We believe that DNAnet, Smart DNA and Backtrac enhance law enforcement effectiveness by providing forensic quality evidence. The DNAnet, SmartDNA and Backtrac Asset Marking program provides a simple and cost-effective way for asset owners to deter crime and protect their property, a way for law enforcement to identify the rightful owners of lost or stolen property, and a way to tell criminals…stay away because you will get caught!.

Our Smart DNA is being used to protect the automobiles of one major European automotive manufacturer against the theft of their automotive parts after being imported into at least one E.U. country. New cars are marked with a unique code applied at point of importation or delivery to the customer. Customer details are registered on a secure database. The DNA molecular tag provides absolute identification to the vehicle. The molecular tags are covert and difficult to remove. If found, vehicles and their component parts are traceable back to the car, from anywhere on the globe. If the car is stolen and recovered, police will be able to link the criminal to the crime, and will know exactly where to return the vehicle. Highly visible warning stickers are displayed on the windshield of the car, deterring theft in the first place. To date, over 70,000 high-end cars have been marked with Smart DNA.

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 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 newly released 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.

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

Following our acquisition of substantially all the assets of Vandalia Research, Inc. in September 2015, we are able to produce specific, high-quality DNA sequences with the PCR production system known as Triathlon, which is well suited to meet these diagnostic and reagent needs. 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.

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. The World Health Organization (WHO) estimates the annual worldwide “take” from counterfeit drugs to be £13 billion (approximately $19.6 billion as of December 2015), a figure that is expected to double by the end of this decade. In some 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 Drug Supply Chain Security.

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 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.

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 FDA review of the addition of the 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 U.S. Food and Drug Administration (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 offering a seamless solution for pharmaceutical company customers.

During January 2018, we entered into a Memorandum of Understanding with ACG to develop SigNature® molecularly tagged empty hard-shell capsules to enhance product traceability and authentication. ACG is one of the world's largest pharmaceutical and nutraceutical capsule manufacturers, with the empty capsules market estimated to exceed $2 billion by 2023. For information on our Memordandum of Understanding with ACG please see "Distribution of our Products and Commercial Agreements".

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 20%, a 2017 market size of over $17 billion, it is projected to be a $63 billion industry by 2024. 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 tenants 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 have entered into a development and marketing agreement whereby we will develop 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. Together with our expertise in the physical molecular tagging of various materials in numerous vertical markets, we jointly are well positioned to address the provenance concerns of the cannabis industry on a global basis.

We have initially positioned our joint provenance solution under the banner of, "Etch Biotrace" which includes an end to end seed-to-sale solution, a blockchain offering, and the power of our CertainT molecular tagging and tracking capabilities. It is the combination of both capabilities that allows us to be strongly positioned to serve the cannabis needs on a global basis.

With both powerful tagging solutions, we are well poised to move to the next step which is a trial(s) with advanced thinking growers or processors as well as state programs that are either about to launch or already have launched a cannabis program and are looking for ways to provide more control over their cannabis supply chain.

Agrochemicals

The agrochemical industry is faced with an increased prevalence of illegal trade, counterfeiting and brand piracy. From the adulteration and counterfeiting of leading herbicides, pesticides and fertilizers with inferior materials, to the substitution of genetically modified seeds with low yield alternatives, crops are at risk more than ever. These issues threaten company reputations, supply systems, export markets and government tax revenues.

In Europe, Africa and other areas of the world, use of counterfeit and illegally traded pesticides is increasing. Untested and unregulated products may threaten the health of farmers and consumers and pose risks to the natural environment. Counterfeit pesticides threaten the integrity of those industries that depend on the benefits of pesticide use.

Fighting counterfeit pesticides is a complex task. We believe that enforcement of regulations governing pesticide use is inadequate and has led in recent years to an increase in use of illegal, counterfeit pesticides.

According to research by International Growth Center (2015), the vast majority of fertilizer samples from the Uganda study were substandard. Additionally, very few of the allegedly improved seeds showed success in producing large crops. In short, the agricultural inputs sold at retail level in Uganda are often ‘fake’ or of very poor quality. In the case of fertilizer, according to estimations by the Vietnam Fertilizer Association (2016), the country’s economy loses US$2 billion every year as a result of fake products. According to local market surveillance bodies, fake fertilizer manufacturers use many different techniques to cheat customers, including the use of formulas that differ from what is printed on the package and imitating established market brands.

Without appropriate restoration of the organic and mineral content of depleted soils, farmers often clear new land, contributing to the global deforestation problem. By improving the quality of arable land, farmers can turn less to deforestation, which represents as much as 30% of global greenhouse emissions. Africa, with a huge agricultural potential, uses less than 15 kgs of fertilizer per hectare, only a tenth of the global average. As a result, 75 percent of African soils are degraded, costing the continent $4 billion per year. FAO (Food and Agricultural Organization of the United Nations) forecasts the global fertilizer demand to be 199 million metric tons in 2019.

Our Market Response

On August 8, 2017, we announced the introduction of our molecular tag to the fertilizer industry in co-operation with Rosier S.A. (“Rosier”), a mineral fertilizer manufacturer based in Moustier, Belgium. Rosier sells high quality mineral fertilizers globally, and in Europe, through its exclusive distributor, Borealis L.A.T. Together with Rosier we launched a pilot to DNA-tag fertilizer pellets in order to detect the dilution of genuine fertilizer with sub-standard material within a given batch, and to be able to trace the batch to its original manufacturing location. Since the initiation of this study, we, in partnership with Rosier, have effectively marked fertilizer pellets and have successfully authenticated and detected the dilution of fertilizer with unmarked material in a variety of laboratory and in-field tests over a nine-month period. A marked shipment of fertilizer has travelled through the supply chain in West Africa and pellets have been analyzed in the field utilizing our in-field DNA detection technology (SigNify® IF) to provide definitive real-time authentication of the SigNature DNA molecular tags, ensuring that the fertilizer had not been adulterated with unmarked material. The pellets tested were proven to be genuine and demonstration of the technology gained further support for the use of molecular taggants to combat counterfeiting and to aid the many countries that are affected by adulterated fertilizer. During fiscal 2018 we had our first commercial shipment of concentrate to tag

fertilizer.

During October 2018, we signed a statement of work with a life sciences company to conduct a feasibility evaluation for the tagging and authentication of seeds. In prior years, we have performed feasibility studies for the authenticity and detection of crop protection materials supporting this market. The learnings from these proofs of concept and the fertilizer solution create a foundation upon which a future market may be built as adjacent to our natural textiles businesses.

Future Markets:

Nucleic Acid-Based Therapeutics

Nucleic acid-based drugs and biologics have emerged as a new class of treatments for unmet medical needs. Under LRx, we are currently pursuing three types of nucleic acid-based therapeutic applications for PCR-produced DNA: (i) adoptive cell therapy; (ii) DNA vaccines; and (iii) RNA-based therapeutics. 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.

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 canddiate 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."

Sales and Marketing

We have nine employees engaged in sales and marketing, of which six 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 then authenticating DNA obtained from those marked products both in our laboratories and in the field, with the development of portable infield DNA readers. 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. In short, we have considerable experience working with 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 $2.8 million and $2.3 million on research and development activities for the fiscal years ended September 30, 2018 and 2017, respectively.

Under LRx, our research and development efforts are focused on the development of linear DNA expression vectors for use in nucleic acid-based medicines including drugs and biologics and associated methods of linear 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 sources of DNA that are readily available in nature, which we are able to replicate to use in our product offerings.

Manufacturing

We have the capability to manufacture SigNature DNA molecular tags and all of our products at our laboratories in Stony Brook. We also have in-house capabilities to complete all authentications. We are also engaged in the large-scale production of specific DNA sequences using PCR.

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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.

Office of the Secretary of Defense. 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, runs from June 1, 2017 to May 31 2019, and was granted via a Rapid Innovation Fund (RIF) that provides DLA with innovative technologies that can be rapidly inserted into acquisition programs to meet specific defense needs. Management oversight for this RIF contract has been from DLA HQ located in Fort Belvoir, Virginia. This firm-fixed price contract follows our prior RIF contract, which expired during August 2016, 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 will extend our authentication platform to facilitate broader use in protecting high-risk or mission-critical material purchased by DLA.

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. We will be required by the agreement to establish an independent testing laboratory in Ahmedabad, India. Finished product made from this tagged fiber will be offered for sale under the PimaCott®, HomeGrown® LoneStar™ 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.

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 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 guaranteed minimum annual revenues, in order to maintain exclusivity, as well as trademark licensing royalties to us.

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® enchanced secure sewing threads for brand protection. A prior statement of work dated July 25, 2017 between Applied DNA and A&E demonstrated Applied DNA's SigNature®T DNA-based authentication. This collaboration with A&E represents execution on the Company's growth strategy to expand its base of business in its core markets and broaden the application of it

molecular tagging technology platform in adjacent markets.

BLC Leather Technology Center Limited (BLC). During May 2018, we completed a one-year research project with BLC under a sponsored research agreement we entered into in March 2017 for the development of a DNA based supply chain track and trace system. The results of the research project helped validate that our technology can be used in the harsh leather-production environment to provide forensic traceability for leather from farm to shop. In November 2018, we entered a follow-on collaboration agreement with BLC to facilitate the commercialization of such technology. Under the terms of the collaboration agreement, we and BLC agree to jointly develop business and marketing plans, with BLC receiving a share of the revenue we receive relating to the DNA-based tracking system. The agreement expires in November 2023.

Videojet. 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. On October 5, 2018, this agreement was renewed for an additional one-year term.

TheraCann International. 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 have entered into a development and marketing agreement whereby we will develop 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 platform.

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 Colorcon's product offerings and 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 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 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.

ACG Associated Capsules Private Limited (ACG). During January 2018, we entered into a Memorandum of Understanding with ACG to develop SigNature® molecularly tagged empty hard-shell capsules to enhance product traceability and authentication. ACG is one of the world's largest pharmaceutical and nutraceutical capsule manufacturers, with the empty capsules market estimated to exceed $2 billion by 2023. Discussions between us and ACG toward a definitive agreement incorporating are underway, although no assurance can be given that a definitive agreement will be entered into.

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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 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. Under the terms of the agreements, iCell will receive a percentage of net sales derived from products incorporating the licensed CD 19 Antigen Receptor within North America, as well as development milestone payments and a fundraising milestone. The development milestone payments are triggered up on the completion of defined phases of clinical research for a product candidate incorporating the CD 19 Antigen Receptor. The fundraising milestone payment is triggered by an initial funding event of LRx.

Everledger, Inc. During December 2018, we entered into a Joint Development Agreement with Everledger, Inc. (Everledger), an independent emerging technology enterprise. We intend to develop and market a combined physical and digital supply chain traceability and certification solution utilizing the our CertainT molecular tagging and authentication systems together with Everledger's blockchain-based platform.

Customer Concentration

Our revenues earned from sale of products and services for the fiscal year ended September 30, 2018 includes 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 82% of our accounts receivable. Our revenues earned from sale of products and services for the fiscal year ended September 30, 2017 included 29%, 26%, 13% and 10%, respectively from four customers. These four customers accounted for approximately 97% of our total accounts receivable at September 30, 2017. At September 30, 2017, 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., Alp Vision Sa, Authentix Inc., Brandwatch Technologies, Chromologic LLC, Collectors Universe Inc., Collotype Labels International, Data Dot Technology, De La Rue Plc., Digimarc Corp., DNA Technologies, Inc., DuPont Authentication Systems, FractureCode Corporation, Haelixa, ICA Bremen GmbH, ID Global Solutions Corporation, IEH Corporation Informium AG, Eastman Kodak Company, L-1 Identity Solutions Inc., opSec Security Group plc., MicroTagTemed Ltd., Nanotech Security Corp., Nokomis, Inc., Oritain Global Limited, ProoftagSAS, SafeTraces Inc., Selectamark Security Systems plc, Spectra Systems Corp., SmartWater Technology, Inc., Sun Chemical Corp, TraceTag International, TruTag Technologies Inc., YottaMark Inc., and Safe Traces, Inc. Some of our competitors that operate in the biotechnology markets include: Intrexon Corp,. Aldervron, LLC, Cobra Biologics, Limited, Integrated DNA Technologies, Inc., Ziopharm Oncology, Inc., MaxCyte Inc. and Touchlight Genetics Ltd.

Some examples of competing security products include:

- *integrated circuit chip and magnetic strips* (integrated circuit chips that receive and, if authentic, send a correct electric signal back to the reader, and magnetic strips that contain information, both of which are common components of debit and credit cards);
- *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 75 patents, 53 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 2033. 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.”

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.

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.

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.

Employees

As of September 30, 2018 we had a total of 59 employees, consisting of 3 in management, 12 in research and development, 1 in life sciences, 5 in forensics, 6 in quality assurance and compliance, 4 in finance and accounting, 1 in legal, 9 in operations, 9 in sales and marketing, 1 in human resources, 2 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. As we continue to expand, we will incur additional costs for human capital. 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, 2018, the employment contract 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:

There is substantial doubt relating to our ability to continue as a going concern.

We have recurring net losses, which have resulted in an accumulated deficit of $248,366,083 as of September 30, 2018. We have incurred a net loss of $11,692,928 for the fiscal year ended September 30, 2018. At September 30, 2018, we had cash and cash equivalents of $1,659,564. We have concluded that these factors raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the financial statements.

In addition, the report from our independent registered public accounting firm for the year ended September 30, 2018 includes an explanatory paragraph stating that our significant losses and needs to raise additional funds to meet our obligations and sustain operations raise substantial doubt about our ability to continue as a going concern. We will continue to seek to raise additional working capital through public equity, private equity or debt financings. If we fail to raise additional working capital, or do so on commercially unfavorable terms, it would materially and adversely affect our business, prospects, financial condition and results of operations, and we may be unable to continue as a going concern. Future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially

reasonable terms, if at all.

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 $11.7 million and $12.9 million for the fiscal years ended September 30, 2018 and 2017, 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 may 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 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, 2018 included an aggregate of 65% of our total revenues 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 82% of our total accounts receivable. Our revenues earned from sale of products and services for the fiscal year ended September 30, 2017 included an aggregate of 78% from four customers of our total revenues. These four customers accounted for approximately 97% of our total accounts receivable at September 30, 2017. At September 30, 2017, 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.

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.

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 and November 2018, we issued an aggregate of $2.2 million in principal amount of secured convertible notes, a majority of which are owned by our chairman, president and chief executive officer. These convertible notes may be converted into common stock, which, if converted by Dr. Hayward, would increase the amount of control he has over the Company. The Company may be adversely impacted if any related party agreement or transaction is made on unfavorable terms.

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 Chairman, Chief Executive Officer and President. 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, 2018, the employment contract 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 are owned by our chairman, president and chief executive officer. These convertible notes may be converted into common stock, which, if converted by Dr. Hayward, would increase the amount of control he has over the Company. 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., Alp Vision Sa, Authentix Inc., Brandwatch Technologies, Chromologic LLC, Collectors Universe Inc., Collotype Labels International, Data Dot Technology, De La Rue Plc., Digimarc Corp., DNA Technologies, Inc., DuPont Authentication Systems, FractureCode Corporation, Haelixa, ICA Bremen GmbH, ID Global Solutions Corporation, IEHCorporationInformium AG, Eastman Kodak Company, L-1 Identity Solutions Inc., opSec Security Group plc., MicroTagTemed Ltd., Nanotech Security Corp., Nokomis, Inc., Oritain Global Limited, ProoftagSAS, SafeTraces Inc., Selectamark Security Systems plc, Spectra Systems Corp., SmartWater Technology, Inc., Sun Chemical Corp, TraceTag International, TruTag Technologies Inc., YottaMark Inc., Safe Traces, 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 derive 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 will be seasonal, 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.

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.

Shifting enforcement priorities of U.S. federal laws relating to cannabis.

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 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, including revenue from our agreements with Colorcon 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 regulations (“cGMPs”), 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 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.

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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.

Our future growth, if any, may be attributable to acquisitions of new product lines and new businesses. Future acquisitions, if successfully consummated, would likely create increased working capital requirements, which would likely precede by several months any material contribution of an acquisition to our net income. Our failure to manage growth or future acquisitions successfully could seriously harm our operating results. Also, acquisition costs could cause our operating results to vary significantly from quarter to quarter. Furthermore, our stockholders would be diluted if we financed the acquisitions by incurring convertible debt or issuing securities.

A percentage of our sales occur outside of the U.S. As a result, we are subject to the economic, political, regulatory and other risks of international operations.

For fiscal 2018 and 2017, 45% and 27%, 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 continue to 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.

We are subject to numerous regulatory, legal, operational, and other risks as a result of our international operations which could adversely impact our businesses in many ways.

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 our Chief Executive Officer. See "—If we are unable to continue to retain the services of Dr. Hayward, we may not be able to continue our operations" in this Item 1A.

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 United States 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 September 30, 2018, 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 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 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 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, prospects, 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 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.

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 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; HIPAA; HIPAA, as amended by HITECH; 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. The holders of our publicly traded warrants may require their repurchase in certain circumstances.

As of December 14, 2018, we had 30,112,057 shares of common stock issued and outstanding, outstanding options to purchase 6,177,214 shares of common stock and outstanding warrants to purchase 12,208,527 shares of common stock. The issuance of shares upon exercise of our outstanding options and warrants will cause immediate and substantial dilution to our stockholders. Under our publicly traded warrants (including additional 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 and April 2015, our registered direct public offering (the "Registered Direct Offering") and concurrent private placement, during November 2015, our private placements completed in November 2016 and June 2017 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 convertible notes in August 2018 and November 2018 could result in dilution to investors if the holders convert their notes into shares of our common stock.

Conversion of our 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 the 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 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 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.

On August 31, 2018 we entered into a securities purchase agreement pursuant to which we issued and sold an aggregate of $1.65 million in principal amount of secured convertible notes and on November 29, 2018 we entered into a second securities purchase agreement pursuant to which we issued and sold an aggregate of $550 thousand in principal amount of secured convertible notes (together, the “Notes”) which are due and payable in full on August 30, 2021 and November 28, 2021, respectively. A majority of the Notes are owned by our chairman, president and chief executive officer. Until the principal and accrued but unpaid interest under the Notes is paid in full, or the Notes are converted into shares of common stock, our obligations under the 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 CSC Corporation, as collateral agent for the purchasers of the Notes. The secured assets include substantially all of our intellectual property. 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 Notes, holders of the Notes may choose to enforce their remedies and ultimately realize on the collateral securing the 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 and publicly traded warrants are listed on The Nasdaq Capital Market under the symbols "APDN" and "APDNW," respectively. For our common stock and publicly traded warrants to continue to be listed on The Nasdaq Capital Market, we must meet the current continued listing requirements, including the requirements that (1) our stock must maintain a minimum closing bid price of $1.00 (the "Minimum Bid Price Requirement"); and (2) we must maintain net income from continuing operations (in the latest fiscal year or two of the three last fiscal years) of at least $500,000, a market value of listed securities of at least $35 million or stockholders' equity of at least $2.5 million (the "Minimum Stockholders' Equity Requirement").

As of September 30, 2018, our stockholders' equity was below the Minimum Stockholders' Equity Requirement. We are currently evaluating potential solutions to regain compliance with the Minimum Stockholders' Equity Requirement. The Minimum Stockholders' Equity Requirement is not subject to an automatic grace period. There can be no assurance that we will meet the Minimum Stockholders' Equity Requirement or the Minimum Bid Price Requirement during any compliance period or in the future, or otherwise meet The Nasdaq Capital Market compliance standards, or that The Nasdaq Capital Market will grant the Company any relief from delisting as necessary, or that we will be able to ultimately meet applicable The Nasdaq Capital Market requirements for any such relief.

If we were unable to meet The Nasdaq Capital Market's listing requirements, our common stock and warrants could be delisted from The Nasdaq Capital Market. If our securities were to be delisted from The Nasdaq Capital Market, our securities could begin to trade on the Over-The-Counter Bulletin Board or on one of the markets operated by OTC Markets Group, including OTC Pink (formerly known as the "pink sheets"), as the case may be. In such event, our securities could once again 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 securities could have an adverse effect on the market price of, and the efficiency of the trading market for our securities, 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.

Any material weaknesses in our internal control over financing 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 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, The Nasdaq Capital Market 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.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our reputation and materially adversely affect our business, financial condition and results of operations.

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 is $458,098 per annum. 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. We set up a satellite testing facility in Ahmedabad, India 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 are listed on The NASDAQ Capital Market under the symbol “APDNW”. There is no certainty that the common stock and warrants will continue to be listed or that any liquidity exists for our stockholders, or warrant holders.

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, 2018 and 2017:

	Fiscal 2018		Fiscal 2017	
Common Stock:	High	Low	High	Low
First Quarter	$3.45	$1.52	$3.15	$1.73
Second Quarter	$1.75	$1.36	$2.05	$1.40
Third Quarter	$1.59	$1.21	$1.94	$1.94
Fourth Quarter	$1.84	$1.10	$2.88	$1.55

	Fiscal 2018		Fiscal 2017	
Warrants:	High	Low	High	Low
First Quarter	$0.85	$0.21	$1.16	$0.35
Second Quarter	$0.44	$0.25	$0.55	$0.35
Third Quarter	$0.36	$0.12	$0.50	$0.22
Fourth Quarter	$0.30	$0.13	$1.04	$0.30

Holders

As of December 10, 2018, we had approximately 576 holders of record of our common stock and 3 holders of record of our publicly traded warrants. 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 and warrants 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.

Introduction

Using our large scale polymerase chain reaction (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 and 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 wholly owned subsidiary, LRx, we supply DNA for the use in in vitro medical diagnostics, preclinical biotechnology and drug and biologic manufacturing markets, and are also engaged in preclinical and animal drug candidate development and commercialization activities focusing on therapeutically relevant DNA drug constructs manufacturers via through our PCR-based DNA production platform Triathlon™ PCR systems.

General

To date, the substantial portion of our revenues have been generated from sales of our SigNature molecular tags 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 government 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 our PCR-produced linear DNA products and services for in vitro medical diagnostics, biotechnology research and drug and biologic manufacturing. We have continued to incur expenses in expanding our business and increasing our personnel 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, cannabis and PCR-produced linear DNA products and services (for therapeutics, diagnostics and vaccines). Currently approximately twenty percent of our annual revenue comes from the textile market. 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. 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.

We have continued to incur expenses in expanding our business to meet current and anticipated future demand. We have limited sources of liquidity. Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements for the year ended September 30, 2018 included in this Annual Report on Form 10-K. 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, bulk DNA production (for therapeutics, diagnostics and vaccines), cash-in-transit, consumer asset marking, printing and packaging businesses, and

agrochemicals. 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 addition, we seek to develop, acquire and commercialize, 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 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 drug construct manufacturers through our Triathlon™ PCR systems. LRx uses the Triathlon™ PCR system to rapidly produce customized DNA for use by our CRO/CMO clients, our drug and biologic partners, and for our proprietary pre-clinical gene therapies. LRx's proprietary process enables large, gram-scale production of DNA through PCR for bio-based therapeutics, adoptive cell therapies, vaccines (including cancer), 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

We recognize revenue in accordance with Accounting Standards Codification ("ASC") 605, Revenue Recognition ("ASC 605"). ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and/or service has been performed; (3) the selling price is fixed and determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the fixed nature of the selling prices of the products delivered or services provided and the collectability of those amounts. Provisions for allowances and other adjustments are provided for in the same period the related sales are recorded. We defer any revenue for which the product has not been delivered, service has not been provided, or is subject to refund until such time that we and the customer jointly determine that the product has been delivered, the service has been provided, or no refund will be required.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer. Consideration received is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party is available. The applicable revenue recognition criteria are then applied to each of the units.

Revenue for government contract awards, which supports our development efforts on specific projects, is recognized as milestones are achieved as per the contract. Revenue for firm fixed price government contract awards are recognized over the period of the contract. We recognized revenue of $748,040 and $249,348, from these contract awards during the fiscal years ended September 30, 2018 and 2017, respectively.

The Company has a licensing agreement with Himatsingka that operates in the cotton industry. The shipment to this customer during June 2018 included extended payment terms, as compared to those defined in the contract. The extended payment terms for this shipment are three equal installments due 90, 180 and 270 days from shipment. Due to the extended payment terms, this shipment was originally recorded to deferred revenue and the deferred revenue will be recognized to revenue as the payments become due and assuming all other conditions for revenue recognition have been satisfied. At September 30, 2018, the amount included in deferred revenue related to the shipment with extended payment terms was $766,192. 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 our fiscal year.

Equity Based Compensation

We account for stock-based compensation for employees and directors in accordance with AS 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 our common stock options is estimated using the Black Scholes option-pricing model with the following assumptions: expected volatility, dividend rate, risk free interest rate and the expected life. We expense 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. We estimate the number of awards expected to be forfeited and adjust the estimate when it is no longer probable that the employee will fulfill the service conditions.

We account for stock-based compensation awards issued to non-employees for services, as prescribed by ASC 718-10, at either the fair value of the services rendered, or the instruments issued in exchange for such services, whichever is more readily determinable, using the measurement date guidelines enumerated in ASC 505-50.

Use of Estimates

The preparation of the financial statements in conformity with Accounting Principles Generally Accepted in the United States ("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 recoverability of long-lived assets, including the values assigned to goodwill, intangible assets and

property, plant and equipment, fair value calculations for stock based compensation, 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, 2018 to the Fiscal Year Ended September 30, 2017

Revenues

Product revenues

For the fiscal years ended September 30, 2018 and 2017, we generated $1,827,626 and $3,733,995 in revenues from product sales, respectively. The decrease in product revenues of $1,906,369 or 51% for the fiscal year ended September 30, 2018 is attributable to a decrease in revenue of approximately $2,237,000 in the textile industry for protecting cotton and synthetic supply chains. Decreases in the textile division were offset partially by an increase in revenue from DNA Production of $342,943.

Service revenues

For the fiscal years ended September 30, 2018 and 2017, we generated $2,075,717 and $1,017,265 in revenues from sales of services, respectively. The increase in service revenues of $1,058,452 or 104% for the fiscal year ended September 30, 2018 is attributable to an increase in the government contract award of approximately $500,000 as well as an increase of approximately $729,000 related to feasibility projects. This increase was comprised of $354,000 for a cannabis pilot as well as the recognition of $375,000 for pharmaceuticals. These increases were partially offset by the completion of a fertilizer pilot of $95,000 during the prior fiscal year.

Costs and Expenses

Cost of Revenues

Cost of revenues for the fiscal years ended September 30, 2018 and 2017 were $1,206,814 and $1,077,232, respectively. Cost of revenues as a percentage of product revenue were 66% and 29% for the fiscal years ended September 30, 2018 and 2017, respectively. This increase in cost of revenues as a percentage of product revenues is due to decreased sales to the textile industry which carry higher margins. To a lesser extent, the increase of costs of revenues as a percentage of product revenues is due to lower product revenue during the current fiscal year and therefore, our production decreased, and, as a result, our fixed production costs, primarily comprised of payroll expenses and rent and utilities allocated to our production facilities, were not fully absorbed by product sales.

Selling, General and Administrative

Selling, general and administrative expenses for the fiscal year ended September 30, 2018 decreased by $2,281,040 or 17% to $11,043,463 from $13,324,503 in the same period in fiscal 2017. The decrease is primarily attributable to an decrease in stock based compensation expense of approximately $1,900,000, related to the recognition of expense related to certain performance based options during the prior fiscal year, these same performance based options were cancelled during the fiscal year ended September 30, 2018; therefore, the performance conditions were no longer probable and the options did not vest and the related expense of $415,786 was reversed during the current fiscal year. The decrease also related to a decrease in bad debt of $403,000 as a result of the write-off of a portion of our accounts receivable during the prior fiscal year, as well as a decrease of $252,000 in legal expenses. These decreases were offset by an increase in payroll of $298,000 primarily resulting from the accrual of the Chief Executive Officer’s bonus, offset by a reduction in regular payroll for deferred salary accrual recorded during the fiscal third quarter.

Research and Development

Research and development expenses increased by $469,216 or 21% for the fiscal year ended September 30, 2018 compared to the same period in fiscal 2017 to $2,751,578 from $2,282,362. The increase is primarily attributable to development costs incurred in relation the government development contract award.

Depreciation and Amortization

Depreciation and amortization decreased by $339,509 or 38% compared to the same period in 2017 from $887,305 for the fiscal year ended September 30, 2017 to $547,796 for the fiscal year ended September 30, 2018.The decrease is attributable to impairment of approximately $253,000 of internally developed software during the fiscal year ended September 30, 2017.

Interest income (expense)

Interest income (expense) for the fiscal year ended September 30, 2018, decreased to expense of $9,615 from income of $2,763 in the same period of 2017. The decrease in interest income was due to interest earned on the convertible notes payable for the fiscal year ended September 30, 2018.

Other (expense) income

Other (expense) income for the fiscal year ended September 30, 2018, decreased to expense of $37,005 from expense of $38,388 in the same period of 2017.

Net Loss

Net loss decreased $1,162,839, or 9% to $11,692,928 for the fiscal year ended September 30, 2018 compared to $12,855,767 for the fiscal year ended September 30, 2017 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, 2018, we had working capital of $1,180,185. For the fiscal year ended September 30, 2018, we used cash in operating activities of $6,917,209 consisting primarily of our loss of $11,692,928 net with non-cash adjustments of $547,796 in depreciation and amortization charges, $1,356,351 for stock-based compensation, $20,552 of bad debt expense and $1,479 in amortization of debt issuance costs. Additionally, we had a net decrease in operating assets of $917,659 and a net increase in operating liabilities of $1,931,882. Cash used in investing activities was $266,008, for the purchase of property and equipment. Cash provided by financing activities was $5,883,000, which included net proceeds from the sale of common stock and warrants related to a private placement in December 2017 and the proceeds from the sale of senior secured convertible promissory notes during August 2018. In addition, on November 29, 2018, we closed on senior secured convertible promissory notes that resulted in gross proceeds to us of $550,000.

We have recurring net losses, which have resulted in an accumulated deficit of $248,366,083 as of September 30, 2018. We have incurred a net loss of $11,692,928 for the fiscal year ended September 30, 2018. At September 30, 2018, we had cash and cash equivalents of $1,659,564. These factors raise substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of the financial statements. The ability of the Company to continue as a going concern is dependent on the Company's ability to further implement its business plan, raise capital, and generate revenues. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Our current capital resources include cash and cash equivalents, accounts receivable and inventories. Historically, we have financed our operations principally from the sale of equity securities. As discussed in Note G, to the accompanying consolidated financial statements, on August 31, 2018 and November 29, 2018, we closed on $1,650,000 million and $550,000, respectively, of senior secured convertible notes by way of a private placement with accredited investors and certain members of our management team and Board of Directors.

We expect capital expenditures to be less than $200,000 in fiscal 2019. Our primary investments will be in laboratory equipment to support prototyping, manufacturing, our authentication services, and outside services for our detector and reader development. These capital expenditures include one-time set up costs associated with the establishment of our laboratory space located in India.

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

Recent Debt and Equity Financing Transactions

Fiscal 2018

On December 22, 2017, we closed a securities purchase agreement with certain institutional investors for the purchase and sale of 2,735,000 shares of our common stock and warrants to purchase an aggregate of 2,735,000 shares of common stock in a registered direct offering with aggregate gross proceeds of $4,786,250, at a combined purchase price of $1.75 per share. The warrants will be immediately exercisable at a price of $2.00 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 $0.44. 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 $5.00 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.”

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 31st Notes") bearing interest at a rate of 6% per annum (the "Private Placement"). As part of the August 31st Notes, our management and Board of Directors purchased Notes with a principal amount of $1,185,000.

The August 31st 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 $2.50. 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 $2.50 if the price of the common stock remains at a closing price of $3.50 or more for a period of twenty consecutive trading days.

Upon any Change in Control (as defined in the August 31st 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 31st 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 31st 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 31st Notes 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).

The Private Placement was completed in reliance upon the exemption from registration provided for by Section 4(a)(2) of the Securities Act and by Rule 506 of Regulation D promulgated under the Securities Act. Each of the Purchasers represented to in the Purchase Agreement that he or she is an “accredited investor” as that term is defined in Rule 501 of Regulation D.

Fiscal 2017

On November 2, 2016, we entered into a securities purchase agreement with an institutional investor providing for the purchase of $5 million of common stock and warrants at a combined price of $2.20 per share of common stock and warrant (the “Private Placement”). In the Private Placement, we sold 2,272,727 shares of our common stock and warrants to purchase 2,272,727 shares of our common stock. The warrants have the same terms as our existing publicly traded warrants (APDNW) with an exercise price of $3.50 per share and an expiration date of November 20, 2019. The offering closed on November 7, 2016.

We agreed to file a registration statement providing for the resale of these securities on Form S-3 by December 7, 2016. On December 6, 2016, we filed the Form S-3, which was declared effective by the SEC on December 13, 2016. Upon effectiveness of the registration statement, the common stock and warrants issued in the Private Placement became freely tradeable on The NASDAQ Capital Market under the symbols "APDN" and "APDNW", respectively.

The aggregate gross proceeds to us from the Fiscal 2017 Private Placement were $5 million before deducting the placement agents' fee and other offering expenses. As a result of the placement agents’ fee and other offering expenses attributable to the Fiscal 2017Private Placement, the net proceeds were $4,319,863.

In connection with the closing of the Fiscal 2017 Private Placement, as partial compensation, on November 7, 2016, we granted warrants to purchase an aggregate of 68,182 shares of our common stock to the our placement agents, Maxim Group LLC and Imperial Capital LLC (the “Placement Agent Warrants”) at an exercise price of $2.53 (115% of the public offering price), subject to adjustment as set forth therein (including for stock dividends and splits and certain other distributions and “Fundamental Transactions,” as defined therein). The Placement Agent Warrants will be exercisable beginning six months following the closing date of the Private Placement and terminate at 5:00 P.M. (Eastern Standard Time) on November 7, 2021. In addition, the Placement Agent Warrants provide for cashless exercise, which the Placement Agents may elect if there is no effective registration statement registering the resale of the shares issuable upon exercise of the Placement Agent Warrants. The number of shares of common stock that may be acquired by the Placement Agents upon any exercise of the Placement Agent Warrants (or otherwise in respect hereof) shall be limited to the extent necessary to insure that, following such exercise, the total number of shares of common stock then beneficially owned by the Placement Agent and its Affiliates (as defined therein) and any other Persons whose beneficial ownership of common stock would be aggregated with the Placement Agent pursuant to the Securities Exchange Act of 1934, as amended (the “Exchange Act”), does not exceed 9.99% of the total number of

issued and outstanding shares of common stock.

On June 28, 2017 we entered into subscription agreements for a private placement of our common stock, with a group of investors, including a strategic investor which is also a key customer and intellectual property licensee of ours as well as all of our executive officers and all members of the Board of Directors. As a result of the private placement we issued 1,025,574 shares of common stock at a price of $1.76 per share for total gross proceeds of $1,805,000. As part of the private placement, our management and Board of Directors purchased 315,346 shares of common stock for gross proceeds of $555,000. The issuance of the Common Stock was exempt from the registration requirements of the Securities Act of 1933 (the “Securities Act”) pursuant to Section 4(a)(2) of such Securities Act and Regulation D promulgated thereunder and such Common Stock will therefore be restricted. Each investor gave representations that he, she or it was an “accredited investor” (as defined under Rule 501 of Regulation D) and that he, she or it is purchasing such securities without a present view toward a distribution of the securities. In addition, there was no general solicitation conducted in connection with the offer and sale of the securities.

Subsequent Events

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 29th Notes"). The November 29th Notes are substantially similar to our August 31 Notes 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 31 Notes.

Product Research and Development

We anticipate spending approximately $3,000,000 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, 2018 and 2017.

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-25 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, 2018, 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, 2018. 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, 2018, 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, 2018. 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, 2018.

Changes in Internal Control over Financial Reporting

The Company utilizes an outside consulting firm to assist in the analysis of technical accounting matters, which are then reviewed by the Company's chief financial officer and financial reporting manager. Other than this one change, there were no additional 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.

Not applicable.

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 2018 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after September 30, 2018. 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, 2018 and 2017 and for the years ended September 30, 2018 and 2017, 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 18, 2018 /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 18, 2018
/s/ **BETH M. JANTZEN** Beth M. Jantzen	Chief Financial Officer (*Principal Financial Officer and* *Principal Accounting Officer*)	December 18, 2018
/s/ **JOHN BITZER, III** John Bitzer, III	Director	December 18, 2018
/s/ **ROBERT CATELL** Robert Catell	Director	December 18, 2018
/s/ **JOSEPH D. CECCOLI** Joseph D. Ceccoli	Director	December 18, 2018
/s/ **CHARLES S. RYAN** Charles S. Ryan	Director	December 18, 2018

/s/ **YACOV A. SHAMASH** Yacov A. Shamash	Director	December 18, 2018
/s/ **SANFORD R. SIMON** Sanford R. Simon	Director	December 18, 2018
/s/ **ELIZABETH M. SCHMALZ FERGUSON** Betsy M. Schmalz Ferguson	Director	December 18, 2018

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.

		Incorporated by Reference				Filed or Furnished Herewith
Exhibit Number	**Description**	**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	Form of Certificate of Designations of the Series A Convertible Preferred Stock	8-K	3.1	002-90539	11/29/2012	
3.6	Form of Certificate of Designations of the Series B Convertible Preferred Stock	8-K	3.1	002-90539	7/22/2013	
3.7	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	
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	Form of Warrant, dated July 15, 2011, issued to the investors named on the signature pages	10-K	10.29	002-90539	12/9/2011
10.5†	Employment Agreement, dated July 1, 2017, between James A. Hayward and Applied DNA Sciences, Inc.	8-K	10.1	001-36745	8/2/2016
10.6*	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
10.7	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
10.8	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
10.9†	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
10.10	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
10.11	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
10.12*	Term sheet for Mutual Cooperation with Borealis AG dated March 31, 2014	8-K/A	10.1	002-90539	7/22/2014
10.13	Form of Subscription Agreement dated June 3, 2014	8-K	10.1	002-90539	6/6/2014
10.14	Form of Warrant dated June 3, 2014	8-K	10.2	002-90539	6/6/2014
10.15	Form of Award/Contract issued by U.S. Missile Defense Agency dated July 14, 2014	8-K	10.1	002-90539	7/18/2014
10.16	Form of Promissory Note	8-K	10.1	002-90539	9/17/2014
10.17	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

		Incorporated by Reference				Filed or Furnished Herewith
Exhibit Number	**Description**	**Form**	**Exhibit**	**File No.**	**Date Filed**	
10.18	Warrant Repurchase Option Agreement dated October 28, 2014 between Applied DNA Sciences, Inc. and Crede CG III, Ltd.	S-1/A	10.28	333-199121	10/30/2014	
10.19	Letter Agreement dated November 11, 2014 between Applied DNA Sciences, Inc. and James A. Hayward regarding Exchange of 12.5% Promissory Note	S-1/A	10.29	333-199121	11/12/2014	
10.20	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	
10.21	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	
10.22	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	
10.23*	Mutual License Agreement dated March 25, 2015 between Applied DNA Sciences, Inc. and Divatex Home Fashion, Inc.	10-Q	10.1	001-36745	5/11/2015	
10.24	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	
10.25**	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	
10.26	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	
10.27	Form of Securities Purchase Agreement	8-K/A	10.2	001-36745	11/23/2015	
10.28	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	
10.29	Securities Purchase Agreement dated November 2, 2016	8-K	10.2	001-36745	11/2/2016	
10.30	Registration Rights Agreement dated November 2, 2016	8-K	10.3	001-36745	11/2/2016	
10.31	Second Amendment to Warrant Agreement dated November 2, 2016	8-K	10.4	001-36745	11/2/2016	
10.32	Form of Subscription Agreement	8-K	10.1	001-36745	6/28/2017	
10.33	Form of Convertible Note	8-K	10.1	001-36745	12/6/2018	

10.34	Registration Rights Agreement, dated November 29, 2018	8-K	10.2	001-36745	12/6/2018	
10.35	Securities Purchase Agreement, dated November 29, 2018	8-K	10.3	001-36745	12/6/2018	
10.36	Form of Convertible Note	8-K/A	10.1	001-36745	12/10/2018	
10.37	Registration Rights Agreement, dated August 31, 2018	8-K/A	10.2	001-36745	12/10/2018	
10.38	Securities Purchase Agreement, dated August 31, 2018	8-K/A	10.3	001-36745	12/10/2018	
10.39	Collateral Agency Agreement dated October 19, 2018					Filed
10.40	Security Agreement dated October 19, 2018					Filed
10.41	First Amendment to Security Agreement dated November 26, 2018					Filed
10.42	Guaranty and Security Agreement dated October 19, 2018					Filed
10.43	Intellectual Property Security Agreement dated October 19, 2018					Filed
10.44	Intellectual Property Security Agreement dated October 19, 2018					Filed
10.45	Securities Purchase Agreement, dated August 31, 2018					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.

** 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, 2018 and 2017, the related consolidated statements of operations, stockholders’ equity and cash flows for each of the two years in the period ended September 30, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note A, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note A. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 18, 2018

APPLIED DNA SCIENCES, INC.

CONSOLIDATED BALANCE SHEETS

SEPTEMBER 30, 2018 AND 2017

	September 30, 2018	**2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$1,659,564	$2,959,781
Accounts receivable, net of allowance of $13,133 and $10,000 at September 30, 2018 and 2017, respectively	1,485,938	2,587,969
Inventories	221,369	326,468
Prepaid expenses and other current assets	635,174	366,954
Total current assets	4,002,045	6,241,172
Property and equipment, net	419,774	523,688
Other assets:		
Deposits	62,325	61,626
Goodwill	285,386	285,386
Intangible assets, net	864,203	1,042,076
Total Assets	$5,633,733	$8,153,948
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities (including related party of $5,844 at September 30, 2018)	$965,167	$944,133
Deferred revenue	1,856,693	351,735
Total current liabilities	2,821,860	1,295,868
Long term accrued liabilities	470,739	-
Secured convertible notes payable, net of debt issuance costs (including related party of $1,139,490 at September 30, 2018)	1,586,631	-
Total liabilities	4,879,230	1,295,868
Commitments and contingencies		
Stockholders' Equity:		
	-	-

Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- shares issued and outstanding as of September 30, 2018 and 2017		
Series A Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2018 and 2017	-	-
Series B Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2018 and 2017	-	-
Common stock, par value $0.001 per share; 500,000,000 shares authorized; 30,112,057 and 27,377,057 shares issued and outstanding as of September 30, 2018 and 2017, respectively	30,112	27,377
Additional paid in capital	249,090,474	243,503,858
Accumulated deficit	(248,366,083)	(236,673,155)
Total stockholders' equity	754,503	6,858,080
Total Liabilities and Stockholders' Equity	$5,633,733	$8,153,948

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
Revenues:		
Product revenues	$1,827,626	$3,733,995
Service revenues	2,075,717	1,017,265
Total revenues	3,903,343	4,751,260
Cost of revenues	1,206,814	1,077,232
Operating expenses:		
Selling, general and administrative	11,043,463	13,324,503
Research and development	2,751,578	2,282,362
Depreciation and amortization	547,796	887,305
Total operating expenses	14,342,837	16,494,170
LOSS FROM OPERATIONS	(11,646,308)	(12,820,142)
Other (expense) income:		
Interest (expense) income, net (including related party interest of $5,844 for the year ended September 30, 2018)	(9,615)	2,763
Other expense, net	(37,005)	(38,388)
Loss before provision for income taxes	(11,692,928)	(12,855,767)
Provision for income taxes	-	-
NET LOSS	$(11,692,928)	$(12,855,767)
Net loss per share-basic and diluted	$(0.40)	$(0.49)
Weighted average shares outstanding-basic and diluted	29,497,619	26,378,991

See the accompanying notes to the consolidated financial statements

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APPLIED DNA SCIENCES, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

YEARS ENDED SEPTEMBER 30, 2018 and 2017

	Common Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Total
Balance, October 1, 2016	24,078,756	$24,079	$234,158,711	$(223,817,388)	$10,365,402
Common stock issued for consulting services	1,025,574	1,025	1,770,252	—	1,771,277
Shares issued in underwritten public offerings, net of offering costs	2,272,727	2,273	4,317,590	—	4,319,863
Stock based compensation expense	—	—	3,257,305	—	3,257,305
Net loss	—	—	—	(12,855,767)	(12,855,767)
Balance, September 30, 2017	27,377,057	$27,377	$243,503,858	$(236,673,155)	$6,858,080
Common stock issued in private placement, net of offering costs	2,735,000	2,735	4,230,265	—	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	30,112,057	$30,112	$249,090,474	$(248,366,083)	$754,503

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC.

CONSOLIDATED STATEMENT OF CASH FLOWS

YEARS ENDED SEPTEMBER 30, 2018 AND 2017

	2018	2017
Cash flows from operating activities:		
Net loss	$(11,692,928)	$(12,855,767)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	547,796	633,328
Impairment expense	-	253,977
Stock based compensation expense	1,356,351	3,257,305
Amortization of debt issuance costs	1,479	-
Provision for bad debts	20,552	423,920
Change in operating assets and liabilities:		
Accounts receivable	1,081,480	3,084,311
Inventories	105,099	(28,709)
Prepaid expenses, other current assets and deposits	(268,920)	(167,448)
Accounts payable and accrued liabilities	426,924	(610,504)
Deferred revenue	1,504,958	(1,469,597)
Net cash used in operating activities	(6,917,209)	(7,479,184)
Cash flows from investing activities:		
Purchases of property and equipment	(266,008)	(145,436)
Net cash used in investing activities	(266,008)	(145,436)
Cash flows from financing activities:		
Net proceeds from sale of common stock and warrants	4,233,000	6,105,127
Net proceeds from secured convertible promissory notes (including related party of $1,185,000 for the year ended September 30, 2018)	1,650,000	-
Net cash provided by financing activities	5,883,000	6,105,127
Net decrease in cash and cash equivalents	(1,300,217)	(1,519,493)
Cash and cash equivalents at beginning of year	2,959,781	4,479,274
Cash and cash equivalents at end of year	$1,659,564	$2,959,781
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:		
Debt issuance costs included in accounts payable and accrued liabilities	$64,848	$-
Reclassification of deferred offering costs to additional paid in capital	$-	$13,986

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

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 $248,366,083 as of September 30, 2018. The Company incurred a net loss of $11,692,928 and generated negative operating cash flow of $6,917,209 for the fiscal year ended September 30, 2018. At September 30, 2018 the Company had cash and cash equivalents of $1,659,564 and working capital of $1,180,185. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the financial statements. The ability of the Company to continue as a going concern is dependent on the Company's ability to further implement its business plan, raise capital, and generate revenues. The Financial Statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The Company's current capital resources include cash and cash equivalents, accounts receivable and inventories. Historically, the Company has financed its operations principally from the sale of equity securities.

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 plant-based or other 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 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 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.

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 recoverability of long-lived assets, including the values assigned to goodwill, intangible assets and property and equipment, fair value calculations for stock based compensation, 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.

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") 605, Revenue Recognition ("ASC 605"). ASC 605 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and/or service has been performed; (3) the selling price is fixed and determinable; and (4) collectability is reasonably assured. Determination of criteria (3) and (4) are based on management's judgments regarding the fixed nature of the selling prices of the products delivered or services provided and the collectability of those amounts. Provisions for allowances and other adjustments are provided for in the same period the related sales are recorded. The Company defers any revenue for which the product has not been delivered, service has not been provided, or is subject to refund until such time that the Company and the customer jointly determine that the product has been delivered, the service has been provided, or no refund will be required. At September 30, 2018 and 2017, the Company recorded total deferred revenue of $1,856,693 and $351,735, respectively.

Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer. Consideration received is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.

Revenue for government contract awards, which supports the Company's development efforts on specific projects, is recognized as firm fixed price government contract awards and are recognized over the period of the contract. The Company recognized revenue from a government contract of $748,040 and $249,348 for the fiscal years ended September 30, 2018 and 2017, respectively.

The Company has a licensing agreement with a company that operates in the cotton industry. The shipment to this customer during fiscal 2018 included extended payment terms, as compared to those defined in the contract and therefore is included in deferred revenue as of September 30, 2018. The extended payment terms for this shipment are three equal installments due 90, 180 and 270 days from shipment. The deferred revenue will be recognized to revenue as the payments become due assuming all other conditions for revenue recognition have been satisfied. At September 30, 2018, the amount included in deferred revenue related to the shipment with extended payment terms was $766,192. 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.

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, 2018 and 2017, the Company has an allowance for doubtful accounts of $13,133 and $10,000, respectively. The Company writes-off receivables that are deemed uncollectible.

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

Inventories

Inventories, which consist primarily of raw materials and finished goods, are stated at the lower of cost or net realizable value, which 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, 2018 and 2017, 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, 2018 and 2017. Tax years 2014 through 2017 remain subject to future examination by the applicable taxing authorities.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act makes broad and complex changes to the U.S. tax code that will affect the Company's fiscal year ending September 30, 2018, including, but not limited to, reducing the U.S. federal corporate tax rate. The Tax Act reduces the federal corporate tax rate to 21% in the fiscal year ending September 30, 2018. As the Company has a September 30 fiscal year-end, the lower corporate income tax rate will be phased in, resulting in a U.S. federal statutory rate of approximately 24.3% for fiscal 2018 and a 21% U.S. federal statutory rate for subsequent fiscal years. The reduction of the corporate tax rate caused the Company to reduce its deferred tax asset to the lower federal base rate of 21% and the Company adjusted the valuation allowance against the deferred tax asset by the same amount, this also resulted in a decrease to the deferred tax asset and valuation allowance of $6,865,546. The Company has a full allowance against the deferred tax asset and as a result there was no impact to income tax expense for the twelve month period ended September 30, 2018. The Tax Act imposes a one-time transition tax that requires companies to increase U.S. taxable income for accumulated foreign subsidiary earnings not previously subject to U.S. income tax at a rate of 15.5% to the extent of foreign cash and certain other net current assets and 8% on the remaining earnings. As the foreign subsidiaries of the Company have a cumulative net deficit position, there is no impact for this transition tax.

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 lease terms. Property and equipment consist of:

	September 30,	
	2018	**2017**
Computer equipment	$135,621	$85,413
Lab equipment	1,951,955	1,770,407
Furniture	74,781	44,592
Leasehold improvements	293,672	289,573
Total	2,456,029	2,189,985
Accumulated depreciation	2,036,255	1,666,297
Property and equipment, net	$419,774	$523,688

Depreciation expense for the fiscal years ended September 30, 2018 and 2017 were $369,924 and $403,482, respectively.

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APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

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. For the fiscal year ended September 30, 2017, the Company recorded an impairment charge of $253,977, as determined by non-recurring Level 3 inputs, related to capitalized software which is included in depreciation and amortization expense in the consolidated statements of operations.

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, 2018 and 2017, 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, 2018 and 2017 are as follows:

	2018	2017
Warrants	12,208,527	9,540,455
Options	6,183,214	5,333,227
	18,391,741	14,873,682

Stock-Based Compensation

The Company accounts for stock-based compensation for employees and directors 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 is 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 in cash flows from operating activities. All excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payments awards) are recognized as income tax expense or benefit in the consolidated statement of operations. The Company estimates the number of awards expected to be forfeited and adjusts the estimate when it is no longer probable that the employee will fulfill the service conditions.

The Company accounts for stock-based compensation awards issued to non-employees for services, as prescribed by ASC 718-10, at either the fair value of the services rendered or the instruments issued in exchange for such services, whichever is more readily determinable, using the measurement date guidelines enumerated in ASC 505-50.

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 temporary cash investments 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, 2018 include 24%, 16%, 14% and 11%, respectively from four customers of the Company's total revenues. These customers accounted for approximately 96% of the Company's total accounts receivable at September 30, 2018. At September 30, 2018, one customer accounted for an aggregate of 82% of the Company's total accounts receivable.

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APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

The Company's revenues earned from sale of products and services for the fiscal years ended September 30, 2017 include 29%, 26%, 13% and 10%, respectively from four customers of the Company's total revenues. These customers accounted for approximately 97% of the Company's total accounts receivable at September 30, 2017. At September 30, 2017, one customer accounted for an aggregate of 80% of the Company's total accounts receivable.

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, 2018 and 2017, the Company incurred research and development expenses of $2,751,578 and $2,282,362, respectively.

Advertising

The Company follows the policy of charging the costs of advertising to expense as incurred. The Company charged to operations $287,156 and $315,266, as advertising costs for the fiscal years ended September 30, 2018 and 2017, 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, 2018 and 2017, the Company performed its 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.

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.

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

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.

Recently Issued Accounting Principles

In November 2018, the Financial Accounting Standards Board ("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 is to clarify certain transactions between collaborative arrangement participants which 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", 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. Early adoption is permitted. The Company does not expect the adoption of ASU 2018-18 to have a material impact on its consolidated financial statements and related disclosures.

In July 2017, the FASB issued a two-part Accounting Standards Update ("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 2018-11 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 20178-11 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 is currently evaluating the impact of adopting this guidance.

In May 2017, the FASB issued ASU 2017-09, Compensation – "Stock Compensation (Topic 718): Scope of Modification Accounting", 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 does not expect the adoption of ASU 2017-09 to have a material impact on its consolidated financial statements and related disclosures.

In January 2017, the FASB ASU 2017-01, "Business Combinations (Topic 805): Clarifying the Definition of a Business" ("ASU 2017-01"). The amendments in this update are to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company does not expect the adoption of ASU 2017-01 to 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 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 to determine the impact it may have on its consolidated financial statements.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE B – SUMMARY OF ACCOUNTING POLICIES, continued

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”), which was subsequently modified in August 2015 by ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date. This guidance will be effective for fiscal years (and interim reporting periods within those years) beginning after December 15, 2017, which for the Company is the first quarter of fiscal 2019. The core principle of ASU No. 2014-09 is that companies should recognize revenue when the transfer of promised goods or services to customers occurs in an amount that reflects what the company expects to receive. It requires additional disclosures to describe the nature, amount, timing and uncertainty of revenue and cash flows from contracts with customers. In 2016 and 2017, the FASB issued additional ASUs that clarify the implementation guidance on principal versus agent considerations (ASU 2016-08), on identifying performance obligations and licensing (ASU 2016-10), and on narrow-scope improvements and practical expedients (ASU 2016-12), revenue recognition criteria and other technical corrections (ASU 2016-20) as well as clarifying the scope of asset derecognition guidance and accounting for partial sales of nonfinancial assets (ASU 2017-05). The Company performed an evaluation of the impact, including a review of current accounting policies and practices, as well as customer contracts, to identify differences upon the adoption of the new standard. Based on the evaluation, the Company has identified certain customer contracts, which will require different recognition under the new guidance. The Company had determined that the revenue under certain of its research and development contracts should be recognized on an overtime basis 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 is 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 guidance will be adopted using the modified retrospective basis with a cumulative adjustment to opening retained earnings in fiscal 2019; the cumulative adjustment is expected to be approximately $500,000.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE C – INVENTORIES

Inventories consist of the following at September 30, 2018 and 2017:

	2018	2017
Raw materials	$147,984	$193,069
Finished goods	73,385	133,399
Total	$221,369	$326,468

NOTE D – INTANGIBLE ASSETS

Intangible assets at September 30, 2018 and 2017 are as follows:

	2018	2017
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	831,368	653,495
Intangible assets, net	$864,203	$1,042,076

Total amortization expense charged to operations for the fiscal years ended September 30, 2018 and 2017 were $177,872 and $483,823, respectively. Impairment expense of $253,977 relating to internally developed software was included in amortization expense included in depreciation and amortization within the consolidated statements of operations for the fiscal year ended September 30, 2017.

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE E – INTANGIBLE ASSETS

The following table presents the estimated amortization expense of the intangible assets for each of the five succeeding years as of September 30, 2018:

	Amount
2019	$129,435
2020	129,435
2021	91,967
2022	91,967
2023	91,967
Thereafter	329,432
Total	$864,203

NOTE F – ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities at September 30, 2018 and 2017 are as follows:

	2018	**2017**
Accounts payable	$500,849	$382,984
Accrued salaries payable	401,130	446,012
Other accrued expenses	63,188	115,137
Total	$965,167	$944,133

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 "Purchaser"), pursuant to which the Company issued and sold an aggregate of $1,650,000 in principal amount of secured convertible notes (the "August 31st Notes") bearing interest at a rate of 6% per annum. As part of the August 31st Notes, the Company's management and members of the Board of Directors including the Chairman, President and Chief Executive Officer, purchased August 31st Notes with a principal amount of $1,185,000.

The August 31st 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 31st Note, together with any and all accrued and unpaid interest, by the conversion price of $2.50. The Company has the right to require the Purchasers to convert all or any part of their August 31st Notes into shares of its Common Stock at a conversion price of $2.50 if the price of the Common Stock remains at a closing price of $3.50 or more for a period of twenty consecutive trading days.

Upon any Change in Control (as defined in the August 31st Notes), the Purchasers have the right to require the Company to redeem the August 31st Notes, in whole or in part, at a redemption price equal to such August 31st Notes' outstanding principal balance plus accrued interest.

The August 31st 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 31st Notes, in whole or in part, at a redemption price equal to such notes' outstanding principal balance plus accrued interest.

The August 31st 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 31st Notes is paid in full, or converted into shares of common stock pursuant to their terms, the Company's obligations under the August 31st 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.

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE G – SECURED CONVERTIBLE NOTES PAYABLE, continued

The Company has 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 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 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 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).

The Company recorded $64,848 to debt issuance costs based on the cost incurred to complete the financing. During the fiscal year ended September 30, 2018, the Company amortized $1,479 of debt issuance costs resulting in unamortized debt issuance costs of $63,369 and carrying value of $1,586,631 at September 30, 2018. The debt issuance cost will be amortized over the life of the Notes. During the fiscal year ended September 30, 2018, the Company incurred approximately $8,136 of interest expense and for the fiscal year ended September 30, 2018. The effective interest for the fiscal year ended September 30, 2018 was 7.4%.

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 29th Notes"). The November 29th Notes are substantially similar to the Company's August 31 Notes 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 31 Notes.

NOTE H – CAPITAL STOCK

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 2,735,000 shares of our common stock and warrants to purchase an aggregate of 2,735,000 shares of common stock in a registered direct offering with an aggregate gross proceeds of $4,786,250, at a combined purchase price of $1.75 per share. The warrants will be immediately exercisable at a price of $2.00 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 $0.44. 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.”

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE H – CAPITAL STOCK, continued

Common Stock Transactions during the Fiscal Year Ended September 30, 2017:

On November 2, 2016, the Company entered into a securities purchase agreement with an institutional investor providing for the purchase of $5 million of common stock and warrants at a combined price of $2.20 per share of common stock and warrant (the "Private Placement"). In the Private Placement, the Company sold 2,272,727 shares of its common stock and warrants to purchase 2,272,727 shares of its common stock. The warrants have the same terms as the Company's existing publicly traded warrants (APDNW) with an exercise price of $3.50 per share and an expiration date of November 20, 2019. The offering closed on November 7, 2016.

The Company filed a registration statement providing for the resale of these securities on Form S-3 by December 7, 2016. Upon effectiveness of the registration statement, it is expected that the common stock and warrants issued in the Private Placement will be freely tradeable on The NASDAQ Capital Market under the symbols "APDN" and "APDNW", respectively.

The aggregate gross proceeds to the Company from the Private Placement were $5 million before deducting the placement agents' fee and other offering expenses.

In connection with the closing of this Private Placement, as partial compensation, on November 7, 2016, the Company granted warrants to purchase an aggregate of 68,182 shares of its common stock to the Company's placement agents, Maxim Group LLC and Imperial Capital LLC (the "Placement Agent Warrants") at an exercise price of $2.53 (115% of the public offering price), subject to adjustment as set forth therein (including for stock dividends and splits and certain other distributions and "Fundamental Transactions," as defined therein). The Placement Agent Warrants will be exercisable beginning six months following the closing date of the Private Placement and terminate at 5:00 P.M. (Eastern Standard Time) on November 7, 2021. In addition, the Placement Agent Warrants provide for cashless exercise, which the Placement Agents may elect if there is no effective registration statement registering the resale of the shares issuable upon exercise of the Placement Agent Warrants. The number of shares of common stock that may be acquired by the Placement Agents upon any exercise of the Placement Agent Warrants (or otherwise in respect

hereof) shall be limited to the extent necessary to insure that, following such exercise, the total number of shares of common stock then beneficially owned by the Placement Agent and its Affiliates (as defined therein) and any other Persons whose beneficial ownership of common stock would be aggregated with the Placement Agent pursuant to the Exchange Act, does not exceed 9.99% of the total number of issued and outstanding shares of common stock.

On June 28, 2017 the Company entered into subscription agreements for a private placement of its common stock, with a group of investors, including a strategic investor which is also a key customer and intellectual property licensee of the Company as well as all of the Company's executive officers and all members of the Board of Directors (the "June Private Placement"). As a result of the June Private Placement, the Company issued 1,025,574 shares of common stock at a price of $1.76 per share for total gross proceeds of $1,805,000. As part of the June Private Placement, the Company's management and Board of Directors purchased 315,346 shares of common stock for gross proceeds of $555,000. The issuance of the Common Stock was exempt from the registration requirements of the Securities Act of 1933 pursuant to Section 4(a)(2) of such Securities Act and Regulation D promulgated thereunder and such Common Stock therefore is restricted. Each investor gave representations that he, she or it was an "accredited investor" (as defined under Rule 501 of Regulation D) and that he, she or it is purchasing such securities without a present view toward a distribution of the securities. In addition, there was no general solicitation conducted in connection with the offer and sale of the securities.

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, 2017	9,540,455	$ 3.60
Granted	2,735,000	2.00
Exercised	(-)	(-)
Cancelled or expired	(66,928)	(2.88)
Balance, September 30, 2018	12,208,527	$ 3.24

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

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 Incentive Plan. In 2007, 2008, 2012 and 2015, the Board of Directors and holders of a majority of the outstanding shares of common stock approved various increases in the number of shares of common stock that can be issued as stock awards and stock options thereunder to an aggregate of 8,333,333 shares and the number of shares of common stock that can be covered by awards made to any participant in any calendar year to 833,334 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 our success with an award of options to purchase shares of common stock. As of September 30, 2018, a total of 275,752 shares have been issued and options to purchase 6,704,115 shares have been granted under the Incentive Plan.

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

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, 2017	5,333,227	$ 3.71		
Granted	2,188,141	2.00		
Exercised	-	-		
Cancelled or expired	(1,338,154)	3.58		
Outstanding at September 30, 2018	6,183,214	$3.13		
Vested at September 30, 2018	5,392,896	3.31	$ 273,951	5.81
Non-vested at September 30, 2018	790,318	$10,542		8.92

For the fiscal year ended September 30, 2018, the Company issued an aggregate of 2,188,141 (including award modifications of 666,667) options to employees, consultants, members of the strategic advisory board and non-employee board of director members. Included in these grants was 500,000 options granted to executives.

For the fiscal year ended September 30, 2017, the Company issued 1,099,844 (including award modifications of 119,182 options) options to employees, consultants, members of the strategic advisory board and non-employee board of director members. Included in these grants was 280,000 options granted to executives and 5,000 performance based options issued to a consultant. These performance based options vest when a certain performance condition is met by the consultant.

The fair value of options granted during the fiscal years ended September 30, 2018 and 2017 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:

	2018	2017
Stock price	$1.31	$2.11
Exercise price	$2.00	$2.31
Expected term	4.42	5.38
Dividend yield	-	-
Volatility	86 %	111 %
Risk free rate	2.70%	2.0 %

The Company recorded $1,356,351 and $3,257,305 as stock compensation expense within selling, general and administrative for fiscal years ended September 30, 2018 and 2017, respectively. Included in this amount is $145,053 and $89,951 for the fiscal years ended September 30, 2018 and 2017, respectively for employee stock option modifications. These modifications extended the term of the option for an employee in fiscal 2018 and extended the terms of the options for a former employee in fiscal 2017. As of September 30, 2018, unrecorded compensation cost related to non-vested awards was $619,060, which is expected to be recognized over a weighted average period of approximately 0.81 years. The weighted average grant date fair value per share for options granted during the fiscal years ended September 30, 2018 and 2017 was $0.75 and $1.58, respectively.

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE J – INCOME TAXES

The income tax provision (benefit) for the fiscal years ended September 30, 2018 and 2017 consists of the following:

	2018	2017
Federal:		
Current	$-	-
Deferred	4,430,000	(4,303,000)
	4,430,000	(4,303,000)
State and local:		
Current	-	-
Deferred	(925,000)	(376,000)
	(925,000)	(376,000)
Change in valuation allowance	(3,505,000)	4,679,000
Income tax provision (benefit)	$-	-

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, 2018 and 2017 as follows:

	2018	2017
Statutory federal income tax rate	24.28 %	34.00 %
Statutory state and local income tax rate (1%, as of September 30, 2018 and 2017), net of federal benefit	2.50 %	1.62 %
Stock based compensation	(2.29 %)	(2.65 %)
Other permanent differences	4.24 %	3.42 %
Impact of change in Federal statutory tax rate	(58.71%)	- %
Change in valuation allowance	29.98 %	(36.39%)
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, 2018	2017
Deferred tax assets (liabilities):		
Stock based compensation	$1,947,000	$2,836,000
Depreciation and amortization	339,000	500,000
Net operating loss carry forward	13,248,000	16,143,000
Tax credits	944,000	521,000
Other	69,000	52,000
Less: valuation allowance	(16,547,000)	(20,052,000)
Net deferred tax asset	$-	$-

APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

NOTE J– INCOME TAXES, continued

As of September 30, 2018, the Company has approximately $53,619,000 of Federal and $73,236,000 of State net operating loss "NOL" carryforwards available which begin to expire after 2022. 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 decreased by $3,505,000.

Additionally, deferred tax asset at September 30, 2017 has been revised as follows: deferred tax asset related to amortization of debt discounts is decreased by $16,311,000; the valuation allowance decreased by $16,311,000, completely offsetting the increase in the deferred tax assets. The revision resulted in no change to the net tax provision of the Company as of September 30, 2017 and for the fiscal year ended.

The Company has Federal research and development credits of approximately $597,000 that will begin to expire after 2034. The Company also has state investment tax credits of $340,000 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, 2018. The base rent during the additional three-year period is $458,098 per annum. 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. 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, 2018 and 2017 were $528,234 and $552,240, respectively.

Future minimum rental payments (excluding real estate tax and maintenance costs) as of September 30, 2018 are as follows:

For the fiscal year ending September 30,

2019	$316,457
2020	7,104
2021	595
Total	$324,156

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 Chief Executive Officer ("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, 2018, 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.

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APPLIED DNA SCIENCES, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2018 and 2017

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 May 7, 2016, the CEO's annual salary was voluntarily reduced by $100,000. Effective May 20, 2017, the CEO's annual salary was voluntarily reduced by an additional $50,000. Accordingly, his current annual base salary as of September 30, 2018 is $250,000.

Effective March 15, 2018, the Compensation Committee of the Company's Board of Directors, approved a bonus of $118,750 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 $395,708. The accrual for the Revenue Bonus of $360,125 is recorded to long term accrued liabilities on the balance sheet as of September 30, 2018.

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,	
	2018	2017
Americas	$ 2,141,169	$ 3,485,691
Europe	1,004,452	1,055,125
Asia and other	757,722	210,444
Total	$ 3,903,343	$ 4,751,260