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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, 2021

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

For the transition period from_____ to _____

Commission File Number **001-36745**

APPLIED DNA SCIENCES, INC.

(Exact name of registrant as specified in its charter)

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

50 Health Sciences Drive, Stony Brook, New York	**11790**	**(631) 240-8800**
(Address of principal executive offices)	(Zip Code)	(Registrant's telephone number, including area code)

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

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

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

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

□ Yes 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 whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. □

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 Stock Market as of the last business day of the Registrant's most recently completed second fiscal quarter (March 31, 2021), was approximately $45.8 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, 2021 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 2, 2021, the Registrant had outstanding 7,486,120 shares of common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K will be incorporated by reference from certain portions of the Registrant's definitive Proxy Statement for its 2022 Annual Meeting of Shareholders, or will be included in an amendment hereto, to be filed not later than 120 days after the close of the fiscal year ended September 30, 2021. 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 other representatives may make forward-looking statements orally or in writing to analysts, investors, representatives of the media and others.

Forward-looking statements can generally be identified by the fact that they do not relate strictly to historical or current facts and include, but are not limited to, statements using terminology such as "can", "may", "could", "should", "assume", "forecasts", "believe", "designated to", "will", "expect", "plan", "anticipate", "estimate", "potential", "position", "predicts", "strategy", "guidance", "intend", "budget", "seek", "project" or "continue", or the negative thereof or other comparable terminology regarding beliefs, plans, expectations or intentions regarding the future, including risks relating to the continuing outbreak of COVID-19. 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.

Our forward-looking statements address, among other things:

- our expectations of future revenues, expenditures, capital or other funding requirements;
- the adequacy of our cash and working capital to fund present and planned operations and growth;
- the substantial doubt relating to our ability to continue as a going concern;
- our business strategy and the timing of our expansion plans;
- our expectations concerning product candidates for our technologies;
- our expectations concerning existing or potential development and license agreements for third-party collaborations and joint ventures;
- our expectations of when different phases of clinical activity may commence and conclude;
- the effect of governmental regulations generally;
- our expectations of when regulatory submissions may be filed or when regulatory approvals may be received;
- our expectations of when commercial sales of new products may commence and when actual revenue from the product sales may be received; and;

- our expectations of when or if we will become profitable.

Any or all of our forward-looking statements may turn out to be wrong. They may be affected by inaccurate assumptions that we might make or by known or unknown risks and uncertainties. Actual outcomes and results may differ materially from what is expressed or implied in our forward-looking statements. Among the factors that could affect future results are:

- the inherent uncertainties of product and service development based on our new and as yet not fully proven technologies;
- the risks and uncertainties regarding the actual effect on humans of seemingly safe and efficacious formulations and treatments when tested clinically;
- Our Linea™ COVID-19 Assay Kits and COVID-19 testing may become obsolete or suffer a decline in demand for a variety of reasons;
- the inherent uncertainties associated with clinical trials of product candidates;
- the inherent uncertainties associated with the process of obtaining regulatory clearance or approval to market product candidates;
- the inherent uncertainties associated with commercialization of products and/or services that have received regulatory approval;
- economic and industry conditions generally and in our specific markets;
- the volatility of, and decline in, our stock price; and
- our ability to obtain the necessary financing to fund our operations and effect our strategic development plan.

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

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 currently used in the United States include Applied DNA Sciences®, SigNature® molecular tags, SigNature® T molecular tags, fiberTyping®, DNAnet®, SigNify®, Beacon®, CertainT®, LinearDNA™, Linea™ COVID-19 Assay Kit, Linea™ SARS-CoV-2 Mutation Panel and safeCircle™ COVID-19 testing. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. All trademarks, service marks and trade names included or incorporated by reference in this Annual Report on Form 10-K are the property of the respective owners.

ITEM 1. BUSINESS.

Overview

We develop and market DNA-based technology solutions utilizing our LinearDNA™ large-scale polymerase chain reaction ("PCR") based manufacturing platform. Our proprietary platform produces large quantities of DNA for use in nucleic acid-based in vitro diagnostics and preclinical nucleic-acid based drug development and manufacturing markets ("Biotherapeutic Contract Research and Manufacturing") and for supply chain security, anti-counterfeiting and anti-theft technology purposes ("Non-Biologic Tagging"). In response to the SARS-CoV-2 ("COVID-19") pandemic, we developed a PCR-based molecular diagnostic test for COVID-19, which was granted Emergency Use Authorization ("EUA") by the U.S. Food and Drug Administration ("FDA") in May 2020. We currently manufacture and sell our EUA authorized COVID-19 molecular diagnostic test kit under the Linea™ COVID-19 Assay Kit™ ("COVID-19 Diagnostic Test Kit"). In addition, and in further response to the COVID-19 pandemic, we developed and are currently offering COVID-19 testing services under our wholly owned subsidiary, Applied DNA Clinical Labs, LLC ("ADCL"). ADCL currently holds a New York clinical laboratory permit and a Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a ("CLIA") certification for virology ("Clinical Testing Laboratory"). Using the Company's COVID-19 Diagnostic Test Kit, ADCL currently offers to clients a high throughput pooled COVID-19 testing program, known as safeCircle(TM), which utilizes high-sensitivity pooled testing to help prevent virus spread by quickly identifying infections within a community, school, or workplace. safeCircle provides to its clients rapid testing results using real-time PCR (RT-PCR) testing ("COVID-19 Testing Services"). The Company is also developing an invasive circulating tumor cell capture and identification technology ("iCTC Technology") which uses a patented functional assay to capture live invasive circulating tumor cell and associated lymphocytes that can be identified and expanded for further analysis, including genetic sequencing.

The LinearDNA platform was developed to empower the rapid large-scale manufacture of high-fidelity DNA for biotherapeutic applications without the use of bacteria and their extrachromosomal plasmids. Our LinearDNA PCR platform is capable of producing large scale DNA, which we believe offers many benefits over the limitations of other large-scale DNA manufacturing systems, including:

- Speed – Production of DNA via the LinearDNA™ platform can be measured in terms of hours, not days and weeks like other large-scale DNA manufacturing platforms.
- Scale – The LinearDNA™ platform is flexible and can be adapted to encompass large quantity production.
- Purity – DNA produced via PCR is pure, resulting in only large quantities of the target DNA sequence. Unwanted DNA sequences such as bacterially derived DNA are not present.
- Customization – DNA produced via PCR can be easily chemically modified to suit specific customer applications.

Corporate History

We are a Delaware corporation, which was initially formed in 1983 under the laws of the State of Florida as Datalink Systems, Inc. In 1998, we reincorporated in the State of Nevada, and in 2002, we changed our name to our current name, Applied DNA Sciences, Inc. In December 2008, we reincorporated from Nevada to the State of Delaware. LineaRx ("LRx"), Inc. was incorporated in Delaware on September 11, 2018. ADCL was formed in Delaware on June 12, 2020.

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, bulk DNA production, as well the manufacture of our Linea™ COVID-19 Assay Kit and the performance of our COVID-19 Testing. 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

Biotherapeutic Contract Research and Manufacturing

Our patented continuous flow PCR systems and other proprietary PCR-based production technology and post-processing systems that comprise the LinearDNA platform allow for the large-scale enzymatic production of specific DNA sequences. The LinearDNA platform is currently being used for customers to manufacture DNA as components of in vitro diagnostic tests and for preclinical nucleic acid-based drug development in the fields of adoptive cell therapies (CAR T and TCR therapies), DNA vaccines (anti-viral and cancer), RNA therapies, clustered regularly interspaced short palindromic repeats (CRISPR) based therapies and gene therapies. We believe our LinearDNA™ platform confers a distinct competitive advantage in cost, cleanliness, and time-to-market as compared to other DNA manufacturing systems.

We provide preclinical contract research and manufacturing services for the nucleic acid-based therapeutic markets. We work with biotech and pharmaceutical companies to convert conventional nucleic-acid based preclinical biotherapeutics into PCR-produced LinearDNA-based forms that can be produced on our LinearDNA platform. In addition, we also use our LinearDNA platform to produce very large-scale quantities of DNA for the in vitro diagnostic market where our DNA is used for both commercially available diagnostics and diagnostics under development.

We also seek to develop, acquire, and commercialize, ourselves or with partners, a diverse portfolio of nucleic acid-based therapeutics based on PCR-produced LinearDNA 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 via our LinearDNA production platform. We seek to develop, acquire and commercialize, alone or with partners, a diverse portfolio of nucleic acid-based therapeutics based on PCR-produced linearDNA which we believe will improve existing nucleic acid-based therapeutics or create new nucleic acid-based therapeutics that address unmet medical needs. To this end, we are currently working with our development partners Takis S.R.L. and Evvivax S.R.L. ("Takis/Evvivax") to develop an amplicon-based linearDNA vaccine for COVID-19 that would be manufactured on our LinearDNA platform. Together with our development partners, our amplicon-based linear COVID-19 vaccine candidate has shown potential therapeutic effect in preclinical cell, mouse and feline animal studies. In September 2020, we entered into an Animal Clinical Trial Agreement with Takis/Evvivax and with Veterinary Oncology Services, PLLC, an affiliate of Guardian Veterinary Specialists ("GVS"), a multi-specialty veterinary hospital. In November 2020, we, together with Takis/Evvivax and GVS, announced receipt of approvals from the New York State Department of Agriculture and Markets and the U.S. Department of Agriculture ("USDA") on an advanced clinical strategy to conduct a veterinary trial of a vaccine candidate. Our jointly developed amplicon-based LinearDNA vaccine for COVID-19 is currently in a veterinary clinical trial in domestic feline. In April 2021, the Company announced preliminary data from its veterinary clinical trial in felines conducted with Takis/Evvivax and GVS. The preliminary data showed that all felines in the trial produced SARS-CoV-2 neutralizing antibodies after a single prime dose of the vaccine candidate. Subsequently in May 2021, we announced additional preliminary data from our feline clinical trial that showed a booster injection of the amplicon-based linear DNA vaccine candidate delivered 30 days after the prime vaccination elected a 5-fold increase in neutralizing antibody titers, with every member of the trial cohort producing neutralizing antibody titers. In June 2021, we further announced preliminary data from an in vitro neutralization study of sera from the feline trial cohort against the B.1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants. The preliminary data showed that the amplicon-based linear DNA vaccine candidate induced neutralizing antibodies against the 1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants in 100% of the trial cohort. In October 2020, Applied DNA and The Cornell University School of Veterinary Medicine began a SARS-CoV-2 challenge trial in ferrets to assess the protective efficacy of the LinearDNA vaccine against live SARS-CoV-2 virus.

COVID-19 Diagnostic Test Kit

On May 13, 2020 we received an EUA from the FDA for the clinical use of the Linea™ COVID-19 Assay Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens including anterior nasal swabs, self-collected at a healthcare location or collected by a healthcare worker, and nasopharyngeal and oropharyngeal swabs, mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates, and bronchoalveolar lavage specimens collected by a healthcare worker from individuals who are suspected of COVID-19 by their healthcare provider. Under the EUA, testing is limited to laboratories certified under CLIA, that meet requirements to perform high complexity tests. Subsequently, during July and November 2020, we were granted EUA amendments that expand the installed base of PCR equipment platforms on which our Linea™ COVID-19 Assay Kit can be processed and significantly increased the daily testing capacity of the Linea™ COVID-19 Assay Kit through the use of automation. On May 11, 2021, the EUA was amended to expand the intended use of the Linea™ COVID-19 Assay Kit to include use with anterior nasal swab specimens that are self-collected in the presence of a healthcare provider from individuals without symptoms or other reasons to suspect COVID-19 when tested at least weekly and with no more than 168 hours between serially collected specimens. The expanded intended use allows ADCL and other certified laboratory users of the Linea™ COVID-19 Assay Kit, to provide serial screening testing to individuals with the return of individual testing results. The May 11, 2021 amended EUA also updated the Linea™ COVID-19 Assay Kit's Instructions for Use to include the KingFisher™ Flex Purification System, a high-throughput robotic nucleic acid extraction system. The scope of the EUA, as amended, is expressly limited to use consistent with the Instructions for Use by authorized laboratories, certified under CLIA to perform high complexity tests. The EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated or until the EUA's prior termination or revocation. Our Linea™ COVID-19 Assay Kit has not been FDA cleared or approved, and the EUA's limited authorization is only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

In late November 2021, the SARS-CoV-2 Omicron Variant of Concern (B.1.1.529) (the "Omicron VOC") was detected. The Omicron VOC contains over thirty mutations in the Spike region of the SARS-CoV-2 genome. On November 29, 2021, the Company announced that initial in silico analysis show that the analytical sensitivity of the Linea COVID-19 Assay Kit may be impacted by the Omicron VOC, resulting in a unique detection pattern that may be specific for the Omicron variant. More specifically, the Linea COVID-19 Assay Kit unique detection pattern may result in false negative results in patients infected with the Omicron variant when tested with the Linea 1.0 Assay as a primary diagnostic. In addition, the Company announced that the Linea COVID-19 Assay Kit may have utility as a reflex test for COVID-19 positive samples from third-party assays to detect whether a sample potentially contains the Omicron VOC. Specifically, the Linea 1.0 Assay may be potentially used as a reflex test to indicate the presence of Omicron in samples that have tested positive for COVID-19 via third-party assays that cannot discriminate for the new variant because these same samples will test negative on the Linea 1.0 Assay due to the kit's unique detection pattern. The Company also announced a Linea 2.0 Assay, a laboratory developed test (LDT) targeting the N and E genes of SARS-CoV-2, for which validation data has been submitted to New York State Department of Health. In silico analysis has shown that the Linea 2.0 Assay can detect Omicron as well as all other known variants of concern and variants of interest.

We currently manufacture the Linea™ COVID-19 Assay Kit at our facilities in Stony Brook, New York. The Company's COVID-19 Assay Test Kit is predominantly utilized by ADCL to provide safeCircle high-throughput pooled COVID-19 testing services.

COVID-19 Testing Services

Under our ADCL subsidiary, on May 10, 2021 we received our New York clinical laboratory permit and our CLIA certification from the New York State Department of Health CLEP, which is currently permitted for virology. As part of our COVID-19 Testing Services our laboratory provides individual COVID-19 testing utilizing our EUA-authorized Linea COVID-19 Assay Kit, pooled screening testing under our July 13, 2021 LDT submission to NYSDOH and pooled surveillance testing that is not regulated by FDA, CDC or CMS.

On November 15, 2021 FDA revised its guidance document titled "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)" (FDA COVID-19 Testing Guidance) to require all COVID-19 diagnostic assays conducted as Laboratory-Developed Tests (LDTs) to apply for EUA authorization within a 60-day period from the revised guidance's issuance date. The FDA Guidance provides an exception for certain notified states, who can authorize in-state laboratories to develop and perform COVID-19 tests under the authority of their own State law in instances where the laboratory did not otherwise submit an EUA request to FDA.

On July 13, 2021, ADCL submitted data supporting the validation of a high-throughput robotic 5-sample pooling workflow utilizing the Linea COVID-19 Assay Kit to the New York State Department of Health (NYSDOH), which is currently pending. New York State falls within the exemption contemplated by FDA's revised COVID-19 Testing Guidance, meaning ADCL can obtain NYSDOH authorization for conducting the test in lieu of an EUA from FDA. Pursuant to current NYSDOH guidance, ADCL is currently performing the validated workflow in its COVID-19 testing during the pendency of the NYSDOH review.

In the event that NYSDOH declines to authorize ADCL's performance of the Linea COVID-19 assay on pooled samples, ADCL will be required to submit an EUA to FDA in order to continue performing the validated pooling workflow in its COVID-19 testing. Pursuant to the revised FDA COVID-19 Testing Guidance, laboratories can continue performing validated assays during the pendency of the EUA review by FDA. It is important to note that FDA retains the authority to review, or decline to review, as well as authorize, or decline to authorize, any EUA request for any product. ADCL cannot, therefore, guarantee that it will ultimately obtain authorization to perform its Linea COVID-19 assay on pooled samples if it is required to submit an EUA.

In addition to COVID-19 testing, we intend to work towards expanding our New York clinical laboratory permit and CLIA certifications to include, among other diagnostic tests, our iCTC Technology, which would allow us to further commercialize this technology.

Clinical Testing Laboratory

Under our ADCL subsidiary, on May 10, 2021 we received our New York clinical laboratory permit and our CLIA certification from the New York State Department of Health CLEP for virology. On July 13, 2021, ADCL submitted data supporting the validation of a high-throughput robotic 5-sample pooling workflow utilizing the Linea COVID-19 Assay Kit to the New York State Department of Health (NYSDOH), which is currently pending. Pursuant to current NYSDOH guidance, ADCL is performing the validated workflow in its COVID-19 testing during the pendency of the NYSDOH review.

iCTC Technology

We seek to further develop, manufacture and commercialize our Vita-Assay™ iCTC Technology acquired from Vitatex, Inc. in August 2019. Our iCTC Technology uses a patented functional assay to capture live invasive circulating tumor cell and associated lymphocytes that can be identified and expanded for further analysis, including genetic sequencing. We believe our iCTC Technology can be used as an early cancer diagnostic tool, to facilitate cancer disease progression monitoring, to assess metastatic tumor risk and to discover epitopes to serve as targets for nucleic acid-based immunotherapies. Our iCTC Technology has been used and is currently being used in a human cancer drug candidate clinical trial to monitor cancer disease progression in the trial subjects as a RUO diagnostic assay. We believe our iCTC Technology has several advantages over existing in vitro circulating tumor cell diagnostic technologies that do not capture live iCTC cells. The Company seeks to further develop and commercialize this technology and to potentially integrate aspects of the iCTC Technology with the LinearDNA platform for cancer research and nucleic acid-based drug development.

Non-Biologic Tagging and Security Products and Services

Our supply chain security business allows our customers to use non-biologic DNA (molecular) tags manufactured on our LinearDNA platform to mark objects in a unique manner and then identify these objects by detecting the absence or presence of the molecular tag. We believe our molecular tags are not economically feasible nor practical to replicate, and that our disruptive tracking platform offers broad commercial relevance across many industry verticals.

The underlying strategy in our tagging business is to become an authenticity and traceability platform provider for large complex supply chains, particularly in process industries in which contracts for our products and services are typically larger and recurring over 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. 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.

SigNature® Molecular Tags, SigNature® T Molecular Tags, fiberTyping®, SigNify® Beacon® and CertainT® comprise our principal Non-Biologic tagging and security technology platform.

SigNature® Molecular Tags

SigNature molecular tags manufactured via our LinearDNA platform form the core of our supply chain security technology platform. They provide 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 materials such as cotton, leather, cannabis, ink, varnish, thread, metal coatings, and pharmaceuticals and nutraceuticals. SigNature molecular tag formulations are made to be resistant to challenging environments such as heat, cold, vibration, abrasion, organic solvents, chemicals, UV radiation and other extreme environmental conditions, and can be identified for numerous years after being embedded directly into or on an item. The sequence of each individual molecular tag is recorded and stored in a secure database so that we can later detect it to obtain definitive proof of the presence or absence of a specific molecular tag using a simple in-field test, or in our laboratories. Our in-lab forensic testing capability delivers Certificate of DNA Authentication ("CODA") or an expert witness report, with expert witness services for some cases. Because DNA can be amplified with high fidelity, only minute quantities of our molecular tags extracted from our customers' goods 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.

Our SigNature molecular tags can be uniquely designed for specific industries. For example, our SigNature T molecular tags, designed for textiles and apparel industry, are specially engineered to adhere tenaciously to textile substrates, which make them resistant to standard textile production conditions. The result is an enduring forensic level molecular tag that remains present from the fiber stage through to the finished product. Overall SigNature molecular tags now exist on hundreds of millions of commodity goods ranging from consumer product packaging to microcircuits to cotton and synthetic fibers.

SigNify®

SigNify IF portable DNA readers and SigNify consumable reagent test kits provide definitive real-time authentication of molecular tags in the field, providing a front-line solution for supply chain integrity backed with forensic-level molecular tag authentication.

CertainT®

The CertainT trademark indicates the use of our tagging, testing and tracking platforms and solutions, enabling manufacturers, brands and trade organizations to convey proof of their product claims.

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. 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.

Our Strategy

Our products and services are offered in the United States, Europe and Asia. At the present time, we are focusing our efforts on DNA manufacturing services via the LinearDNA platform for *in vitro* medical diagnostics, preclinical biotechnology research, preclinical biotherapeutic candidates, the manufacturing and sale of our Linea™ COVID-19 Assay Kit, our testing as a service offerings, primarily as it relates to our COVID-19 Testing, and our supply chain security business, primarily in the areas of textile and apparel, pharmaceuticals and nutraceuticals. 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.

Historically, 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. However, most of our near-term growth in revenues has been derived from sales of our Linea™ COVID-19 Assay Kit, and our COVID-19 Testing Services. We also expect future growth in revenues to be derived from the manufacturing of DNA products for the biotechnology and *in vitro* diagnostic markets on our LinearDNA platform. To a lesser extent, we expect to grow revenues from the sale of 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, although we have seen a decrease in such revenues principally due to the impact of COVID-19. We are also seeking to establish a revenue stream from our iCTC Technology.

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, biotherapeutics and *in vitro* diagnostics, non-biologic DNA tagging technologies and other supply chain provenance technologies.

Markets

Diagnostics and Reagents

DNA-based molecular 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. According to estimates from the International Agency for Research on Cancer (IARC), in 2018 there were 17.0 million new cancer cases and 9.5 million cancer deaths worldwide. By 2040, the global burden is expected to grow to 27.5 million new cancer cases and 16.3 million cancer deaths. 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. In addition, the Global Covid-19 diagnostics market generated $73.19 million in the first quarter of calendar 2020 and is anticipated to hit $9.94 billion by the fourth quarter of calendar 2020 (Allied Market Research, "Global Covid-19 Diagnostics Market to Garner $9.94 Billion by Fourth Quarter of 2020" (November 2, 2020)).

Our Market Response

Our PCR-produced LinearDNA is used by customers who provide patient diagnosis through the *in vitro* examination of specimens. The linearDNA we provide to our *in vitro* diagnostic customers is produced through our large-scale PCR process, using our proprietary technology, with optimized performance for the final diagnostic assay. In addition to performance optimization, we believe that the production of LinearDNA in large lots with quantifiable reproducibility improves the efficiency of our customer's quality control for incoming raw materials and improve the overall quality, accuracy and reproducibility of their diagnostic products. Cell-based DNA production methods are often complicated by impurities. In contrast, we believe our PCR-based production method offers a high degree of purity and efficiency.

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

We have also developed a patent-pending nucleic acid-based in vitro diagnostic, (Linea™ COVID-19 Assay Kit) to detect the presence of SARS-CoV-2 (the virus that causes COVID-19) RNA in patient specimens. During April 2020, we entered into an agreement with Stony Brook University Hospital for the validation of our Linea™ COVID-19 Assay Kit. As disclosed in more detail above, on May 13, 2020, we received an EUA from the FDA for the clinical use of the Linea COVID-19 Assay Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens. Under the EUA, testing is limited to laboratories certified under CLIA that meet requirements to perform high complexity tests which certification the Company has applied for but has not yet obtained. Subsequently, during July and November 2020, the Company was granted EUA amendments that expand the installed base of PCR equipment platforms on which the Company's Linea™ COVID-19 Assay Kit can be processed and increases the throughput of the Linea™ COVID-19 Assay Kit through the use of automated RNA extraction. In May 2021, FDA amended the EUA to expand the scope of the intended use of Linea COVID-19 Assay Kit to include serial asymptomatic screening. The scope of the EUA, as amended, is expressly limited to use consistent with the Instructions for Use by authorized laboratories, certified under the CLIA to perform high complexity tests. The EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated or until the EUA's prior termination or revocation. Our Linea COVID-19 Assay Kit has not been FDA cleared or approved, and the EUA's limited authorization is only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. We currently manufacture the Linea COVID-19 Assay Kit at our facilities in Stony Brook, New York.

In addition, through our ADCL subsidiary, we currently offer COVID-19 testing to customers as a Testing-as-a-Service (TaaS) offering branded under the safeCircle trademark. safeCircle is a turnkey testing solution that provides for all aspects of large population COVID-19 testing – from sample collection to results reporting – for institutions of higher education, K-12 schools, businesses, and healthcare facilities, among other institutions with large populations. safeCircle utilizes frequent, high-sensitivity pooled RT-PCR testing to help prevent virus spread by quickly identifying infections within a community, school, or workplace. Testing is conducted utilizing our Linea COVID-19 Assay Kit that provides rapid results using real-time PCR (RT-PCR testing) with results returned typically within 24 to 48 hours from our CLEP-permitted, CLIA-certified laboratory. We currently provide safeCircle™ pooled testing to primary/secondary/higher education institutions, private clients, businesses, and college athletic programs.

In addition, starting in February 2021, we began the development of the Linea SARS-CoV-2 Mutation Panel (formally the Selective Genomic Surveillance Mutation Panel) for the qPCR-based detection of certain SARS-CoV-2 genetic mutations (the "Mutation Panel"). In May 2021, the Company announced that it had completed technical validation of the Mutation Panel. In October 2021, the Company announced that an EUA request for the Mutation Panel had been filed with FDA. Use of the Mutation Panel is currently limited to Research Use Only (RUO).

Biotherapeutic Contract Research and Manufacturing

Nucleic acid-based drugs and biologics have emerged as a new class of treatments for unmet medical needs. Through LRx, we are currently seeking to commercialize the LinearDNA platform for biotherapeutic applications. The LinearDNA platform is being developed to empower the rapid large-scale manufacture of high-fidelity DNA for biotherapeutic applications without the use of bacteria and their extrachromosomal plasmids. DNA manufactured via the LinearDNA platform is free of adventitious DNA sequences (e.g., bacterial and plasmid sequences which usually contain antimicrobial resistance genes) and can be chemically modified to optimize DNA for specific applications. The platform has been used successfully in various preclinical applications, including DNA vaccines, CAR T, mRNA production and rAAV manufacture. Recently, we have shown LinearDNA COVID-19 vaccines elicit robust neutralizing antibody responses in preclinical animal models of SARS-CoV-2 infection (mouse and feline).

Through LRx, we are currently pursuing several types of nucleic acid-based therapeutic applications for the LinearDNA platform. These applications include: (i) adoptive cell therapy; (ii) DNA vaccines; (iii) RNA-based therapeutics and (iv) gene therapies. To date, the most prominent use of adoptive cell therapy is for CAR T-cell immuno-oncology therapies, wherein autologous or allogeneic cells are collected and genetically modified to kill cancer cells. At least 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. Current CAR T-cell therapies are manufactured via bacterial plasmid and viral vector-based methods. We believe 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 LinearDNA platform may reduce DNA vaccine costs and manufacturing timeframes.

In addition RNA-based therapeutics, such as mRNA vaccines, 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, manufacturing timeframes and manufacturing complexities.

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

Our Market Response

During September 2018, we formed a new, majority owned subsidiary LRx to develop and commercialize our extensive experience in the design, manufacture and chemical modification of DNA via our large scale PCR-based LinearDNA production platform 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 LinearDNA 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 LinearDNA to improve existing nucleic acid-based therapeutics or to create new nucleic acid-based therapeutics that address unmet medical needs.

In September 2018, LRx signed a Joint Development Agreement with 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." During February 2020 we expanded our existing Joint Development Agreement (JDA) with Takis/Evvivax to include the preclinical development of five linear DNA vaccine candidates against COVID-19. Together with our development partners, our amplicon-based linear COVID-19 vaccine candidates have shown promising efficacy in preclinical cell and small animal studies. In addition, on September 16, 2020, we announced the initiation of a veterinary clinical trial of one of the Company's five amplicon-based linear COVID-19 vaccine candidates. In November 2020, we, together with Takis/Evvivax and our clinical research partner GVS, announced receipt of approvals from the New York State Department of Agriculture and Markets and the USDA on an advanced clinical strategy to conduct a veterinary trial of a vaccine candidate. Our jointly developed amplicon-based LinearDNA vaccine for COVID-19 is currently in a veterinary clinical trial in domestic feline. In April 2021, the Company announced preliminary data from its veterinary clinical trial in felines conducted with Takis/Evvivax and GVS. The preliminary data showed that all felines in the trial produced SARS-CoV-2 neutralizing antibodies after a single prime dose of the vaccine candidate. Subsequently in May 2021, we announced additional preliminary data from our feline clinical trial that showed a booster injection of the amplicon-based linear DNA vaccine candidate delivered 30 days after the prime vaccination elected a 5-fold increase in neutralizing antibody titers, with every member of the trial cohort producing neutralizing antibody titers. In June 2021, we further announced preliminary data from an in vitro neutralization study of sera from the feline trial cohort against the B.1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants. The preliminary data showed that the amplicon-based linear DNA vaccine candidate induced neutralizing antibodies against the 1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants in 100% of the trial cohort. In October 2020, Applied DNA and The Cornell University School of Veterinary Medicine began a SARS-CoV-2 challenge trial in ferrets to assess the protective efficacy of the LinearDNA vaccine against live SARS-CoV-2 virus.

Non-Biologic Tagging

Pharmaceutical and Nutraceutical Supply Chain

The pharmaceutical industry 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. According to a 2017 report by PricewaterhouseCoopers ("Fighting counterfeit pharmaceuticals: New defenses for an underestimated - and growing – menace" (June 2017)), the counterfeit drug market earns between $163 billion to $217 billion per year, making it one of the most lucrative types of illegally-copied goods. The National Association of Boards of Pharmacy estimates that counterfeit drugs account for 1% of all drugs sold in the United States. The global anti-counterfeit packaging market size is projected to grow from USD 106.3 billion in 2020 to USD 188.2 billion by 2025, at a CAGR of 12.09% from 2020 to 2025. The market is driven by factors such as strong growth in the demand from the food & beverage and pharmaceutical & healthcare sectors. The growing pharmaceutical & healthcare industry and rise in counterfeit products in the market are the major drivers of the anti-counterfeit packaging market. Applied DNA's use of molecular tagging on both the packaging and directly embedded into the dosage itself is targeted at this market segment.

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. A joint report issued by the Organization for Economic Cooperation and Development (OECD) and the European Union's Intellectual Property Office (EUIPO) in April 2020 identified the most frequently counterfeited drug products from 2014 to 2016. Most did not contain the active ingredients in the correct proportions, and many contained undeclared substances that are potentially harmful. The study noted that forensic tests of samples suggest that 90% of counterfeit medicines can cause harm to patients. The report also found that 96% of websites offering pharmaceuticals are operating illegally, and that more than 50% and 33% of fake medicines seized in recent years have come from India and China, respectively. The COVID-19 pandemic is exacerbating this situation. Interpol, during its annual Operation Pangea in March (the same week that the WHO declared the novel coronavirus outbreak a pandemic) seized over $14 million worth of dangerous pharmaceuticals in just seven days. [1] ("The COVID-19 Pandemic Magnifies Pharmaceutical Supply Chain Issues" (September 2020)).

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 paid to us at the signing of the Agreements. We will receive the second milestone payment upon initial approval by a regulatory authority for application in a Solid Oral Dosage Form ("SODF") pharmaceutical or nutraceutical product application. The Agreements generally expire on the later of October 1, 2032 or the last expiration date of any patent licensed pursuant to the Agreements.

In April 2018, we filed our Drug Master File with the U.S. FDA to allow confidential information about the chemistry, manufacturing and controls processes of our product to be made available to the FDA for inspection should an end-user company choose to have the FDA review the addition of SigNature molecular tag to their product. In May 2018, the FDA acknowledged receipt of our filing. In April 2020, we were accepted to participate in the FDA's Emerging Technology Program for guidance in regulatory activities with customers.

We continue to expand the formulation of our SigNature tags with Colorcon into coatings and inks for targeted pharmaceutical companies, following the October 2011, 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, under Colorcon's brand SoteriaRx® we believe we will be able to offer a seamless solution for pharmaceutical company customers.

On February 19, 2020 we entered into a multi-year Master Services Agreement and a Trademark Licensing Agreement (the "Agreements") with Nutrition21, LLC ("Nutrition21") to cover commercial production of Nitrosigine®, as well as potential expansion to other products within the Nutrition21 portfolio. Separately, a Broker Agreement was also signed between the parties to enable Nutrition21 to represent Applied DNA's CertainT platform throughout its extensive network in the dietary supplement market. Commercial shipments of SigNature tags for Nitrosigine and a second product, nooLVL®, are now in their third and second production cycles, respectively. Development is underway for additional Nutrition21 products. We are providing authentication services for both products on a periodic basis.

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. In addition, brand protection and authenticity continue to be at the forefront of intellectual property theft and fraud. We believe that CertainT, an integrated platform to Tag, Test, and Track fiber, yarn and fabrics all the way to finished goods, enables brands and manufacturers to preserve the integrity authenticity and quality of materials in a global supply chain. As a result, brands, manufacturers, and consumers will have confidence that claims and ingredients listed on the label are proven in the finished product.

Our Market Response

CertainT molecular business solutions are relevant to natural fibers like cotton, wool, down and feather, and leather, as well as man-made fiber, recycled polyester, acrylic, viscose and other synthetic materials used in apparel, footwear and home textiles globally. As part of the CertainT platform, our patented SigNature T technology for molecular tagging and authentication has been proven to be scalable and commercially applicable in integrated textile supply chains such as cotton, recycled polyester, leather as well as thread. Our CertainT platform involves the creation of unique SigNature T molecular tag that can be used to tag a customer's textile material and enable authentication at any point within the supply chain.

For cotton, once tagged, the 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 can 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, Upland and Egyptian cotton fibers. 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 addition, we have developed and installed fully automated, secure DNA Transfer Systems that allow for traceability and monitoring of all molecularly-tagged cotton at multiple gins in Arkansas, Texas, California as well as in Egypt.

In June 2021, together with American & Efird ("A&E"), we introduced anti-counterfeiting technology for sustainable sewing threads that uses our CertainT molecular technology.

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. Under the terms of the Agreement, Himatsingka America will be solely responsible for promoting, marketing and selling on a worldwide basis the Company's technology with respect to finished and unfinished cotton products. The Agreement grants Himatsingka America an exclusive license to use our technology in respect of cotton, subject to certain carve-outs including governmental users, non-commercial trade associations and others. The Agreement has a term that continues until June 23, 2042, except in the case of patents, in which case the term continues with respect to a patent until such patent is no longer in effect. The Agreement also provides that Himatsingka America will make royalty payments on a quarterly basis in arrears in the event that our technology is used on non-home products. Himatsingka America is responsible for the inspection and compliance within the supply chain.

Himatsingka America is generally required to use our technology during the term of the Agreement, subject, among other things, to their customers' requirements. We have established an independent testing laboratory in Ahmedabad, India, which is required by the agreement. Finished products made from this tagged fiber have been offered for sale under the PimaCott®, HomeGrown®, 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."

Sales and Marketing

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

Research and Development

In our Biotherapeutic Contract Research and Manufacturing business, our research and development efforts are focused on the development of PCR-produced linearDNA expression vectors for use in nucleic acid-based therapies including drugs and biologics and associated PCR-based methods of linearDNA expression vector manufacture. Methods for viral free transfection, high-level cellular expression and linear DNA based rAAV manufacture are under development. In addition, we are developing several linearDNA based COVID-19 and cancer vaccine candidates in collaboration with Takis/Evvivax.

Under our COVID-19 Diagnostic Kit and COVID-19 Testing Services business, our research and development efforts are focused on the development of high-throughput high-sensitivity molecular diagnostic assays for COVID-19 and other pathogens.

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

We incurred approximately $3.8 million and $3.3 million on research and development activities for the fiscal years ended September 30, 2021 and 2020, respectively.

Raw Materials and Suppliers

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

Manufacturing

We have the capability to manufacture specific sequences of SigNature DNA molecular tags and amplicon-based DNA for biopharma applications using PCR at large scale and to produce all the resulting finished products at our laboratories in Stony Brook. We also manufacture COVID-19 diagnostic assay kits. We also have in-house capabilities to complete all authentications in our Stony Brook location and textile authentications in our India location.

Distribution of our Products/Services and Commercial Agreements

Our products/services 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:

Suffolk County Community College. During September 2021, ADCL was awarded a testing contract by Suffolk County Community College ("SCCC") to monitor for the prevalence of COVID–19 among its unvaccinated staff and faculty in support of SCCC's reopening in the fall. Testing began in late September 2021. The initial contract term is for one year and includes two one-year options for renewal exercisable at SCCC's discretion. The Contract contains no minimum testing requirement; it stipulates a fixed monthly fee for sample collection site services and a separate fixed fee per individual COVID-19 test. Under the Contract, ADCL will deploy safeCircle™, to provide cost-effective COVID-19 testing. Testing will be conducted at ACDL's CLEP/CLIA-certified laboratory using the Company's Linea™ COVID-19 Assay Kit both in a pooled screening modality and to perform reflex individual diagnostic testing of samples contained in a positive pool. ADCL will serve as prime contractor with subcontractor CLEARED4's health verification platform to be used for appointments, sample tracking, reporting, program management, and mobile access pass visibility.

City University of New York. During August 2021 ADCL was awarded a competitively-bid COVID-19 testing contract by the City University of New York (CUNY) Board of Trustees to facilitate the University's reopening in the fall (the "Contract"). The Contract term is 12 months, has a maximum value not to exceed $35.0 million, and contains no minimum weekly testing commitment. The Contract specifies ADCL's deployment of safeCircle™, to provide weekly asymptomatic diagnostic COVID-19 screening of on-campus unvaccinated students, staff, and faculty, and a random sampling of vaccinated individuals across the CUNY school system. ADCL's solution includes the use of subcontractor CLEARED4's health verification platform for appointments, sample tracking, and value-add services of campus access management. As prime contractor, ADCL will also provide on-site staffing and sample transport and logistics.

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

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

Collaboration and Licensing Agreements

CLEARED4. During December 2020 ADCL entered into a reseller and sales referral partnership with CLEARED4 a digital healthcare company focused on COVID-19 vaccine management and testing administration. Under the terms of the agreement, ADCL can resell subscriptions to CLEARED4's platform as part of ADCL's safeCircle™ COVID-19 testing programs, and CLEARED4 can refer its clients seeking pooled COVID-19 testing to ADCL. Together with CLEARED4, we have integrated ADCL's safeCircle laboratory testing operations with CLEARED4's digital health platform as a value-added option for current and prospective ADCL clients. CLEARED4 has also integrated ADCL's safeCircle testing solutions into its digital health platform and can offer safeCircle to its existing and prospective clients to enhance their COVID-19 safety protocols. The majority of ADCL's safeCircle customers also utilized the CLEARED4 platform. On November 5, 2021, we announced that safeCircle testing integrated with the CLEARED4 Platform can provide a single integrated solution for vaccine status management and weekly COVID-19 testing for unvaccinated individuals as required by OSHA's Emergency Temporary Standard of the same date.

Takis S.R.L. and Evvivax S.R.L. During September 2018 we signed a joint development agreement with 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. During February 2020 we expanded our existing Joint Development Agreement (JDA) with Takis/Evvivax to include the preclinical development of a linear DNA vaccine against COVID-19. In addition, in September 2020, we entered into an Animal Clinical Trial Agreement with Takis/Evvivax and with Veterinary Oncology Services, PLLC, an affiliate of Guardian Veterinary Specialists ("GVS"), a multi-specialty veterinary hospital. In November 2020, we, together with Takis/Evvivax and GVS, announced receipt of approvals from the New York State Department of Agriculture and Markets and the USDA on an advanced clinical strategy to conduct a veterinary trial of an amplicon-based linear DNA vaccine COVID-19 candidate. Our jointly developed amplicon-based DNA vaccine for COVID-19 is currently in a veterinary clinical trial in domestic feline cats, with the end goal of applying for a USDA Animal and Plant Health Inspection Service conditional license to enable commercial veterinary sales for veterinary applications. In April 2021, we announced preliminary data from our veterinary clinical trial in felines conducted with Takis/Evvivax and GVS. The preliminary data showed that all felines in the trial produced SARS-CoV-2 neutralizing antibodies after a single prime dose of the vaccine candidate. Subsequently in May 2021, we announced additional preliminary data from our feline clinical trial that showed a booster injection of the amplicon-based linear DNA vaccine candidate delivered 30 days after the prime vaccination elected a 5-fold increase in neutralizing antibody titers, with every member of the trial cohort producing neutralizing antibody titers. In June 2021, we further announced preliminary data from an in vitro neutralization study of sera from the feline trial cohort against the B.1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants. The preliminary data showed that the amplicon-based linear DNA vaccine candidate induced neutralizing antibodies against the 1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants in 100% of the trial cohort.

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

Customer Concentration

Our revenues earned from sale of products and services for the fiscal year ended September 30, 2021 includes 18% and 13% respectively from two customers. At September 30, 2021, two customers accounted for 67% of our accounts receivable. Our revenues earned from sale of products and services for the fiscal year ended September 30, 2020 includes 13%, 12%, 11% and 10%, respectively from four customers. At September 30, 2020, four customers accounted for 74% of our 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

Some of our competitors that operate in the nucleic-acid based therapeutic, biologics and DNA manufacturing markets include: Precigen, Inc., Aldevron, LLC, Cobra Biologics, Limited, Integrated DNA Technologies, Inc., 4basebio PLC, Ziopharm Oncology, Inc., MaxCyte, Inc., Touchlight Genetics Ltd., Generation Bio, Co., Novartis AG, Kite Pharma, Inc. and Juno Therapeutics, Inc.

Some of our competitors that operate in the in vitro diagnostics and/or clinical laboratory markets include: Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, Biocept Inc., Chembio Diagnostics, Co-Diagnostics, Inc., OpGen, Inc., PerkinElmer, Inc., Roche Molecular Systems, Inc., Thermo Fisher Scientific Inc., Hologic, Inc., Becton, Dickinson and Company, Abbott Molecular Inc., Canon Inc. and Bio-Rad Laboratories, Inc.

Some of our competitors that operate in the anti-counterfeiting and fraud prevention markets include: AlpVision Sa, Authentix, Inc., Brandwatch Technologies, Inc., Chromologic LLC, Collectors Universe, Inc., DataDot Technology Limited, De La Rue Plc., Digimarc Corporation, DNA Technologies, Inc., Haelixa Ltd., ICA Bremen GmbH, IEH Corporation, Informium AG, opSec Security Group plc., MicroTag Temed Ltd., Nanotech Security Corp., Nokomis, Inc., Oritain Global Limited, SafeTraces, Inc., Selectamark Security Systems plc, SmartWater Technology, Inc., Sun Chemical Corporation, TraceTag International Ltd., TruTag Technologies, Inc., Tailorlux gmbH and YottaMark, Inc.

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; and
- applications support.

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 96 issued patents, 37 pending patent applications, 31 trademark registrations, and 8 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 2037. 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 August 7, 2019 we entered into an Amended and Restated Exclusive Licensing Agreement with The Research Foundation for the State University of New York (the "RF") for a patent estate relating to the iCTC Technology. Under the terms of the Amended and Restated Exclusive Licensing Agreement, LRx is provided exclusive world-wide rights to the iCTC Technology patent estate that was previously licensed from the RF by Vitatex, Inc.

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 Non-Biologic Products

We do not require any governmental approvals of our currently commercialized non-biologic products or services.

Government Regulations for COVID-19 Diagnostic and COVID-19 Testing

Our Linea™ COVID-19 Assay Kit has not been approved or cleared by the FDA. It is being sold under an EUA issued by the FDA in May 2020 for the clinical use of the LineaTM COVID-19 Assay Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens including anterior nasal swabs, self-collected at a healthcare location or collected by a healthcare worker, and nasopharyngeal and oropharyngeal swabs, mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates, and bronchoalveolar lavage specimens collected by a healthcare worker from individuals who are suspected of COVID-19 by their healthcare provider. Under the EUA, testing is limited to laboratories certified under CLIA that meet requirements to perform high complexity tests. In July and November 2020, we were granted amendments to our EUA that expand the installed base of PCR equipment platforms on which our Linea™ COVID-19 Assay Kit can be processed and significantly increased the daily testing capacity of the Linea™ COVID-19 Assay Kit through the use of robotic automation. In May 2021, the EUA was amended for use with anterior nasal swab specimens that are self-collected in the presence of a healthcare provider from individuals without symptoms or other reasons to suspect COVID-19 when tested at least weekly and with no more than 168 hours between serially collected specimens. The scope of the EUA, as amended, is expressly limited to use consistent with the Instructions for Use by authorized laboratories, certified under CLIA to perform high complexity tests. The EUA will be effective until the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated or until the EUA's prior termination or revocation. Our EUA and other information relating to our Linea™ COVID-19 Assay Kits can be found at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitrodiagnostics-euas.

Surveillance testing is not regulated by the FDA and CMS has stated that CLIA certification is not required to conduct surveillance testing. ADCL is offering its safeCircle™ surveillance testing in compliance with current CDC, FDA, CMS and New York State Department of Health recommendations.

In late November 2021, the SARS-CoV-2 Omicron Variant of Concern (B.1.1.529) (the "Omicron VOC") was detected. The Omicron VOC contains over thirty mutations in the Spike region of the SARS-CoV-2 genome. On November 29, 2021, the Company announced that initial in silico analysis show that the analytical sensitivity of the Linea COVID-19 Assay Kit may be impacted by the Omicron VOC, resulting in a unique detection pattern that may be specific for the Omicron variant. More specifically, the Linea COVID-19 Assay Kit unique detection pattern may result in false negative results in patients infected with the Omicron variant when tested with the Linea 1.0 Assay as a primary diagnostic. In addition, the Company announced that the Linea COVID-19 Assay Kit may have utility as a reflex test for COVID-19 positive samples from third-party assays to detect whether a sample potentially contains the Omicron VOC. Specifically, the Linea 1.0 Assay may be potentially used as a reflex test to indicate the presence of Omicron in samples that have tested positive for COVID-19 via third-party assays that cannot discriminate for the new variant because these same samples will test negative on the Linea 1.0 Assay due to the kit's unique detection pattern. The Company also announced a Linea 2.0 Assay, a laboratory developed test (LDT) targeting the N and E genes of SARS-CoV-2, for which validation data has been submitted to New York State Department of Health. In silico analysis has shown that the Linea 2.0 Assay can detect Omicron as well as all other known variants of concern and variants of interest.

On November 15, 2021 FDA revised its guidance document titled "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)" (FDA COVID-19 Testing Guidance) to require all COVID-19 diagnostic assays conducted as Laboratory-Developed Tests (LDTs) to apply for EUA authorization within a 60-day period from the revised guidance's issuance date. The FDA Guidance provides an exception for certain notified states, who can authorize in-state laboratories to develop and perform COVID-19 tests under the authority of their own State law in instances where the laboratory did not otherwise submit an EUA request to FDA.

On July 13, 2021, ADCL submitted data supporting the validation of a high-throughput robotic 5-sample pooling workflow utilizing the Linea COVID-19 Assay Kit to the New York State Department of Health (NYSDOH), which is currently pending. New York State falls within the exemption contemplated by FDA's revised COVID-19 Testing Guidance, meaning ADCL can obtain NYSDOH authorization for conducting the test in lieu of an EUA from FDA. Pursuant to current NYSDOH guidance, ADCL is currently performing the validated workflow in its COVID-19 testing during the pendency of the NYSDOH review.

In the event that NYSDOH declines to authorize ADCL's performance of the Linea COVID-19 assay on pooled samples, ADCL will be required to submit an EUA to FDA in order to continue performing the validated pooling workflow in its COVID-19 testing. Pursuant

to the revised FDA COVID-19 Testing Guidance, laboratories can continue performing validated assays during the pendency of the EUA review by FDA. It is important to note that FDA retains the authority to review, or decline to review, as well as authorize, or decline to authorize, any EUA request for any product. ADCL cannot, therefore, guarantee that it will ultimately obtain authorization to perform its Linea COVID-19 assay on pooled samples if it is required to submit an EUA.

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. Some of our product candidates may be incorporated into drugs and biologics that are or will be subject to regulation as described in the next section. Some of our products may be drugs or biologics that are subjected themselves to regulation as described in the following section. In either case, we are unlikely to receive material revenues until the related drug or biologic candidate 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 a Complete Response letter or to not approve pending New Drug Applications (NDA) or Biologics Licensing Applications (BLAs), or to issue warning letters, untitled letters, Form 483s, 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, untitled letters, Form 483s, 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 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 a New Drug Application ("NDA") or Biologics Licensing Application ("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 Practices ("cGMP") 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.

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. 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 conducts a preliminary review of all NDAs or BLAs 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 ensure 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.

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

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

Laboratory Developed Tests

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

In March 2017, a draft bill "The Diagnostics Accuracy and Innovation Act" ("DAIA") was introduced in Congress. The bill would establish a new regulatory framework for the oversight of in vitro clinical tests ("IVCTs") which include LDTs. Following review and comment from FDA on the provisions of DAIA, a revised version of the bill, now called "The Verifying Accurate, Leading-edge IVCT Development Act" (VALID) was introduced in Congress in 2020 and re-introduced in 2021. Under the bill, a risk-based approach will be used to regulate IVCTs, while grandfathering existing IVCTs. Under the new framework, each test will be classified as high-risk or low-risk. Pre-market review will be required for high-risk tests. To market a high-risk IVCT, reasonable assurance of analytical and clinical validity for the intended use must be established. Under VALID, a precertification process would be established which will allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre-certified, low-risk IVCTs, and potentially some high-risk IVCTs, developed by the laboratory will not be subject to pre-market review. The new regulatory framework will include quality control and post-market reporting requirements. The FDA will have the authority to withdraw from the market IVCTs that present an unreasonable and substantial risk of illness or injury when used as intended.

Clinical Laboratory Improvement Amendments

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

Emergency Use Authorizations

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. When issuing an EUA, the FDA imposes conditions of authorization, with which the company must comply. Such conditions include, but may not be limited to, compliance with labeling, distribution of materials designed to ensure proper use, reporting obligations, and restrictions on advertising and promotion. The EUA is only effective for the duration of the COVID-19 public health emergency. The FDA may revoke or terminate the EUA sooner if, for example, we fail to comply with the terms of the EUA or our test is determined to be less accurate than it was initially believed to be. The FDA may revoke an EUA if there is a failure to comply with the conditions of authorization.

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 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 of 2009 ("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 the Affordable Care Act (the "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.
- the Foreign Corrupt Practices Act ("FCPA") which prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence

any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business.

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 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.

Compliance with Environmental Law

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

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.

Employees

As of September 30, 2021, we had a total of 101 employees (78 fulltime and 23 part-time), consisting of 4 in executive management, 13 in research and development, 3 in forensics, 3 in quality assurance and compliance, 3 in quality control, 3 in finance and accounting, 13 in operations/production, 8 in sales and marketing, 1 in human resources, 1 in shared services, 4 in information services, 3 in product development, 20 in clinical laboratory operations and 22 in clinical field operations. Expenses related to travel, marketing, salaries, and general overhead will be increased as necessary to support our growth in revenue. Any projected increase in human capital is dependent upon our ability to generate revenues and obtain sources of funding. Since June 2012, we have been working with Insperity Inc. to assist in managing many of our back-end administrative human resources, benefits, and payroll responsibilities. We are an at-will employer and generally do not enter into employment agreements requiring our employees to continue in our employment for any period of time, with the exception of our Chief Executive Officer, Dr. James A. Hayward. The initial term of Dr. Hayward's current employment agreement was 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, 2021, the employment contract automatically renewed for an additional year.

Available Information

We are subject to the informational requirements of the Exchange Act, which requires us to file our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to such reports and other information with the SEC. Because we file documents electronically with the SEC, you may 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.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, discussed in more detail in the following section. These risks include, among others, the following key risks:

- The COVID-19 global pandemic may materially and adversely impact our business, financial condition and results of operations.
- The substantial doubt relating to our ability to continue as a going concern.
- We have a history of net losses.
- 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 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.
- Our Linea™ COVID-19 Assay Kit is being sold under a FDA EUA which could be revoked or terminated by the FDA at any time and will cease to be effective once the public health emergency justifying its use ends.
- Our COVID-19 Testing may become obsolete for a variety of reasons, including an end to the current pandemic. The utility will also be diminished if positivity rates reach levels high enough to render COVID-19 testing ineffective or inefficient. 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.
- Our Linea™ COVID-19 Assay Kits could become obsolete or their utility could be significantly diminished.
- Pharmaceutical and biologic-related revenue will be dependent on our collaborators' and customers' demand for our manufacturing services.
- 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 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.
- Intellectual property litigation could harm our business, financial condition and results of operations.
- Our joint pursuit of a potential vaccine for COVID-19 is at an early stage and may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all, and compete successfully with vaccines developed by larger companies.
- Pharmaceutical and biologic-related revenue is generally dependent on regulatory approval, oversight and compliance.
- 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.
- Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, or limit their commercial potential, if approved.

- If the FDA were to begin to enforce regulation of Laboratory Developed Tests ("LDTs"), we could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.
- If we fail to comply with laboratory licensing requirements, we could lose the ability to offer our clinical testing services or experience disruptions to our business.
- If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected.
- We need to expand our sales, marketing and support organizations to increase market acceptance of our products and services.
- If we are unable to continue to retain the services of Dr. Hayward, we may not be able to continue 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.
- 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.

In addition to the above key 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. 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. In addition to the factors discussed elsewhere in this report and our other reports and documents filed with the SEC, 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.

The COVID-19 global pandemic may continue to materially and adversely impact our business, financial condition and results of operations.

Our business has been and could continue to be materially and adversely affected by the outbreak of a widespread health epidemic. The present coronavirus (or COVID-19) pandemic had disrupted our operations and affected our business. If government authorities impose mandatory closures, work-from-home orders and social distancing protocols or impose other restrictions that could materially adversely affect our ability to adequately staff and maintain our operations. Portions of our business are considered "essential" such as our government and pharmaceutical contracts, as well as our vaccine and diagnostic candidate development and our COVID-19 Testing. However, we have experienced, and may continue to experience in the future, facility closures related to our "nonessential" businesses. As the COVID-19 outbreak and responses to it continue to evolve, we may experience adverse impacts on our operations, including our ability to secure supplies, and our ability to access capital on favorable terms, or at all, may be impaired. There may also be long-term effects on our customers in and the economies of affected countries. Although the duration and ultimate impact of these factors is unknown at this time, the decline in economic conditions due to COVID-19, or another disease-causing similar impacts, may adversely affect our business, financial condition and results of operations and such impact may be material. At this time, the COVID pandemic is not having a materially adverse impact on the Company's business or operations, but the future course of the pandemic is unknown,

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 $284,122,092 as of September 30, 2021. We have incurred a net loss of $14,278,439 for the fiscal year ended September 30, 2021. At September 30, 2021, we had cash and cash equivalents of $6,554,948. 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, 2021 includes an explanatory paragraph stating that our significant losses and need 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. 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.

Our new emphasis on biotherapeutic contract research and manufacturing and COVID-19 diagnostic and testing may reduce our ability to maintain and expand our existing Non-Biologic Tagging businesses

Our new emphasis on biotherapeutic contract research and manufacturing and COVID-19 diagnostic and testing may divert funding and our limited managerial and other resources from our existing non-biologic tagging businesses. This may have the effect of reducing opportunities to grow or maintain revenues in our existing businesses while at the same time we may fail in our biotherapeutic contracts research and manufacturing and COVID-19 diagnostic and testing efforts.

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

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

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 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 be more effective than other commercially available alternatives.

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, 2021 included an aggregate of 31% of our total revenues from two customers. At September 30, 2021, two customers accounted for an aggregate of 67% of our total accounts receivable. Our revenue earned from the sale of products and services for the fiscal year ended September 30, 2020 included an aggregate of 46% of our total revenues from four customers. At September 30, 2020, four customers accounted for an aggregate of 74% 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.

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

Our revenues and profitability are difficult to predict due to the nature of the markets in which we compete, as well as our recent entry into new markets and products, such as our Linea™ COVID-19 Assay Kit and our COVID-19 Testing, fluctuating user demand, the uncertainty of current and future global economic conditions, and for many other reasons, including that our operating results are highly dependent on the volume and timing of orders received during a quarter, which are difficult to forecast. Customers generally order on an as-needed basis and we typically do not obtain firm, long-term purchase commitments from our customers. The quarterly fluctuations in operating results described above may cause a decline in the price of our common stock.

Risks Relating to Our Product Candidates, Manufacturing, Development, and Industries:

Our Linea™ COVID-19 Assay Kit is being sold under an FDA EUA.

Our Linea™ COVID-19 Assay Kit has not been cleared or approved by FDA, but has been authorized for sale under an EUA. The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency when there are no adequate, approved, and available alternatives. The EUA authorizes our test to be used by laboratories certified to perform high complexity testing under CLIA. The EUA includes conditions of authorization with which we must comply, including, but not limited to, compliance with labeling, distribution of materials designed to ensure proper use, reporting obligations, and restrictions on advertising and promotion. Distributors of and laboratories using our Linea™ COVID-19 Assay Kit must also comply with the relevant provisions of our EUA. The EUA is only effective for the duration of the COVID-19 public health emergency. The FDA may revoke or terminate the EUA sooner if, for example, we fail to comply with the terms of the EUA or our test is determined to be less accurate than it was initially believed to be. We cannot predict how long the EUA will remain in place. If the EUA is revoked or terminated, it could significantly harm our business, results of operations, and profits.

Our Linea™ COVID-19 Assay Kit may result in false negatives.

False negative test results are a risk with all laboratory tests, including COVID-19 molecular diagnostic tests. A false negative occurs with a COVID-19 molecular diagnostic when an individual who is infected with the virus tests negative for the virus. False negatives can occur in the presence or absence of a mutation in the COVID-19 virus. In the presence of a mutation in the virus, false negatives can occur if a mutation occurs in the region of the virus that the test is designed to assess. The risk of false negatives in the presence of a mutation is increased with tests that only assess a single region of the COVID-19 virus as compared to tests that assess more than one region of the virus. Our Linea™ COVID-19 Assay Kit test assesses two regions of the virus, thus potentially reducing the likelihood of false negatives in the presence of one or more COVID-19 mutations. Regardless, false negatives may occur with our Linea™ COVID-19 Assay Kit in the presence or absence of one or more COVID-19 mutations. If false negatives occur with our Linea™ COVID-19 Assay Kit, individuals will incorrectly believe they do not have COVID-19 and could further spread the virus thereby jeopardizing the health of others. Also, if it is determined that results of the Linea™ COVID-19 Assay Kit are not accurate or reliable, our EUA could be terminated by the FDA. As a result, our business, financial condition and results of operations could be significantly harmed.

Other companies may develop and obtain authorization for molecular diagnostics that can detect the 69—70del mutation.

The 69—70del mutation is a mutation that is found in several variants of COVID-19, including, but not limited to the so called "UK Variant" or the B.1.1.7 variant. The B.1.1.7 variant has been associated with an increased risk of transmission. According to an Alert to Health Care Providers and Clinical Laboratory Staff and a Letter to Health Care Providers and Clinical Laboratory Staff both issued by the FDA on January 8, 2021, there are currently only two EUA authorized COVID-19 molecular diagnostics that can indicate a sample contains the 69—70del mutation, including our Linea™ COVID-19 Assay Kit. Other companies may develop and obtain Emergency Use Authorization for COVID-19 molecular diagnostics that can detect the 69—70del mutation. Such tests would compete with our test and could negatively impact sales of our Linea™ COVID-19 Assay Kit.

Our safeCircle™ COVID-19 testing service could become obsolete or its utility could be significantly diminished.

Surveillance testing is not regulated by the FDA and CMS has stated that CLIA certification is not required to conduct surveillance testing. ADCL is offering its safeCircle™ surveillance testing in compliance with current CDC, FDA, CMS and New York State Department of Health recommendations. The regulatory framework or recommendations regarding COVID-19 Surveillance Testing could change at any time. In addition, our pooled COVID-19 screening testing is conducted pursuant to validation data submitted to the NYSDOH on July 13, 2021, which is currently pending. In the event that NYSDOH declines to authorize ADCL's performance of the Linea COVID-19 assay on pooled samples, ADCL will be required to submit an EUA to FDA in order to continue performing the validated pooling workflow in its COVID-19 testing. Pursuant to the revised FDA COVID-19 Testing Guidance published on November 15, 2021, laboratories can continue performing validated assays during the pendency of the EUA review by FDA. It is important to note that FDA retains the authority to review, or decline to review, as well as authorize, or decline to authorize, any EUA request for any product. ADCL cannot, therefore, guarantee that it will ultimately obtain authorization to perform its Linea COVID-19 assay on pooled samples if it is required to submit an EUA.

Further, our COVID-19 testing may become obsolete for a variety of reasons, including an end to the current pandemic or the development and widespread distribution of a vaccine, including the vaccines developed by Pfizer-BioNTech, Moderna, and Johnson & Johnson for which the FDA has granted emergency use authorization or approval. In addition, the utility of these services will also diminish if positivity rates reach levels high enough to render surveillance testing ineffective or inefficient.

Our Linea™ COVID-19 Assay Kits could become obsolete or their utility could be significantly diminished.

Our Linea™ COVID-19 Assay Kits may become obsolete for a variety of reasons, including an end to the current pandemic or the development and widespread distribution of a vaccine, including the vaccine developed by Pfizer-BioNTech, Moderna and Johnson & Johnson for which the FDA has granted emergency use authorization or approval. In addition, the Linea™ COVID-19 Assay Kits may have their utility significantly reduced if the SARS-CoV-2 virus evolves new genomic mutations that impact the analytical sensitivity of the Assay Kits.

Our joint pursuit of a potential vaccine for COVID-19 is at an early stage and may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all , and compete successfully with vaccines developed by larger companies.

In response to the global outbreak of coronavirus, we are jointly pursuing the development of linear DNA vaccine candidates in collaboration with Takis/Evvivax for veterinary applications. Our joint development of vaccine candidates is in early stages, and we may be unable to produce a successful vaccine candidate in a timely manner, if at all. Additionally, development of an effective vaccine candidate depends on the success of our and our partner's manufacturing capabilities, and we may face challenges in clinical trials, licensing, distribution channels, intellectual property disputes or challenges, and the need to establish teams of people with the relevant skills worldwide. We may also face challenges with sourcing a sufficient amount of raw materials to support the demand for a vaccine. We may be unable to effectively create a supply chain for any vaccine candidate that will adequately support demand.

We would require additional funding in order to enable the development of vaccine candidates. Our commitment of financial resources and personnel to the joint development of these vaccine candidates may cause delays in or otherwise negatively impact our other development programs and could prove futile, as future demand for any successful vaccine is unknown.

In addition, another party may be successful in producing a more efficacious vaccine or other treatment for COVID-19 which may reduce or eliminate demand for any successful vaccine that we may jointly develop. [On December 11, 2020, the FDA issued the first EUA to Pfizer-BioNTech for a vaccine for the prevention of COVID-19 in individuals 16 years of age and older. The EUA allowed the COVID-19 vaccine to be distributed in the U.S. The Pfizer-BioNTech vaccine received FDA approval on August 23, 2021 for use in individuals 16 years and older. The vaccine is available under an EUA for individuals between 5 years of age and 15 years of age. In addition to the Pfizer-BioNTech vaccine, the FDA has issued EUAs for COVID-19 vaccines developed by Moderna and Johnson & Johnson. Other entities, including AstraZeneca PLC, GlaxoSmithKline plc, and Sanofi, may develop COVID-19 vaccines that are more effective than any we may jointly develop, may develop a COVID-19 vaccine that becomes the standard of care, may develop a COVID-19 vaccine at a lower cost or earlier than we are able to jointly develop any COVID-19 vaccine, or may be more successful at commercializing a COVID-19 vaccine.] These other organizations are much larger than we are and have access to larger pools of capital and broader manufacturing infrastructure. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our joint COVID-19 vaccine development efforts or for us to ultimately commercialize any vaccine candidate, if approved

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 cGMP regulations, the FDA may deny NDA or BLA approval until the deficiencies are corrected. Even if our collaborators or customers obtain regulatory approval for any of their product candidates, there is no assurance that they will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our collaborators or customers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

The amount of customer spending on pharmaceutical and 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 nucleic-acid based therapeutic, biologics and DNA manufacturing markets include: Precigen, Inc., Aldevron, LLC, Cobra Biologics, Limited, Integrated DNA Technologies, Inc., 4basebio PLC, Ziopharm Oncology, Inc., MaxCyte, Inc., Touchlight Genetics Ltd., Generation Bio, Co., 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.

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 supply chain security and product authentication 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 supply chain security and product authentication markets include: AlpVision Sa, Authentix, Inc., Brandwatch Technologies, Inc., Chromologic LLC, Collectors Universe, Inc., DataDot Technology Limited, De La Rue Plc., Digimarc Corporation, DNA Technologies, Inc., Haelixa Ltd., ICA Bremen GmbH, IEH Corporation, Informium AG, opSec Security Group plc., MicroTag Temed Ltd., Nanotech Security Corp., Nokomis, Inc., Oritain Global Limited, SafeTraces, Inc., Selectamark Security Systems plc, SmartWater Technology, Inc., Sun Chemical Corporation, TraceTag International Ltd., TruTag Technologies, Inc., Tailorlux gmbH and YottaMark, Inc.

We expect this competition to continue and intensify in the future**.**

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. Under our COVID-19 Diagnostic and Testing businesses, our research and development efforts are focused on the development of high-throughput high-sensitivity molecular assays for COVID-19. 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.

Risks Related to Our Intellectual Property:

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

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

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

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

If a third party claims an intellectual property right to technology we use, we might need to discontinue an important product or product line, alter our products and processes, pay license fees or cease our affected business activities. Although we might under these circumstances attempt to obtain a license to this intellectual property, we may not be able to do so on favorable terms, or at all. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. A court may decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, a court may order us to pay the other party damages for having violated the other party's patents. The drug and biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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

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

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 pathway of a potential vaccine for COVID-19 is continually evolving, and may result in unexpected or unforeseen challenges.

The speed at which all parties are moving to create, test and approve a vaccine for COVID-19 is highly unusual, and evolving or changing plans or priorities at the FDA, including based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory pathway for any of our potential vaccine candidates. For example, any results from clinical testing may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. In addition, the FDA's analysis of any clinical data may differ from our interpretation and the FDA may require that we conduct additional analyses.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in a public health emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an EUA for any vaccine candidate, we would be able to commercialize it prior to FDA approval. The EUA is only effective for the duration of the COVID-19 public health emergency. The FDA may revoke or terminate the EUA sooner if, for example, we fail to comply with the terms of the EUA or our vaccine is determined to be less effective or safe than it was initially believed to be. We cannot predict how long, if ever, an EUA would remain in place.

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

Some of our products may be incorporated into cannabis products which are subject to regulation by federal and state regulatory agencies in the United States and by comparable authorities in foreign countries. Cannabis is a Schedule I substance, as defined under federal law, and its possession and use is generally not permitted under 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. Revenue from the cannabis market is highly dependent on our customers' continuing compliance with federal and state regulations which may change over time. Our business may be materially harmed by their failure to comply with applicable regulations and may subject us to an 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 is highly dependent upon obtaining such approval.

Federal agencies, including the FDA and Federal Trade Commission, 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 will be incorporated into products in the pharmaceutical and biologic market 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 NDA or 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 of their failure to comply with applicable regulations.

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.

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, results of operations, and prospects.

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

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

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

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

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

If the FDA were to begin to enforce regulation of LDTs, we could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements.

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

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

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

In addition, another party may be successful in producing a more efficacious vaccine or other treatment for COVID-19 which may reduce or eliminate demand for any successful vaccine that we may jointly develop. [On December 11, 2020, the FDA issued the first EUA to Pfizer-BioNTech for a vaccine for the prevention of COVID-19 in individuals 16 years of age and older. The EUA allowed the COVID-19 vaccine to be distributed in the U.S. The Pfizer-BioNTech vaccine received FDA approval on August 23, 2021 for use in individuals 16 years and older. The vaccine is available under an EUA for individuals between 5 years of age and 15 years of age. In addition to the Pfizer-BioNTech vaccine, the FDA has issued EUAs for COVID-19 vaccines developed by Moderna and Johnson & Johnson. Other entities, including AstraZeneca PLC, GlaxoSmithKline plc, and Sanofi, may develop COVID-19 vaccines that are more effective than any we may jointly develop, may develop a COVID-19 vaccine that becomes the standard of care, may develop a COVID-19 vaccine at a lower cost or earlier than we are able to jointly develop any COVID-19 vaccine, or may be more successful at commercializing a COVID-19 vaccine.] These other organizations are much larger than we are and have access to larger pools of capital and broader manufacturing infrastructure. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our joint COVID-19 vaccine development efforts or for us to ultimately commercialize any vaccine candidate, if approved

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

CLIA is a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Clinical laboratories must be certified under CLIA in order to perform testing on human specimens, unless they fall within an exception to CLIA certification, such as research laboratories that test human specimens but do not report patient-specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients. CLIA certification is also required to be eligible to bill Federal and State healthcare programs, as well as many private third-party payers, for diagnostic testing and services. Currently, we are supplying our iCTC capture assay and associated testing services under the research exception to CLIA. If we expand our laboratory testing services so that the research exception no longer applies to our iCTC capture, we will no longer be able to offer these services. Further, if we fail to comply with the CLIA research exception with respect to our iCTC capture assay, we could be found to have violated FDA or CLIA regulations or guidances and could have to stop offering these services and potentially be assessed substantial penalties.

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.

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 applicable laws and regulations 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, as amended by HITECH; the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations; FCPA; 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.

Risks Related to Personnel:

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, specifically as it relates to our Linea™ COVID-19 Assay Kit and our COVID-19 testing offering branded under the safeCircle™ trademark. We seek to continue to commercialize the safeCircle™ testing TaaS offering with institutional clients such as schools, colleges and businesses. We seek to further commercialize our EUA authorized Linea COVID-19 Assay Kit and our iCTC Technology. We are also performing testing services in support of our safeCircle™ testing services in accordance with current CDC, FDA, CMS and New York State Department of Health recommendations.

To manage such growth, we may need to improve our:

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

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

Our success depends to a significant extent upon the continued service of Dr. James A. Hayward, our CEO. On July 28, 2016, we entered into an employment agreement with Dr. Hayward. The initial term was from July 1, 2016 through June 30, 2017, with automatic one-year renewal periods. As of June 30, 2021, the employment contract automatically renewed for an additional year. Loss of the services of Dr. Hayward could significantly harm our business, results of operations and financial condition. We do not maintain key-person insurance on the life of Dr. Hayward.

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

We have engaged, and may in the future engage, in transactions with affiliates and other related parties. These transactions may not have been, and may not be, on terms as favorable to us as they could have been if obtained from non-affiliated persons. While an effort has been made, and will continue to be made, to enter into transactions with affiliated persons and other related parties at rates and on terms as favorable as would be charged by others, there will always be an inherent conflict of interest between our interests and those of our affiliates and related parties. On October 7, 2020, we entered into Warrant Exercise Agreements with Dillon Hill Capital, LLC and its affiliate, Dillon Hill Investment Company LLC., a greater than 5% shareholder in the Company, whereby 318,000 of our 2019 Warrants were exercised. The gross proceeds to the Company from this partial exercise of the 2019 Warrants was $1,669,500. In consideration of this partial exercise of the 2019 Warrants and of the consent to repayment of the Notes, we agreed to issue, in addition to the 318,000 shares of common stock issued upon exercise of the 2019 Warrants, 159,000 replacement warrants (the "Replacement Warrants") to the Investors, which is an amount equal to one-half the amount of the 2019 Warrants exercised pursuant to the Warrant Exercise Agreements. The Replacement Warrants have an exercise price of $7.54, the closing price on The Nasdaq Capital Market of the Company's common stock on October 7, 2020. In addition, until January 5, 2021, if the Investors exercised additional 2019 Warrants, the Company agreed to issue to the applicable Investor additional Replacement Warrants in an amount equal to one-half the amount of such exercised 2019 Warrants with each such Replacement Warrant having an exercise price equal to the closing price on The Nasdaq Capital Market of the Company's common stock on such date that the related 2019 Warrants are exercised. No additional warrants were exercised. The Company may be adversely impacted if any related party agreement or transaction is made on unfavorable terms.

Risks Relating to Our Common Stock and Other Securities:

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

As of December 2, 2021, we had 7,486,120 shares of common stock issued and outstanding, outstanding options to purchase 1,063,318 shares of common stock, outstanding warrants to purchase 743,563 shares of common stock, and 3,927,955 shares available for grant under our 2020 Equity Incentive Plan. The issuance of shares upon exercise of our outstanding options and warrants will cause immediate and substantial dilution to our stockholders.

We may be required to repurchase certain of our warrants.

Under our warrants sold privately that have registration rights, in the event of a "Fundamental Transaction" (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50% of our common stock), each warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the warrant for a purchase price in cash equal to the Black Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and/or results of operations and may prevent or deter a third party from acquiring us.

We will 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 will 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.

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters is located at the Long Island High Technology Incubator ("LIHTI"), which is located on the campus of Stony Brook University at 50 Health Sciences Drive, Stony Brook, NY 11790. The lease is for a 30,000 square foot building. The term of the lease commenced on June 15, 2013 and expired on May 31, 2016, with the option to extend the lease for two additional three-year periods. We have exercised our option to extend the lease for one additional three-year period, ending May 31, 2019. The base rent during the additional three-year period was $458,098 per annum. In addition to the office space, we also have 2,200 square feet of laboratory space. On January 20, 2020, we entered into an agreement to amend both of these leases, extending the term for the corporate headquarters as well as the laboratory space until January 15, 2021, with a one-year renewal option. During October 2020, we exercised the one-year renewal option for both of these leases. We also have a satellite testing facility in Ahmedabad, India, which was established during fiscal 2018. On November 17, 2017, we leased 1,108 square feet for an initial three-year term beginning November 1, 2017. During September 2021, the Company renewed this lease with a new expiration date of August 31, 2022.

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". There is no certainty that the common stock will continue to be listed on Nasdaq or that any liquidity will exist for our stockholders.

Holders

As of December 2, 2021, we had approximately 124 holders of record of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. The transfer agent of our common stock is American Stock Transfer & Trust Company, 6201 15th Avenue, Brooklyn, New York 11219.

Dividends

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

ITEM 6. SELECTED FINANCIAL DATA.

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

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

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

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

Introduction

We develop and market DNA-based technology solutions utilizing our LinearDNA™ large-scale PCR based manufacturing platform. Our proprietary platform produces large quantities of DNA for use in the nucleic acid-based in vitro diagnostics and preclinical nucleic-acid based drug development and manufacturing markets ("Biotherapeutic Contract Research and Manufacturing") and for supply chain security, anti-counterfeiting and anti-theft technology purposes ("Non-Biologic Tagging"). In response to the COVID-19 pandemic, we developed a PCR-based molecular diagnostic test for COVID-19, which was granted EUA by the FDA in May 2020. We currently manufacture and sell our EUA authorized COVID-19 molecular diagnostic test kit under the Linea™ COVID-19 Assay Kit trademark ("COVID-19 Diagnostic Test Kit"). In addition, and in further response to the COVID-19 pandemic, we developed and are currently offering, COVID-19 testing services under ADCL. ADCL holds a New York CLIA certification for COVID-19 testing using EUA authorized methods and devices ("Clinical Testing Laboratory"). ADCL's high throughput pooled testing program, known as safeCircle™, utilizes frequent, high-sensitivity pooled testing to help prevent virus spread by quickly identifying infections within a community, school, or workplace. safeCircle provides rapid results using real-time PCR (RT-PCR) testing. Unlike diagnostic testing, which looks for the occurrence of COVID-19 at the individual level, pooled testing looks for infections within a defined population or community and can be used for making health management decisions at the population level. We also are developing an iCTC Technology which uses a patented functional assay to capture live invasive circulating tumor cell and associated lymphocytes that can be identified and expanded for further analysis, including genetic sequencing.

Applied DNA's LinearDNA™ PCR platform is capable of producing large scale DNA, which we believe offers many benefits over the limitations of other large-scale DNA manufacturing systems, including:

- Speed – Production of DNA via the LinearDNA™ platform can be measured in terms of hours, not days and weeks like other large-scale DNA manufacturing platforms.
- Scale – The LinearDNA™ platform is flexible and can be adapted to encompass large quantity production.
- Purity – DNA produced via PCR is pure, resulting in only large quantities of the target DNA sequence. Unwanted DNA sequences such as bacterially derived DNA are not present.
- Customization – DNA produced via PCR can be easily chemically modified to suit specific customer applications.

General

Historically, 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. However, most of our near-term growth in revenues has been derived from sales of our Linea™ COVID-19 Assay Kit, our validated COVID-19 pooled testing under review by NYSDOH, and our COVID-19 Surveillance Testing. We also expect future growth in revenues to be derived from the manufacturing of DNA products for the biotechnology and *in vitro* diagnostic markets. To a lesser extent, we expect to grow revenues from the sale of 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, although we have seen a decrease in such revenues principally due to the impact of COVID-19. We are also seeking to establish a revenue stream from our iCTC Technology. We have continued to incur expenses in expanding our business to meet current and anticipated future demand. We have limited sources of liquidity.

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 follow Financial Accounting Standards Board ("FASB") issued accounting standard updates which clarify the principles for recognizing revenue arising from contracts with customers ("ASC 606" or "Topic 606").

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

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

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

Product Revenues and Authentication Services

The Company's PCR-produced linear DNA products are manufactured in accordance with contracts with customers. The Company recognizes revenue upon satisfying its promises to transfer goods or services to customers under the terms of its contracts. These performance obligations are satisfied at the point in time the Company transfers control of the goods to the customer, which in nearly

all cases is when title to and risk of loss of the goods transfer to the customer. The timing of transfer of title and risk of loss is dictated by customary or explicitly stated contract terms. The Company invoices customers upon shipment, and its collection terms range, on average, from 30 to 60 days.

Authentication Services

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

Clinical Laboratory Testing Services

The Company records revenue for its clinical laboratory testing service contracts, which includes its COVID-19 Testing Services, upon satisfying its promise to provide services to customers under the terms of its contracts. These performance obligations are satisfied at the point in time that Company services are complete, which in nearly all cases is when the testing results are released to the customer.

Research and Development Services

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

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

Equity Based Compensation

We account for stock-based compensation for employees, directors and nonemployees in accordance with ASC 718, Compensation ("ASC 718"). ASC 718 requires all share-based payments, 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 requisite service period (generally the vesting period of the equity grant). The fair value of our common stock options are estimated using the Black Scholes option-pricing model with the following assumptions: expected volatility, dividend rate, risk free interest rate and the expected life. We expense stock-based compensation by using the straight-line method. In accordance with ASC 740, 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 consolidated statements of operations.

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. The most complex and subjective estimates include revenue recognition, allowance for doubtful accounts, recoverability of long-lived assets, including the values assigned to goodwill, intangible assets and property and equipment, fair value calculations for stock-based compensation and warrants, contingencies, and management's anticipated liquidity. Management reviews its estimates on a regular basis and the effects of any material revisions are reflected in the condensed 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, 2021 to the Fiscal Year Ended September 30, 2020

Revenues

Product revenues

For the twelve-month periods ended September 30, 2021 and 2020, we generated $3,295,849 and $615,430 in revenues from product sales, respectively. Product revenue increased by $2,680,419 or 436% for the twelve-month period ended September 30, 2021 as compared to the prior fiscal year. Revenues increased by $1,951,895 in sales of our LineaTM COVID-19 Assay Kit, of which approximately $1,898,000 was attributable to sales pursuant to our contract with Stony Brook University Hospital. Further increases include approximately $810,000 in Textiles related to the shipment of DNA concentrate to protect the supply chain. There were no shipments for cotton during the prior fiscal year due to the global shut down related to the COVID-19 pandemic adversely impacting the textile industry.

Service revenues

For the twelve-month periods ended September 30, 2021 and 2020, we generated $937,735 and $1,238,517 in service revenues, respectively. Service revenue decreased by $300,782 or 24% for the twelve-month period ended September 30, 2021 as compared to the prior fiscal year. The decrease in service revenues is related to a decrease of approximately $285,000 relating to the expiration of a contract in the synthetic textiles industry. Further decreases include $183,455 in cannabis due to the completion of a research pilot, $79,137 in Pharmaceuticals due to a decrease in R&D projects relating to commercialization of a product line and $48,080 in cash and valuables in transit due to a fee reduction to one customer. These decreases were offset by an increase of $226,523 in our biopharmaceutical market.

Clinical laboratory service revenues

For the twelve-month periods ended September 30, 2021 and 2020, we generated $4,794,154 and $77,550 in revenues from clinical laboratory testing services, respectively. Clinical laboratory service revenue increased by $4,716,604 or 6,082% for the twelve-month period ended September 30, 2021 as compared to the prior fiscal year. During the second half of the prior fiscal year, we developed our COVID-19 testing services. The increase in revenue is primarily due to a full twelve months of our COVID-19 testing services during fiscal 2021 compared to only one month of testing during fiscal 2020. Of this increase, $1,181,376 in testing services relating to our contract with the City University of New York.

Costs and Expenses

Cost of Revenues

Cost of revenues for the twelve-month period ended September 30, 2021 increased by $775,759 or 108% from $720,900 for the twelve-month period ended September 30, 2020 to $1,496,659 for the twelve-month period ended September 30, 2021. Cost of revenues as a percentage of product revenues was 45% and 117% for the twelve-month periods ended September 30, 2021 and 2020, respectively. This decrease in cost of revenues as a percentage of product revenues is due to product sales mix, as sales during the twelve-month period ended September 30, 2021 included diagnostic kit sales, as well as DNA concentrate to protect a cotton supply chain, which are at a higher gross margin as compared to the products sold during the prior fiscal year. This decrease was also the result of certain costs of revenues being fixed costs such as payroll and rent, which were not fully absorbed with the low level of product revenues during the twelve-month period ended September 30, 2020 as compared to fiscal 2021.

Selling, General and Administrative

Selling, general and administrative expenses for the twelve-month period ended September 30, 2021 increased by $2,579,372 or 26% to $12,610,552 from $10,031,180 in the twelve-month period ended September 30, 2020. The increase is primarily attributable to an increase in stock-based compensation expense of $666,923 relating to officer and employee stock option grants that vested immediately and an increase in payroll of approximately $1,135,000. The increase in payroll relates to increased headcount, as well as an increase of approximately $550,000 for CEO bonuses, which includes an accrued bonus of $300,000, which was subsequently paid by the issuance of stock options.

Research and Development

Research and development expenses for the twelve-month period ended September 30, 2021 increased by $443,677 or 13% to $3,765,440 from $3,321,763 in the twelve-month period ended September 30, 2020. This increase is primarily due to increased purchases relating to our clinical laboratory build out as well as for research projects related to genetic sequencing and isotopic research analysis projects. These increases were offset by a reduction of approximately $37,000 relating to a government award.

Depreciation and Amortization

Depreciation and amortization expenses for the twelve-month period ended September 30, 2021 increased by $558,708 or 196% to $844,438 from $285,730 in the twelve-month period ended September 30, 2020. This increase is related primarily to assets purchased to support our COVID-19 testing services, as well the production of our LineaTM COVID-19 Assay Kit.

Impairment losses

Impairment losses for the twelve-month period ended September 30, 2021 was $821,741. This relates to the impairment of intellectual property, customer lists and goodwill relating to a 2015 asset purchase.

***Interest (expense)* income**

Interest (expense) income for the fiscal year ended September 30, 2021, decreased to income of $13,675 from expense of $115,830 in the same period of 2020. The decrease in interest expense was due to the repayment of the July 2019 Notes during October 2020.

Other (expense) income

Other income (expense) for the twelve-month periods ended September 30, 2021 and 2020, was expense of $243,576 and $378,075, respectively. The decrease of $134,499 is due to an increase in franchise taxes during the twelve-month period ended September 30, 2020.

Loss on extinguishment of debt

Loss on extinguishment of convertible notes payable of $1,774,662 for the twelve-month period ended September 30, 2021 relates to the repayment of the July 2019 Notes. The loss on extinguishment represents the difference between the fair value of the July 2019 Notes, including the fair value of the Replacement Warrants issued, on the repayment date compared to its carrying value.

Gain on change in fair value of secured convertible notes payable

Gain on extinguishment of notes payable for the twelve-month period ended September 30, 2021 of $839,945 relates to the full forgiveness of the Company's PPP loan. The gain on extinguishment represents the difference between the fair value of the PPP loan on the forgiveness date compared to their carrying value.

Net Loss

Net loss increased $1,249,535, or 10% to $14,278,439 for the fiscal year ended September 30, 2021 compared to $13,028,904 for the fiscal year ended September 30, 2020, due to the factors noted above.

Recently Issued Accounting Pronouncements

See Note C, "Recent Accounting Standards," 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, 2021, we had working capital of $8,025,458. For the fiscal year ended September 30, 2021, we used cash in operating activities of $13,387,955 consisting primarily of our loss of $14,278,439 net with non-cash adjustments of $844,438 in depreciation and amortization charges, writeoff of property and equipment of $208,782 $1,668,003 in stock-based compensation expense, $821,741 for the impairment of goodwill and intangible assets, the loss on extinguishment of convertible notes payable of $1,774,662, the gain on extinguishment of notes payable of $839,945 and $28,629 of bad debt expense. Additionally, we had a net increase in operating assets of $3,480,501 and a net decrease in operating liabilities of $135,325. Cash used in investing activities was $2,548,695, for the purchase of property and equipment. Cash provided by financing activities was $14,704,855, which included net proceeds from a registered direct public offering of 13,756,507, warrant exercises of $2,613,929, and the repayment of convertible notes payable of $1,665,581.

We have recurring net losses. We have incurred a net loss of $14,278,439 for the fiscal year ended September 30, 2021. 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 and equity-linked securities.

We expect capital expenditures to be less than $1,200,000 in fiscal 2022. Our primary investments are expected to be in laboratory equipment related to our biotherapeutic research and development activities.

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

Recent Debt and Equity Financing Transactions

Fiscal 2021

Entry into Warrant Exercise Agreement

On October 7, 2020, we entered into Warrant Exercise Agreements (each, a "Warrant Exercise Agreement") with Dillon Hill Capital, LLC and its affiliate, Dillon Hill Investment Company LLC (together, the "Investors"), whereby 318,000 of our 2019 Warrants were exercised. The 2019 Warrants were issued as part of the Company's November 15, 2019 underwritten public offering. The gross proceeds to the Company from this partial exercise of the 2019 Warrants was $1,669,500.

In consideration of this partial exercise of the 2019 Warrants and of the consent to repayment of the Notes, as described below, the Company agreed to issue, in addition to the 318,000 shares of common stock issued upon exercise of the 2019 Warrants (the "Warrant Shares"), 159,000 replacement warrants (the "Replacement Warrants") to the Investors, which is an amount equal to one-half the amount of the 2019 Warrants exercised pursuant to the Warrant Exercise Agreements. The Replacement Warrants have an exercise price of $7.54, the closing price on The Nasdaq Capital Market of the Company's common stock on October 7, 2020. In addition, until January 5, 2021, if the Investors exercised additional 2019 Warrants, the Company agreed to issue to the applicable Investor additional Replacement Warrants in an amount equal to one-half the amount of such exercised 2019 Warrants with each such Replacement Warrant having an exercise price equal to the closing price on The Nasdaq Capital Market of the Company's common stock on such date that the related 2019 Warrants are exercised. No additional warrants were exercised.

Each Replacement Warrant will be exercisable beginning on the date of issuance thereof and ending on the five year anniversary of such date. The exercise price and number of shares of common stock issuable upon exercise of the Replacement Warrants will be subject to adjustment in the event of any stock dividend, split, recapitalization, reorganization or similar transaction, as described in the Replacement Warrant. Subject to limited exceptions, a holder of a Replacement Warrant will not have the right to exercise any portion of its Replacement Warrant if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided that upon 61 days' prior notice to the Company, the holder may elect to increase or decrease the Beneficial Ownership Limitation, although

in no event may the Beneficial Ownership Limitation exceed 9.99%. Each Replacement Warrant includes an adjustment provision that, subject to certain exceptions, reduces its exercise price if the Company issues common stock or common stock equivalents at a price lower than the then-current exercise price of such Replacement Warrant, subject to a minimum exercise price of 21% of such Replacement Warrant's initial exercise price per share. Under certain limited circumstances, including that the daily volume weighted average price of the common stock for each of 20 consecutive trading days has exceeded three times the exercise price of such Replacement Warrant, the Company may call for cancellation of all or any portion of such Replacement Warrant for which a notice of exercise has not yet been delivered for consideration equal to $0.001 per Warrant Share.

The Replacement Warrants will not be registered nor listed on any exchange but are the subject of registration rights agreements (each, a "Registration Rights Agreement"), entered into with each Investor concurrently with the respective Warrant Exercise Agreement, pursuant to which the Company agrees to file a registration statement by January 20, 2021 with respect to the common stock underlying the Replacement Warrants. If at the time of exercise of the Replacement Warrants there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the applicable Investor, then such Replacement Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Investor will be entitled to receive a number of Warrant Shares as determined by the terms of the Replacement Warrant. A registration statement was filed and went effective on February 2,2021.

The private placement of the Replacement Warrants 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 Investor represented to the Company in its Warrant Exercise Agreement that it is an "accredited investor" as that term is defined in Rule 501 of Regulation D.

On each of December 9 and 10, 2020, the Investors exercised 100,000 of their 2019 Warrants, for an aggregate exercise of 200,000 of their 2019 Warrants, resulting in total net proceeds to the Company of approximately $1.1 million. As a result of these exercises, we issued to the Investors an aggregate of 100,000 additional replacement warrants, which are substantially similar to the Replacement Warrants described above except that 50,000 of the newly-issued replacement warrants have an exercise price of $6.57 and 50,000 of such replacement warrants have an exercise price of $6.46.

Repayment of secured convertible notes

On October 9, 2020, the Company entered into a letter agreement (the "Letter Agreement") with Dillon Hill Capital, LLC (the "Noteholder") as sole holder of the secured convertible notes (the "Notes") for the repayment in full of the Notes, in an aggregate amount of $1,665,581 (the "Payoff Amount"), representing the outstanding principal amount of the Notes plus accrued but unpaid interest through the scheduled maturity of the Notes. The Company paid the Payoff Amount to the Noteholder on October 9, 2020. Pursuant to the Letter Agreement, upon the Noteholder's receipt of the Payoff Amount, the Notes and any other related documents and instruments automatically terminated. Moreover, all of the obligations and liabilities of the Company and its affiliates under the Notes, the Purchase Agreement, and the Security Agreements, and any other related documents and instruments, were automatically satisfied in full, and all related liens, mortgages or other security interests were automatically released.

Registered Direct Public Offering

On January 13, 2021, we closed on a registered direct public offering (the "Offering) of 1,810,000 shares (the "Shares") of our common stock, pursuant to (i) the securities purchase agreement, dated January 10, 2021, by and between the Company and certain institutional investors(the "Purchasers") whereby we agreed to issue and sell the Shares directly to the Purchasers at a price of $8.30 per share of Common Stock and (ii) the placement agency agreement, dated January 10, 2021, by and between the Company and Roth Capital Partners, LLC (the "Placement Agent"). Net proceeds, after deducting underwriting discounts and commissions, and other offering expenses, were approximately $13.8 million.

Fiscal 2020

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

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

After deducting underwriter discounts and commissions and other estimated expenses related to the underwritten public offering, the aggregate net proceeds were approximately $10.8 million.

We also granted the underwriter in the underwritten offering an option to purchase an additional 342,750 shares of our common stock and/or additional 2019 Warrants to purchase 342,750 shares of our common stock to cover any over-allotments made by the underwriters in the sale and distribution of the securities.

The 2019 Warrants include an adjustment provision that, subject to certain exceptions, reduces its exercise price if we issue common stock or common stock equivalents at a price lower than the then-current exercise price of the 2019 Warrants, subject to a minimum exercise price of $1.47 per share.

Subject to limited exceptions, a holder of the 2019 Warrants will not have the right to exercise any portion of its warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that upon 61 days' prior notice to us, the holder may increase the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99%.

The exercise price and number of the shares of common stock issuable upon the exercise of the 2019 Warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the related warrant agreement.

Product Research and Development

We anticipate spending approximately $3,500,000 for product research and development activities during the next twelve months.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Inflation

The effect of inflation on our revenue and operating results was not significant during the fiscal years ended September 30, 2021 and 2020.

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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Management Report on Internal Control over Financial Reporting

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including, our Chief Executive Officer, along with the Chief Financial Officer, on September 30, 2021, 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, 2021. 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, 2021, 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, 2021. 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, 2021.

Changes in Internal Control over Financial Reporting

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

ITEM 9B. OTHER INFORMATION.

None.

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

On December 12, 2019, we entered into a consulting agreement, with Meadow Hill Place, LLC ("Meadow Hill"), a company wholly owned by Scott L. Anchin ("Mr. Anchin"), a board member, whereby Meadow Hill will provide certain advisory services to the Company. The initial term of the agreement ended on June 12, 2020. The agreement provided for compensation in the form of both cash and equity. Meadow Hill was eligible to receive $125,000 for the initial six-month term. In addition, in satisfaction of the equity compensation portion of the agreement, (i) the Company granted an option to purchase 20,834 shares of its common stock to Mr. Anchin on December 12, 2019 at an exercise price equal to $4.26 per share, which vested on June 12, 2020, and (ii) the Company granted an option to purchase 20,786 shares of its common stock to Mr. Anchin on January 2, 2020 at an exercise price equal to $4.43 per share, of which 9,121 vested on July 2, 2020. The consulting agreement was completed on June 12, 2020 in full satisfaction of all obligations. As a result, the agreement was not extended and therefore expired on June 12, 2020. As a result, 11,665 of the options granted on January 2, 2020, which were related to the extension period, did not vest and were cancelled on June 12, 2020.

On each of December 9 and 10, 2020, Dillon Hill Capital, LLC and its affiliate, Dillon Hill Investment Company, LLC, a greater than 5% shareholder, exercised 100,000 of their 2019 Warrants, for an aggregate exercise of 200,000 of their 2019 Warrants, resulting in total net proceeds to the Company of approximately $1.1 million. As a result of these exercises, the Company issued to the Investors an aggregate of 100,000 additional replacement warrants, which are substantially similar to the Replacement Warrants described above except that 50,000 of the newly issued replacement warrants have an exercise price of $6.57 and 50,000 of such replacement warrants have an exercise price of $6.46.

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 2022 Annual Meeting of Stockholders, or will be included in an amendment hereto, which will be filed with the SEC within 120 days after September 30, 2021. 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, 2021 and 2020 and for the years ended September 30, 2021 and 2020, 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 9, 2021

/s/ James A. Hayward
By: 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 9, 2021
/s/ **BETH M. JANTZEN** Beth M. Jantzen	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	December 9, 2021
/s/ **JOHN BITZER, III** John Bitzer, III	Director	December 9, 2021
/s/ **ROBERT CATELL** Robert Catell	Director	December 9, 2021
/s/ **JOSEPH D. CECCOLI** Joseph D. Ceccoli	Director	December 9, 2021
/s/ **SCOTT L. ANCHIN** Scott L. Anchin	Director	December 9, 2021
/s/ **YACOV A. SHAMASH** Yacov A. Shamash	Director	December 9, 2021
/s/ **SANFORD R. SIMON** Sanford R. Simon	Director	December 9, 2021
/s/ **ELIZABETH M. SCHMALZ FERGUSON** Betsy M. Schmalz Ferguson	Director	December 9, 2021

EXHIBIT INDEX

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

Exhibit Number	Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	Exhibit	File No.	Date Filed	
3.1	Conformed version of Certificate of Incorporation of Applied DNA Sciences, Inc., as most recently amended by the Fifth Certificate of Amendment, effective Thursday, September 17, 2020	S-8	4.1	333-249365	10/07/2020	
3.2	By-Laws	8-K	3.2	002-90539	1/16/2009	
4.1	Description of Securities					Filed
4.2	Form of Underwriter's Warrant to be issued to Maxim Group LLC	S-1/A	10.26	333-199121	10/30/2014	
4.3	Form of Underwriter's Warrant	8-K	4.1	001-36745	3/27/2015	
4.4	Form of Purchase Warrant	8-K	4.1	001-36745	11/23/2015	
4.5	Form of Placement Agent Warrant issued to Maxim Group LLC	8-K	4.2	001-36745	11/23/2015	
4.6	Form of Placement Agent Warrant issued to Maxim Group LLC and Imperial Capital, LLC	8-K	4.1	001-36745	11/2/2016	
4.7	Form of Purchase Warrant	8-K	4.1	001-36745	12/20/2017	
4.8	Common Stock Purchase Warrant	8-K	4.1	001-36745	12/21/2018	
4.9	Form of pre-funded warrant.	8-K	4.3	001-36745	11/14/2019	
4.10	Form of common warrant certificate (included in the Warrant Agreement, dated November 15, 2019)	8-K	4.2	001-36745	11/18/2019	
4.11	Form of Indenture	S-3	4.1	333-238557	05/21/2020	
4.12	Form of Common Stock Purchase Warrant	8-K	10.3	001-36745	10/14/2020	
10.1†	Form of employee stock option agreement under the Applied DNA Sciences, Inc. 2005 Incentive Stock Plan	10-Q	4.1	002-90539	05/15/2012	
10.2†	Applied DNA Sciences, Inc. 2005 Incentive Stock Plan, as amended and restated	DEF 14A	Appendix A	001-36745	04/04/2019	
10.3†	Form of employee stock option agreement under the Applied DNA Sciences, Inc. 2005 Incentive Stock Plan, as amended	10-K	10.1	001-36745	12/14/2015	
10.4†	Applied DNA Sciences, Inc. 2020 Equity Incentive Plan	DEF 14A	Appendix A	001-36745	08/03/2020	
10.5†	Applied DNA Sciences, Inc. 2020 Equity Incentive Plan Stock Option Grant Notice and Award Agreement	S-8	10.3	333-249365	10/07/2020	
10.6†	Employment Agreement, dated July 1, 2016, between James A. Hayward and Applied DNA Sciences, Inc.	8-K	10.1	001-36745	8/2/2016	
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	Warrant Agreement, dated November 20, 2014, between Applied DNA Sciences, Inc. and American Stock Transfer & Trust Company, LLC as warrant agent	8-K	4.1	001-36745	11/20/2014
10.11	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
10.12	Second Amendment to Warrant Agreement dated November 2, 2016	8-K	10.4	001-36745	11/2/2016
10.13	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
10.14	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
10.15	Form of Securities Purchase Agreement	8-K/A	10.2	001-36745	11/23/2015
10.16	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
10.17	Securities Purchase Agreement dated November 2, 2016	8-K	10.2	001-36745	11/2/2016
10.18	Registration Rights Agreement dated November 2, 2016	8-K	10.3	001-36745	11/2/2016
10.19*	License Agreement with Himatsingka America, Inc. dated June 23, 2017	10-Q	10.1	001-36745	8/10/2017
10.20	Placement Agency Agreement by and between Applied DNA Sciences, Inc. and Maxim Group LLC, dated December 20, 2017.	8-K	10.1	001-36745	12/20/2017
10.21	Securities Purchase Agreement dated as of December 20, 2017, by and between Applied DNA Sciences, Inc. and the Purchasers named therein.	8-K	10.2	001-36745	12/20/2017
10.22	Registration Rights Agreement, dated November 29, 2018	8-K	10.2	001-36745	12/6/2018
10.23	Securities Purchase Agreement, dated November 29, 2018	8-K	10.3	001-36745	12/6/2018
10.24	Registration Rights Agreement, dated August 31, 2018	8-K/A	10.2	001-36745	12/10/2018
10.25	Securities Purchase Agreement, dated August 31, 2018	10-K	10.45	001-36745	12/18/2018
10.26+	Patent and Know-How License and Cooperation Agreement, dated March 28, 2019, between the Company, APDN (B.V.I.), Inc., and ETCH BioTrace S.A.	10-Q	10.10	001-36745	5/9/2019

10.27	Registration Rights Agreement, dated July 16, 2019 by and among Applied DNA Sciences, Inc. and the investor named on the signature page thereof.	8-K	10.2	001-36745	07/17/2019
10.28	Securities Purchase Agreement, dated July 16, 2019 by and among Applied DNA Sciences, Inc. and the investor named on the signature page thereof.	8-K	10.3	001-36745	07/17/2019
10.29	Asset Purchase Agreement, dated July 29, 2019 by and between LineaRX, Inc. and Vitatex Inc.	8-K	10.1	001-36745	8/12/2019
10.30	Form of Subscription Agreement between investors and Applied DNA Sciences, Inc., dated August 22, 2019.	8-K	10.1	001-36745	8/26/2019
10.31	Underwriting Agreement entered into by and between Applied DNA Sciences, Inc. and Maxim Group LLC, as Representative of the Underwriters listed in Schedule I hereto, dated November 13, 2019.	8-K	1.1	001-36745	11/14/2019
10.32	Warrant Agreement, dated November 15, 2019, between Applied DNA Sciences, Inc. and American Stock Transfer & Trust Company, LLC	8-K	4.1	001-36745	11/18/2019
10.33†	Consulting Agreement, dated as of December 12, 2019, by and between Applied DNA Sciences, Inc. and Meadow Hill Place, LLC	10.Q	10.1	001-36745	08/06/2020
10.34	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
10.35	Agreement of Lease, dated November 1, 2015, by and between Applied DNA Sciences, Inc. and Long Island High Technology Incubator, Inc.	10.Q	10.2	001-36745	08/06/2020
10.36	Option Exercise Notice, dated December 3, 2015, Pursuant to Lease dated June 14, 2013, between Applied DNA Sciences, Inc. and Long Island High Technology Incubator, Inc.	10.Q	10.2	001-36745	05/12/2016
10.37	Temporary Lease Extension Agreement, dated August 9, 2019, by and between Applied DNA Sciences, Inc. and Long Island High Technology Incubator, Inc.	10.Q	10.3	001-36745	08/06/2020
10.38	Amendment to Leases, dated November 4, 2019, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc.	10.Q	10.4	001-36745	08/06/2020
10.39	Amendment to Leases, dated January 17, 2020, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc.	10.Q	10.5	001-36745	08/06/2020
10.40	Warrant Exercise Agreement, dated October 7, 2020, by and between Applied DNA Sciences, Inc. and Dillon Hill Capital, LLC.	8-K	10.1	001-36745	10/14/2020

10.41	Warrant Exercise Agreement, dated October 7, 2020, by and between Applied DNA Sciences, Inc. and Dillon Hill Investment Company LLC.	8-K	10.2	001-36745	10/14/2020	
10.42	Registration Rights Agreement, dated October 7, 2020, by and between Applied DNA Sciences, Inc. and Dillon Hill Capital, LLC.	8-K	10.4	001-36745	10/14/2020	
10.43	Registration Rights Agreement, dated October 7, 2020, by and between Applied DNA Sciences, Inc. and Dillon Hill Investment Company LLC.	8-K	10.5	001-36745	10/14/2020	
10.44	Letter Agreement, dated October 9, 2020, by and among Applied DNA Sciences, Inc., Dillon Hill Capital, LLC, and Delaware Trust Company, as Collateral Agent.	8-K	10.6	001-36745	10/14/2020	
10.45	Consent, dated October 9, 2020, from Dillon Hill Capital, LLC to Applied DNA Sciences, Inc.	8-K	10.7	001-36745	10/14/2020	
10.46+	Joint Development Agreement, dated September 11, 2018, between LineaRx, Inc., Takis S.R.L. and Evvivax S.R.L., as amended by that First Amendment, dated February 3, 2020					Filed
10.47	Animal Clinical Trial Agreement, dated September 14, 2020, between Applied DNA Sciences, Inc., Evvivax S.R.L. and Veterinary Oncology Services, PLLC					Filed
10.48	Letter Agreement dated March 2, 2021, by and between the Company and Dr. James Hayward	8-K	10.1	001-36745	3/4/2021	
10.49	Form of Placement Agency Agreement by and between Applied DNA Sciences, Inc. and Roth Capital Partners, LLC, dated January 10, 2021	8-K	10.1	001-36745	01/11/2021	Filed
10.50	Form of Securities Purchase Agreement	8-K	10.2	001-36745	01/11/2021	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					Furnished
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					Furnished
101 INS	XBRL Instance Document					Filed

101 SCH	XBRL Taxonomy Extension Schema Document	Filed
101 CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed
101 DEF	XBRL Taxonomy Extension Definitions Linkbase Document	Filed
101 LAB	XBRL Taxonomy Extension Labels Linkbase Document	Filed
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed

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

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

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

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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. and Subsidiaries (the "Company") as of September 30, 2021 and 2020, and the related consolidated statements of operations, (deficit) equity and cash flows for each of the two years in the period ended September 30, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2021, 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 B, the Company has recurring net losses. The Company incurred a net loss of $14,278,439 and generated negative operating cash flow of $13,387,955. These factors 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 B. 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

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

Melville, NY
December 9, 2021

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

SEPTEMBER 30, 2021 and 2020

	September 30, 2021 (unaudited)	September 30, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,554,948	$ 7,786,743
Accounts receivable, net of allowance of $29,821 and $11,968 at September 30, 2021 and 2020, respectively	2,804,039	194,319
Inventories	1,369,933	497,367
Prepaid expenses and other current assets	568,881	599,296
Total current assets	11,297,801	9,077,725
Property and equipment, net	3,023,915	1,277,655
Other assets:		
Deposits	95,040	95,083
Goodwill	—	285,386
Intangible assets, net	—	605,330
Total Assets	$ 14,416,756	$ 11,341,179
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,991,343	$ 1,926,427
Promissory notes payable-current portion	—	329,299
Secured convertible notes payable , net of debt issuance costs	—	1,499,116
Deferred revenue	281,000	511,036
Total current liabilities	3,272,343	4,265,878
Long term accrued liabilities	31,467	848,307
Promissory notes payable-long term portion	—	517,488
Total liabilities	3,303,810	5,631,673
Commitments and contingencies (Note K)		
Applied DNA Sciences, Inc. stockholders' equity:		
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- shares issued and outstanding as of September 30, 2021 and 2020, respectively	—	—
Series A Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2021 and 2020, respectively	—	—
Series B Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2021 and 2020, respectively	—	—
Common stock, par value $0.001 per share; 200,000,000 shares authorized as of September 30, 2021 and 2020, 7,486,120 and 5,142,779 shares issued and outstanding as of September 30, 2021 and 2020, respectively	7,488	5,144
Additional paid in capital	295,228,272	275,548,737
Accumulated deficit	(284,122,092)	(269,835,650)
Applied DNA Sciences, Inc. stockholders' equity:	11,113,668	5,718,231
Noncontrolling interest	(722)	(8,725)
Total equity	11,112,946	5,709,506
Total liabilities and equity	$ 14,416,756	$ 11,341,179

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC. AND SUBSIDIAIRES
CONSOLIDATED STATEMENTS OF OPERATIONS
YEARS ENDED SEPTEMBER 30, 2021 and 2020

	2021	2020
Revenues		
Product revenues	$ 3,295,849	$ 615,430
Service revenues	937,735	1,238,517
Clinical laboratory service revenues	4,794,154	77,550
Total revenues	9,027,738	1,931,497
Cost of product revenues	1,496,659	720,900
Cost of clinical laboratory service revenues	2,602,729	106,923
Operating expenses:		
Selling, general and administrative	12,610,552	10,031,180
Research and development	3,765,440	3,321,763
Depreciation and amortization	844,438	285,730
Impairment losses	821,741	—
Total operating expenses	18,042,171	13,638,673
LOSS FROM OPERATIONS	(13,113,821)	(12,534,999)
Interest income (expense), net	13,675	(115,830)
Loss on extinguishment of convertible notes payable	(1,774,662)	—
Gain on extinguishment of notes payable	839,945	—
Other expense, net	(243,576)	(378,075)
Loss before provision for income taxes	(14,278,439)	(13,028,904)
Provision for income taxes	—	—
NET LOSS	(14,278,439)	(13,028,904)
Less: Net (income) loss attributable to noncontrolling interest	(8,003)	1,685
NET LOSS attributable to Applied DNA Sciences, Inc.	(14,286,442)	(13,027,219)
Deemed dividend related to warrant modifications	—	2,842
NET LOSS attributable to common stockholders	$ (14,286,442)	$ (13,030,061)
Net loss per share attributable to common stockholders-basic and diluted	$ (2.07)	$ (3.32)
Weighted average shares outstanding-basic and diluted	6,916,999	3,919,072

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF (DEFICIT) EQUITY
YEARS ENDED SEPTEMBER 30, 2021 and 2020

	Common Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Total
Balance, October 1, 2019	1,207,993	$ 1,208	$ 255,962,922	$ (256,805,589)	$ (7,040)	$ (848,499)
Common stock issued in public offering, net of offering costs	2,285,000	2,285	10,527,745	—	—	10,530,030
Deemed dividend - warrant repricing	—	—	2,842	(2,842)	—	—
Exercise of warrants	1,649,786	1,651	8,054,146	—	—	8,055,797
Stock based compensation expense	—	—	1,001,082	—	—	1,001,082
Net loss	—	—	—	(13,027,219)	(1,685)	(13,028,904)
Balance, September 30, 2020	5,142,779	$ 5,144	$ 275,548,737	$ (269,835,650)	$ (8,725)	$ 5,709,506
Exercise of warrants	520,151	521	2,613,408	—	—	2,613,929
Fair value of warrants issued in connection with convertible note repayment	—	—	1,643,440	—	—	1,643,440
Stock based compensation expense	—	—	1,668,003	—	—	1,668,003
Common stock issued in public offering, net of offering costs	1,810,000	1,810	13,754,697	—	—	13,756,507
Exercise of options cashlessly	13,190	13	(13)	—	—	—
Net loss	—	—	—	(14,286,442)	8,003	(14,278,439)
Balance, September 30, 2021	7,486,120	$ 7,488	$ 295,228,272	$ (284,122,092)	$ (722)	$ 11,112,946

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CASH FLOWS
YEARS ENDED SEPTEMBER 30, 2021 and 2020

	2021	2020
Cash flows from operating activities:		
Net loss	$ (14,278,439)	(13,028,904)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	844,438	285,730
Loss on disposal of property and equipment	208,782	—
Impairment of goodwill and intangible assets	821,741	—
Loss on extinguishment of convertible notes payable	1,774,662	—
Gain on extinguishment of notes payable	(839,945)	—
Stock-based compensation	1,668,003	1,001,082
Amortization of debt issuance costs	—	26,019
Provision for bad debts	28,629	45,280
Change in operating assets and liabilities:		
Accounts receivable	(2,638,350)	600,352
Inventories	(872,566)	(354,738)
Prepaid expenses and other current assets and deposits	30,415	(27,288)
Accounts payable and accrued liabilities	94,711	427,365
Deferred revenue	(230,036)	(117,957)
Net cash used in operating activities	(13,387,955)	(11,143,059)
Cash flows from investing activities:		
Purchase of intangible asset	—	—
Purchase of property and equipment	(2,548,695)	(1,063,698)
Net cash used in investing activities	(2,548,695)	(1,063,698)
Cash flows from financing activities:		
Net proceeds from exercise of warrants	2,613,929	8,055,797
Net proceeds from sale of common stock	13,756,507	—
Net proceeds from sale of common stock and warrants	—	10,639,728
Repayment of convertible notes	(1,665,581)	(107,802)
Proceeds from promissory notes	—	846,789
Net cash provided by financing activities	14,704,855	19,434,512
Net increase in cash and cash equivalents	(1,231,795)	7,227,755
Cash and cash equivalents at beginning of period	7,786,743	558,988
Cash and cash equivalents at end of period	$ 6,554,948	$ 7,786,743
Supplemental Disclosures of Cash Flow Information:		
Cash paid during period for interest	$ —	$ 45,354
Cash paid during period for income taxes	$ —	$ —
Non-cash investing and financing activities:		
Interest paid in kind	$ 28,329	$ 35,625
Property and equipment acquired, and included in accounts payable	$ 181,807	$ 144,025
Deemed dividend-warrant repricing	$ —	$ 2,842
Deferred offering costs reclassified to additional paid in capital	$ —	$ 109,698
Issuance of warrants in settlement of convertible notes payable	$ 1,074,118	$ —

See the accompanying notes to the consolidated financial statements

NOTE A – NATURE OF THE BUSINESS

Applied DNA Sciences, Inc. ("Applied DNA" or the "Company") develops and markets DNA-based technology solutions utilizing its LinearDNA™ large-scale polymerase chain reaction ("PCR") based manufacturing platform. The Company's proprietary platform produces large quantities of DNA for use in the nucleic acid-based in vitro diagnostics and preclinical nucleic-acid based drug development and manufacturing markets ("Biotherapeutic Contract Research and Manufacturing") and for supply chain security, anti-counterfeiting and anti-theft technology purposes ("Non-Biologic Tagging"). In response to the SARS-CoV-2 ("COVID-19") pandemic, the Company developed a PCR-based molecular diagnostic test for COVID-19, which was granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration ("FDA") in May 2020. The Company currently manufactures and sells its EUA authorized COVID-19 molecular diagnostic test kit under the Linea™ COVID-19 Assay Kit trademark ("COVID-19 Diagnostic Test Kit"). In addition, and in further response to the COVID-19 pandemic, the Company developed and is currently offering, COVID-19 testing services under its wholly owned subsidiary, Applied DNA Clinical Labs, LLC ("ADCL"). ADCL currently holds a New York clinical laboratory permit and a Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. §263a ("CLIA") certification for virology ("Clinical Testing Laboratory"). Using the Company's COVID-19 Diagnostic Test Kit, ADCL's currently offers to clients a high throughput pooled COVID-19 testing program, known as safeCircle™, which utilizes high-sensitivity pooled testing to help prevent virus spread by identifying infections within a community, school, or workplace. safeCircle provides to its clients rapid testing results using real-time PCR (RT-PCR) testing. ("COVID-19 Testing Services"). The Company is also developing an invasive circulating tumor cell capture and identification technology ("iCTC Technology") which uses a patented functional assay to capture live invasive circulating tumor cell and associated lymphocytes that can be identified and expanded for further analysis, including genetic sequencing.

Biotherapeutic Contract Research and Manufacturing

The Company's patented continuous flow PCR systems and other proprietary PCR-based production technology and post-processing systems that comprise the LinearDNA™ platform allows for the large-scale enzymatic production of specific DNA sequences. The LinearDNA™ platform is currently being used for customers to manufacture DNA as components of in vitro diagnostic tests and for preclinical nucleic acid-based drug development in the fields of adoptive cell therapies (CAR T and TCR therapies), DNA vaccines (anti-viral and cancer), RNA therapies, clustered regularly interspaced short palindromic repeats (CRISPR) based therapies and gene therapies.

The Company provides preclinical contract research and manufacturing services for the nucleic acid-based therapeutic markets. It works with biotech and pharmaceutical companies to convert conventional nucleic-acid based preclinical biotherapeutics into PCR-produced linear DNA-based forms that can be produced on the Company's LinearDNA™ platform. In addition, it provides contract research services to RNA based drug and biologic customers for preclinical studies. These services include the design, development and manufacture of PCR-produced DNA templates for RNA. In addition, the Company also uses its LinearDNA™ platform to produce very large gram-scale quantities of DNA for the in vitro diagnostic market where the Company's DNA is used for both commercially available diagnostics and diagnostics under development.

The Company is currently directly engaged in preclinical drug candidate development activities focusing on therapeutically relevant DNA constructs manufactured via its LinearDNA™ platform in the fields of DNA-based anti-viral and anti-cancer vaccines, CAR-T cell immunotherapy and the manufacture of rAAV vectors for gene therapy.

NOTE A – NATURE OF THE BUSINESS, continued

Biotherapeutic Contract Research and Manufacturing, continued

The Company is also engaged in preclinical and animal drug candidate development activities focusing on therapeutically relevant DNA constructs manufactured via its LinearDNA production platform. The Company seeks to develop, acquire and commercialize, alone or with partners, a diverse pipeline of nucleic acid-based therapeutics based on PCR-produced linear DNA. To this end, the Company is currently working with its development partners Takis S.R.L. and Evvivax S.R.L. ("Takis/Evvivax") to develop an amplicon-based linear DNA vaccine for COVID-19 that would be manufactured on the Company's LinearDNA™ platform. Together with its development partners, the Company's amplicon-based linear COVID-19 vaccine candidate has shown efficacy in preclinical cell, mouse and feline animal studies. In September 2020, the Company entered into an Animal Clinical Trial Agreement with Takis/Evvivax and with Veterinary Oncology Services, PLLC, an affiliate of Guardian Veterinary Specialists ("GVS"), a multi-specialty veterinary hospital. In November 2020, the Company, together with Takis/Evvivax and GVS, announced receipt of approvals from the New York State Department of Agriculture and Markets and the U.S. Department of Agriculture ("USDA") on an advanced clinical strategy to conduct a veterinary trial of an amplicon-based linear DNA vaccine COVID-19 candidate. The Company's jointly developed amplicon-based LinearDNA vaccine for COVID-19 is currently in a veterinary clinical trial in domestic feline cats, with the end goal of applying for a USDA Animal and Plant Health Inspection Service conditional license to enable commercial veterinary sales for veterinary applications. In April 2021, the Company announced preliminary data from its veterinary clinical trial in felines conducted with Takis/Evvivax and GVS. The preliminary data showed that all felines in the trial produced SARS-CoV-2 neutralizing antibodies after a single prime dose of the vaccine candidate. Subsequently in May 2021, the Company announced additional preliminary data from its feline clinical trial that showed a booster injection of the amplicon-based linear DNA vaccine candidate delivered 30 days after the prime vaccination elected a 5-fold increase in neutralizing antibody titers, with every member of the trial cohort producing neutralizing antibody titers. In June 2021, the Company further announced preliminary data from an in vitro neutralization study of sera from the feline trial cohort against the B.1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants. The preliminary data showed that the amplicon-based linear DNA vaccine candidate induced neutralizing antibodies against the 1.1.7 (U.K.), P1 (Brazil), and B.1.526 (New York) SARS-CoV-2 variants in 100% of the trial cohort. In October 2020, Applied DNA and The Cornell University School of Veterinary Medicine began a SARS-CoV-2 challenge trial in ferrets to assess the protective efficacy of the LinearDNA vaccine against live SARS-CoV-2 virus.

COVID-19 Diagnostic Test Kit

On May 13, 2020 the Company received an EUA from the FDA for the clinical use of the Linea™ COVID-19 Assay Kit for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens including anterior nasal swabs, self-collected at a healthcare location or collected by a healthcare worker, and nasopharyngeal and oropharyngeal swabs, mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates, and bronchoalveolar lavage specimens collected by a healthcare worker from individuals who are suspected of COVID-19 by their healthcare provider. Under the EUA, testing is limited to laboratories certified under CLIA, that meet requirements to perform high complexity tests. Subsequently, during July and November 2020, we were granted EUA amendments that expanded the installed base of PCR equipment platforms on which the Company's Linea™ COVID-19 Assay Kit can be processed and significantly increased the daily testing capacity of the Linea (TM) COVID-19 Assay Kit through the use of automation. On May 11, 2021, the Company received a re-issued EUA that expanded the intended use of the Linea™ COVID-19 Assay Kit to include use with anterior nasal swab specimens that are self-collected in the presence of a healthcare provider from individuals without symptoms or other reasons to suspect COVID-19 when tested at least weekly and with no more than 168 hours between serially collected specimens. The expanded intended use allows ADCL and other certified laboratory users of the Linea™ COVID-19 Assay Kit, to provide serial screening testing to individuals with the return of individual testing results. The May 11, 2021 re-issued EUA also updated the Linea™ COVID-19 Assay Kit's Instructions for Use to include the KingFisher(TM) Flex Purification System, a high-throughput robotic nucleic acid extraction system. The scope of the EUA, as amended, is expressly limited to use consistent with the Instructions for Use by authorized laboratories, certified under CLIA to perform high complexity tests. The EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated or until the EUA's prior termination or revocation. Our Linea (TM) COVID-19 Assay Kit has not been FDA cleared or approved, and the EUA's limited authorization is only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

NOTE A – NATURE OF THE BUSINESS, continued

The Company currently manufactures the Linea™ COVID-19 Assay Kit at its facilities in Stony Brook, New York. The Company's COVID-19 Assay Kit is predominantly utilized by ADCL to provide safeCircle high-throughput pooled COVID-19 testing services.

COVID-19 Testing Services

The Company under its wholly owned subsidiary, ADCL, offers a high throughput COVID-19 testing program to customers as a Testing-as-a-Service (TaaS) offering branded under the safeCircle™ trademark. safeCircle is a turnkey testing solution that provides for all aspects of large population COVID-19 testing – from sample collection to results reporting – for institutes of higher education, K-12 schools, businesses, and healthcare facilities, among other institutions with large populations. safeCircle utilizes serial, high-sensitivity pooled RT-PCR testing to help prevent virus spread by quickly identifying infections within a community, school, or workplace. Testing is conducted utilizing the Company's Linea™ COVID-19 Assay Kit that provides rapid results using real-time PCR (RT-PCR testing) with results returned typically within 24 to 48 hours at the Company's Clinical Laboratory Evaluation Program ("CLEP") permitted, CLIA-certified laboratory. For the majority of safeCircle clients, test scheduling and testing result reporting is provided though the CLEARED4 digital health platform owned and operated by Chelsea Health Solutions, LLC.

The Company currently provides safeCircle™ pooled testing to primary/secondary/higher education institutions, private clients, local governments, and businesses and college athletic programs.

In addition, starting in February 2021, the Company began the development of its Linea SARS-CoV-2 Mutation Panel (formally the Selective Genomic Surveillance Mutation Panel) for the qPCR-based detection of certain SARS-CoV-2 genetic mutations (the "Mutation Panel"). In May 2021, the Company announced that it had completed technical validation of the Mutation Panel. In October 2021, the Company announced that an EUA request for the Mutation Panel had been filed with FDA. Use of the Mutation Panel is currently limited to Research Use Only (RUO).

Clinical Testing Laboratory

Under the Company's ADCL subsidiary, on May 10, 2021 the Company received its New York clinical laboratory permit and its CLIA certification from the New York State Department of Health, CLEP, which is currently permitted for virology. As part of the Company's COVID-19 Testing Services its laboratory provides individual COVID-19 testing utilizing the Company's EUA-authorized Linea COVID-19 Assay Kit, pooled screening testing under its July 13, 2021 LDT submission to NYSDOH and pooled surveillance testing that is not regulated by FDA, CDC or CMS.

On November 15, 2021 FDA revised its guidance document titled "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)" ("FDA COVID-19 Testing Guidance") to require all COVID-19 diagnostic assays conducted as Laboratory-Developed Tests ("LDTs") to apply for EUA authorization within a 60-day period from the revised guidance's issuance date. The FDA Guidance provides an exception for certain notified states, who can authorize in-state laboratories to develop and perform COVID-19 tests under the authority of their own State law in instances where the laboratory did not otherwise submit an EUA request to FDA.

On July 13, 2021, ADCL submitted data supporting the validation of a high-throughput robotic 5-sample pooling workflow utilizing the Linea COVID-19 Assay Kit to the New York State Department of Health ("NYSDOH"), which is currently pending. New York State falls within the exemption contemplated by FDA's revised COVID-19 Testing Guidance, meaning ADCL can obtain NYSDOH authorization for conducting the test in lieu of an EUA from FDA. Pursuant to current NYSDOH guidance, ADCL is currently performing the validated workflow in its COVID-19 testing during the pendency of the NYSDOH review.

NOTE A – NATURE OF THE BUSINESS, continued

In the event that NYSDOH declines to authorize ADCL's performance of the Linea COVID-19 assay on pooled samples, ADCL will be required to submit an EUA to FDA in order to continue performing the validated pooling workflow in its COVID-19 testing. Pursuant to the revised FDA COVID-19 Testing Guidance, laboratories can continue performing validated assays during the pendency of the EUA review by FDA. It is important to note that FDA retains the authority to review, or decline to review, as well as authorize, or decline to authorize, any EUA request for any product. ADCL cannot, therefore, guarantee that it will ultimately obtain authorization to perform its Linea COVID-19 assay on pooled samples if it is required to submit an EUA.

iCTC Technology

The Company's iCTC Technology uses a patented functional assay to capture live invasive circulating tumor cell and associated lymphocytes that can be identified and expanded for further analysis, including genetic sequencing. The Company's iCTC Technology has been used and is currently being used in a human cancer drug candidate clinical trial to monitor cancer disease progression in the trial subjects as a Research Use Only diagnostic assay. The Company seeks to further develop and commercialize this technology and to potentially integrate aspects of the iCTC Technology with its PCR know-how and with the LinearDNA™ platform for cancer research and nucleic acid-based drug development.

Non-Biological Tagging and Related Services

The Company's supply chain security business allows its customers to use non-biologic DNA (molecular) tags, manufactured via its LinearDNA™ platform, to mark objects, and then identify these objects by detecting the absence or presence of the molecular tag. The Company's core products include:

- SigNature® Molecular Tags produced by the Company's LinearDNA™ platform, provide an approach to authenticate goods within large and complex supply chains for materials such as cotton, and leather, in-home textiles and apparel, pharmaceuticals and nutraceuticals, cannabis and other products.

- SigNify® IF portable DNA readers and SigNify consumable reagent test kits provide definitive real-time authentication of molecular tags in the field, providing a front-line solution for supply chain integrity backed with forensic-level molecular tag authentication. Applied DNA's software platform enables customers to track materials throughout a supply chain or product life.

- CertainT trademark indicates the use of Applied DNA's tagging, testing and tracking platforms and solutions, enabling manufacturers, brands and trade organizations to convey proof of their product claims.

NOTE B – GOING CONCERN AND MANAGEMENT'S PLAN

The Company has recurring net losses. The Company incurred a net loss of $14,278,439 and generated negative operating cash flow of $13,387,955 for the fiscal year ended September 30, 2021. 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 and equity-linked securities.

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES

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

Principles of Consolidation

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, ADCL and its majority–owned subsidiary, LineaRx, Inc. ("LRx"). 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 United States of America ("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 significant estimates include revenue recognition, allowance for doubtful accounts, recoverability of long-lived assets, including the values assigned to goodwill, intangible assets and property and equipment, fair value calculations for stock-based compensation and warrants, contingencies, 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.

Revenue Recognition

The Company follows Financial Accounting Standards Board ("FASB") Accounting Standards Codifications ("ASC"), Revenue Recognition ("ASC 606" or "Topic 606").

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

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

Product Revenues and Authentication Services

The Company's PCR-produced linear DNA products are manufactured in accordance with contracts with customers. The Company recognizes revenue upon satisfying its promises to transfer goods or services to customers under the terms of its contracts. These performance obligations are satisfied at the point in time the Company transfers control of the goods to the customer, which in nearly all cases is when title to and risk of loss of the goods transfer to the customer. The timing of transfer of title and risk of loss is dictated by customary or explicitly stated contract terms. The Company invoices customers upon shipment, and its collection terms range, on average, from 30 to 60 days.

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES, continued

Revenue Recognition, continued

Authentication Services

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

Clinical Laboratory Testing Services

The Company records revenue for its clinical laboratory testing service contracts, which includes its COVID-19 Testing Services, upon satisfying its promise to provide services to customers under the terms of its contracts. These performance obligations are satisfied at the point in time that Company services are complete, which in nearly all cases is when the testing results are released to the customer.

Research and Development Services

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

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

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES, continued

Revenue Recognition, continued

Disaggregation of Revenue

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

	Fiscal Years Ended: September 30,	
	2021	2020
Research and development services (over-time)	$ 799,718	$ 1,128,511
Clinical laboratory testing services (point-in-time)	4,794,154	77,550
Product and authentication services (point-in-time):		
Supply chain	1,003,248	38,577
Asset marking	458,409	404,888
Large scale DNA production	—	281,971
Diagnostic test kits	1,972,209	—
Total	$ 9,027,738	$ 1,931,497

Contract balances

As of September 30, 2021, the Company has entered into contracts with customers for which revenue has not yet been recognized. Consideration received from a customer prior to revenue recognition is recorded to a contract liability and is recognized as revenue when the Company satisfies the related performance obligations under the terms of the contract. The Company's contract liabilities, which are reported as deferred revenue on the consolidated balance sheet, consist almost entirely of research and development contracts where consideration has been received and the development services have not yet been fully performed.

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

	Balance sheet classification	October 1, 2020	September 30, 2021	$ change
Contract liabilities	Deferred revenue	$ 511,036	$ 281,000	$ (230,036)

	Balance sheet classification	October 1, 2019	September 30, 2020	$ change
Contract liabilities	Deferred revenue	$ 628,993	$ 511,036	$ (117,957)

For the fiscal year ended September 30, 2020, the Company recognized $591,360 of revenue that was included in Contract liabilities as of October 1, 2019.

For the fiscal year ended September 30, 2021, the Company recognized $277,331 of revenue that was included in Contract liabilities as of October 1, 2020.

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. As of September 30, 2021 and 2020, cash equivalents were $4,417,906 and $5,504,826, respectively.

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES, continued

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, 2021 and 2020, the Company has an allowance for doubtful accounts of $29,821 and $11,968, respectively. The Company writes-off receivables that are deemed uncollectible.

Inventories

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

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, Income Taxes ("ASC 740-10") which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statement or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Temporary differences between taxable income reported for financial reporting purposes and income tax purposes include, but not limited to, accounting for intangibles, equity-based compensation and depreciation and amortization. The Company evaluates the recoverability of deferred tax assets and establishes a valuation allowance when it is more likely than not that some portion or all of the deferred tax asset will not be realized. During the fiscal years ended September 30, 2021 and 2020, the Company incurred losses from operations. Based upon these results and the trends in the Company's performance projected for fiscal year 2021, 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, 2021 and 2020. Tax years 2016 through 2019 remain subject to future examination by the applicable taxing authorities.

Property and Equipment

Property and equipment are stated at cost and depreciated using the straight line method over their estimated useful lives. The estimated useful life for computer equipment, lab equipment and furniture is 3 years, vehicles is 5 years and leasehold improvements are amortized over the shorter of their useful life or the remaining lease terms. Property and equipment consist of:

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES, continued

	September 30,	
	2021	2020
Computer equipment	$ —	$ 90,509
Lab equipment	3,565,057	3,036,397
Furniture	—	74,781
Vehicles	108,361	—
Leasehold improvements	124,825	524,485
Total	3,798,243	3,726,172
Accumulated depreciation	774,328	2,448,517
Property and equipment, net	$ 3,023,915	$ 1,277,655

As of September 30, 2021, there was $6,580 of construction in progress that was included in lab equipment. Depreciation expense for the fiscal years ended September 30, 2021 and 2020 were $767,025 and $156,290, respectively.

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. Based on the qualitative analysis performed by management, as of September 30, 2021, the Company has recorded a non-cash impairment charge of $285,386 and 536,355 to write-off the goodwill and remaining net book value of the intangible assets, respectively. The goodwill, intellectual property and customer lists were from the Vandalia Asset Acquisition and related to the right to produce, sell and have sold, market and develop the Triathlon DNA production system. Since the Company is no longer utilizing this technology, as the Company is now using a different technology to produce these products, the impairment assessment concluded that the asset group was not recoverable and resulted in the full impairment and write-off of the goodwill and intangible assets as of September 30, 2021. See Note E below for further details.

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, warrants, and secured convertible notes.

For the fiscal years ended September 30, 2021 and 2020, 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, 2021 and 2020 are as follows:

	2021	2020
Warrants	745,268	1,038,919
Options	487,377	291,035
Secured convertible note	—	70,962
	1,232,645	1,400,916

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES, continued

Stock-Based Compensation

The Company accounts for stock-based compensation for employees, directors, and nonemployees in accordance with ASC 718, Compensation ("ASC 718"). ASC 718 requires all share-based payments, 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 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 740, 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 consolidated statements of operations.

Concentrations

Financial instruments and related items, which potentially subject the Company to concentrations of credit risk, consist primarily of cash, cash equivalents and trade receivables. The Company places its cash and cash equivalents with high credit quality institutions. At times, such investments may be in excess of the FDIC insurance limit. As of September 30, 2021, the Company had cash and cash equivalents of approximately $6.0 million 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, 2021 included an aggregate of 18%, and 13%, respectively from two customers.

The Company's revenues earned from sale of products and services for the fiscal year ended September 30, 2020 included an aggregate of 13%, 12%, 11% and 10% respectively from four customers.

Two customers accounted for 67% of the Company's accounts receivable at September 30, 2021 and four customers accounted for an aggregate of 74% of the Company's total accounts receivable at September 30, 2020.

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. 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, 2021 and 2020, the Company incurred research and development expenses of $3,765,440 and $3,321,763, respectively.

Advertising

The Company follows the policy of charging the costs of advertising to expense as incurred. The Company charged to operations $283,621 and $55,558, as advertising costs for the fiscal years ended September 30, 2021 and 2020, 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.

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES, continued

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, 2021, as a result of the qualitative analysis performed, the Company has recorded a non-cash impairment charge of $821,740 to write-off the goodwill and remaining net book value of the intangible assets due to a reduction in demand from certain customers and a transition in the way the product is produced for these customers, which no longer utilizes the previously purchased intellectual property.

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 and are included in interest expense in the consolidated financial statements.

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.

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

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

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

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

As of September 30, 2021, there were no transfers between Levels 1, 2 and 3 of the fair value hierarchy.

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES, continued

Recent Accounting Standards

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40)." The objective of this update is to simplify the accounting for convertible preferred stock by removing the existing guidance in ASC 470-20, "Debt: Debt with Conversion and Other Options,", that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in stockholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. This amendment also further revises the guidance in ASU 260, "Earnings per Share," to require entities to calculate diluted earnings per share (EPS) for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for fiscal years beginning after December 15, 2023, with early adoption permitted. The Company does not expect the adoption of ASU 2020-06 to have a significant impact on its consolidated financial statements.

NOTE D – INVENTORIES

Inventories consist of the following at September 30, 2021 and 2020:

	2021	2020
Raw materials	$ 786,938	$ 387,815
Work in progress	—	77,667
Finished goods	582,995	31,885
Total	$ 1,369,933	$ 497,367

NOTE E – INTANGIBLE ASSETS

Intangible assets at September 30, 2021 and 2020 are as follows:

	2021	2020
Internally developed software (5-year useful life)	$ —	$ 157,221
Customer relationships (10-year useful life)	621,000	621,000
Intellectual property (5-15 years)	917,350	917,350
	1,538,350	1,695,571
Less:		
Accumulated amortization	1,001,995	933,020
Impairment losses	536,355	157,221
Intangible assets, net	$ —	$ 605,330

Total amortization expense charged to operations for the fiscal years ended September 30, 2021 and 2020 were $68,976 and $129,441, respectively.

NOTE E – INTANGIBLE ASSETS, continued

During the fourth quarter of 2021, the Company performed an impairment assessment of its customer relationships and intellectual property as a result of the Company no longer using the acquired technology, as well as a reduction in demand and future demand from certain customers impacting projected net sales and cash flows. The Company is now using a different technology to produce these products. The intellectual property and customer lists were purchased as part of the Vandalia Asset Acquisition and related to the right to produce, sell and have sold, market and develop the Triathlon DNA production system, The qualitative impairment assessment concluded that the asset group was not recoverable and resulted in the full impairment of the remaining book value of these intangible assets of $536,355. See Note C above for further details.

NOTE F – ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities at September 30, 2021 and 2020 are as follows:

	2021	2020
Accounts payable	$ 2,010,410	$ 1,250,021
Accrued salaries payable	655,240	525,602
Other accrued expenses	325,693	150,804
Total	$ 2,991,343	$ 1,926,427

NOTE G – NOTES PAYABLE

CARES Act Loan

The Company received a loan of approximately $847,000 on May 1, 2020 from Bank of America as lender pursuant to the PPP of the CARES Act.

All or a portion of the loan may be forgiven by the U.S. Small Business Administration ("SBA") upon application by the Company beginning 60 days but not later than 130 days after loan approval and upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act, loan forgiveness is available for the sum of documented payroll costs, covered rent payments, covered mortgage interest, and covered utilities during the covered period as defined by the CARES Act. The Company used the proceeds from the loan to retain employees, maintain payroll and make lease and utility payments.

For purposes of the CARES Act, payroll costs exclude compensation of an individual employee in excess of $100,000, prorated annually. Not more than 40% of the forgiven amount may be for non-payroll costs. Forgiveness is reduced if full-time headcount declines, or if salaries and wages for employees with salaries of $100,000 or less annually are reduced by more than 25%. In the event the loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal. The Company's PPP loan, including accrued interest was fully forgiven on February 26, 2021. The forgiveness of the loan resulted in a gain on extinguishment of debt of $839,945 for the fiscal year ended September 30, 2021.

Repayment of the July 2019 Notes

On October 9, 2020, the Company entered into a letter agreement (the "Letter Agreement") with Dillon Hill Capital, LLC ("Dillon Hill"), as sole holder of the $1.5 million of secured convertible notes issued in July 2019 (the "July 2019 Notes"), providing for the repayment in full of the July 2019 Notes, in an aggregate amount of $1,665,581 (the "Payoff Amount"), representing the outstanding principal amount of the July 2019 Notes plus accrued but unpaid interest through the scheduled maturity of the July 2019 Notes. The Company paid the Payoff Amount to Dillon Hill on October 9, 2020. As of October 9, 2020, all of the obligations and liabilities of the Company and its affiliates under the July 2019 Notes, the Purchase Agreement, and the Security Agreements, and any other related documents and instruments, were satisfied in full, and all related liens, mortgages or other security interests were automatically released. Based solely on a review of Schedule 13G filings with the SEC, Dillon Hill at the time of the repayment of the July 2019 Notes and thereafter has been a greater than 5% shareholder in the Company's common stock.

NOTE G – NOTES PAYABLE, continued

Warrant Exercise Agreement

In conjunction with the Letter Agreement discussed above, on October 7, 2020, the Company entered into Warrant Exercise Agreements with Dillon Hill and its affiliate, Dillon Hill Investment Company LLC (together, the "Investors"), whereby 318,000 of the warrants issued to the Investors in the Company's November 2019 underwritten public offering (the "2019 Warrants") with an exercise price of $5.25 per share were exercised. The gross proceeds to the Company from this partial exercise of the 2019 Warrants is $1,669,500.

In consideration of this partial exercise of the 2019 Warrants and of the consent to repayment of the July 2019 Notes, as described above, the Company agreed to issue 159,000 replacement warrants (the "Replacement Warrants") to the Investors, which is an amount equal to one-half the amount of the 2019 Warrants exercised pursuant to the Warrant Exercise Agreements. The Replacement Warrants have an exercise price of $ 7.54. The Warrant Exercise Agreements expired on January 5, 2021.

Each Replacement Warrant is exercisable beginning on the date of issuance thereof and ending on the five-year anniversary of such date. The exercise price and number of shares of common stock issuable upon exercise of the Replacement Warrants will be subject to adjustment in the event of any stock dividend, split, recapitalization, reorganization, or similar transaction, as described in the Replacement Warrant.

On each of December 9 and 10, 2020, the Investors exercised 100,000 of their 2019 Warrants, for an aggregate exercise of 200,000 of their 2019 Warrants, resulting in total net proceeds to the Company of approximately $1.1 million. As a result of these exercises, pursuant to the Warrant Exercise Agreements the Company issued to the Investors an aggregate of 100,000 additional replacement warrants, which are substantially similar to the Replacement Warrants described above except that 50,000 of the newly-issued replacement warrants have an exercise price of $6.57 and 50,000 of such replacement warrants have an exercise price of $6.46.

No additional 2019 Warrants were exercised by January 5, 2021 and no additional replacement warrants were issued.

The repayment of the July 2019 Notes resulted in a loss on extinguishment of debt of $1,774,662 for the fiscal year ended September 30, 2021. Included in the loss on extinguishment of debt is $1,643,440 for the fair value of the Replacement Warrants (described above) that were issued in conjunction with the payoff of the July 2019 Notes.

NOTE H – CAPITAL STOCK

On October 31, 2019, the Company filed a Certificate of Amendment of its Certificate of Incorporation with the Secretary of State of the State of Delaware that effected a one-for-forty (1:40) reverse stock split of its common stock, par value $.001 per share, effective November 1, 2019. All warrant, option, share, and per share information in the consolidated financial statements gives retroactive effect to the one-for-forty reverse stock split that was effected on November 1, 2019. On September 16, 2020, the Company filed a Certificate of Amendment to its Certificate of Incorporation with the Secretary of State of the State of Delaware that reduced its authorized shares of common stock from 500,000,000 to 200,000,000.

Common Stock Transactions during the Fiscal Year Ended September 30, 2021:

On January 13, 2021, the Company closed on a registered direct public offering (the "Offering) of 1,810,000 shares (the "Shares") of the Company's common stock, pursuant to (i) the securities purchase agreement, dated January 10, 2021, by and between the Company and certain institutional investors(the "Purchasers") whereby the Company agreed to issue and sell the Shares directly to the Purchasers at a price of $8.30 per share of Common Stock and (ii) the placement agency agreement, dated January 10, 2021, by and between the Company and Roth Capital Partners, LLC (the "Placement Agent"). Net proceeds, after deducting underwriting discounts and commissions, and other offering expenses, were approximately $13.8 million.

NOTE H – CAPITAL STOCK, continued

Common Stock Transactions during the Fiscal Year Ended September 30, 2020:

On November 15, 2019, the Company closed an underwritten public offering (the "Offering") in which, pursuant to the Underwriting Agreement dated November 13, 2019 by and between the Company and Maxim Group LLC ("Maxim"), as Representative of the Underwriters, the Company issued and sold 2,285,000 shares of the Company's common stock and 2,285,000 accompanying warrants each with the right to purchase one share of common stock at an exercise price of $5.25 per share (the "Common Warrants"). The shares of common stock and accompanying Common Warrants were sold at a combined offering price of $5.25 before underwriting discounts. The common stock and the 2019 Warrants are collectively referred to herein as the "Securities." As part of the Offering, the Company granted Maxim a 45-day option to purchase an additional 342,750 shares of common stock and/or additional Common Warrants to purchase 342,750 shares of common stock (the "Option Warrants", together with the 2019 Warrants, the "Warrants") at the public offering price, less discounts and commissions, to cover any over-allotments made by the Underwriters in the sale and distribution of the Securities.

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

As a result of this financing, the exercise price of the 8,375 remaining warrants issued during December 2018 was reduced to an exercise price of $5.60 per share in accordance with the adjustment provision contained in the Warrant Agreement. The incremental change in fair value of these warrants as a result of the triggering event was $2,842 and was recorded as a deemed dividend.

During the fiscal year ended September 30, 2021, 520,151 of the 2019 Warrants were exercised, resulting in net proceeds to the Company of approximately $2.7 million.

During the fiscal year ended September 30, 2020, 1,649,786 of the 2019 Warrants were exercised, resulting in net proceeds to the Company of approximately $8.1 million.

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, 2020	1,038,919	$ 10.83
Granted	259,000	7.14
Exercised	(520,151)	(5.25)
Cancelled or expired	(32,500)	(171.56)
Balance, September 30, 2021	745,268	$ 6.44

Stock Options

During June 2020, the Board of Directors and subsequently during September 2020, the holders of a majority of the outstanding shares of common stock approved the 2020 Equity Incentive Plan (the "2020 Incentive Plan"). The 2020 Incentive Plan, among other things, reserves an additional 3,500,000 shares of the Company's common stock for issuance in the form of equity-based awards to employees, directors, consultants, and other service providers, and those of the Company's affiliates. The maximum total grant date fair value of awards granted under the 2020 Incentive Plan to individuals in their capacity as non-employee directors may not exceed $250,000 in any single calendar year. The 2020 Incentive Plan's expiration date is September 15, 2030.

NOTE I – STOCK OPTIONS AND WARRANTS, continued

Stock Options, continued

The 2020 Incentive Plan is designed to retain directors, executives, and selected employees and consultants by rewarding them for making contributions to the Company's success with an award of options to purchase shares of common stock. As of September 30, 2021, a total of 6,894 shares have been issued and options to purchase 501,240 shares have been granted under the Company's Incentive Plans.

In 2005, the Board of Directors and the holders of a majority of the outstanding shares of common stock approved the 2005 Incentive Stock Plan, as amended and restated as of January 21, 2015 (the "2005 Incentive Plan", collectively with the 2020 Incentive Plan, the "Company's Incentive Plans"). Effective as of September 16, 2020, no further awards will be made under the Company's 2005 Incentive Stock Plan, as amended and restated.

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, 2020	320,990	$ 57.75		
Granted	203,405	6.15		
Exercised	30,955	4.39		
Cancelled or expired	6,063	5.01		
Outstanding at September 30, 2021	487,377	40.26		
Vested at September 30, 2021	478,627	40.90	—	7.54
Non-vested at September 30, 2021	8,750	5.46	—	8.71

For the fiscal year ended September 30, 2021, the Company issued an aggregate of 203,405 options to employees and non-employee board of director members and consultants.

For the fiscal year ended September 30, 2020, the Company issued an aggregate of 155,395 options to employees and non-employee board of director members and consultants.

During November 2021, the Company granted 361,552 options to officers of the Company. These options have a ten year term and vested immediately. Also during November 2021, the Company granted 213,889 options to non-employee board of director members. The options granted to the non-employee board of directors have a ten year term and vest on the one-year anniversary of the date of grant.

The fair value of options granted during the fiscal years ended September 30, 2021 and 2020 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:

	2021	2020
Stock price	$ 6.43	$ 8.40
Exercise price	$ 6.43	$ 8.45
Expected term	5.10	6.85
Dividend yield	—	—
Volatility	141 %	136 %
Risk free rate	0.47 %	0.86 %

NOTE I – STOCK OPTIONS AND WARRANTS, continued

Stock Options, continued

The Company recorded $1,668,003 and $1,001,082 as stock compensation expense within selling, general and administrative for fiscal years ended September 30, 2021 and 2020, respectively. As of September 30, 2021, unrecorded compensation cost related to non-vested awards was $20,485 which is expected to be recognized over a weighted average period of approximately 2.6 years. The weighted average grant date fair value per share for options granted during the fiscal years ended September 30, 2021 and 2020 was $5.72 and $7.49, respectively.

NOTE J – INCOME TAXES

The income tax provision (benefit) for the fiscal years ended September 30, 2021 and 2020 consists of the following:

	2021	2020
Federal:		
Current	$ —	$ —
Deferred	(1,423,000)	(2,914,000)
	(1,423,000)	(2,914,000)
State and local:		
Current	—	—
Deferred	(26,000)	(591,000)
	(26,000)	(591,000)
Foreign:		
Current	—	—
Deferred	18,000	—
	—	—
Change in valuation allowance	1,431,000	3,505,000
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, 2021 and 2020 as follows:

	2021	2020
Statutory federal income tax rate	21.00 %	21.00 %
Statutory state and local income tax rate (1%, as of September 30, 2020 and 2019), net of federal benefit	1.52 %	2.26 %
Stock based compensation	(11.54)%	(1.60)%
Other permanent differences	(0.56)%	3.83 %
Change in deferred tax rate	(0.41)%	1.66 %
Change in valuation allowance	(10.01)%	(27.15)%
Effective tax rate	0.00 %	0.00 %

NOTE J– INCOME TAXES, continued

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,	
	2021	2020
Deferred tax assets (liabilities):		
Stock based compensation	$ 650,000	$ 2,120,000
Depreciation and amortization	247,000	232,000
Net operating loss carry forward	20,115,000	17,499,000
Impairment of intangibles	187,000	—
Tax credits	1,566,000	1,227,000
Other	99,000	355,000
Less: valuation allowance	(22,864,000)	(21,433,000)
Net deferred tax asset	$ —	$ —

As of September 30, 2021, the Company has approximately $84,283,000 of Federal and $35,836,000 of State net operating loss "NOL" carryforwards available which begin to expire after 2022. The Federal NOLs generated in tax years beginning after December 31, 2017 have no expiration period due to the Tax Cuts and Jobs Act that was enacted in 2017. 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 $94,000 and $1,103,000 and any unused amounts can be carried forward to subsequent years.

The Company has provided a full valuation allowance against all of the net deferred tax assets based on management's determination that it is more likely than not that the net deferred tax assets will not be realized in the future. The valuation allowance increased by $1,431,000.

The Company has Federal research and development credits of approximately $1,104,000 that will begin to expire after 2034. The Company also has state investment tax credits of $416,000 that will begin to expire after 2029.

NOTE K – COMMITMENTS AND CONTINGENCIES

Operating leases

The Company leases office space under an operating lease in Stony Brook, New York for its corporate headquarters. The lease is for a 30,000 square foot building. The term of the lease commenced on June 15, 2013 and expired on May 31, 2017, with the option to extend the lease for two additional three-year periods. The Company has exercised its option to extend the lease for one additional three-year period ending May 31, 2019. The base rent during the additional three-year period is $458,098 per annum. During November 2019, the Company extended this lease until January 15, 2020. In addition to the office space, the Company also has 2,200 square feet of laboratory space. On January 20, 2020, the Company entered into an agreement to amend both of these leases, extending the term for the corporate headquarters as well as the laboratory space until January 15, 2021, with a one-year renewal option. During October 2020, the Company exercised the one-year renewal option, extending the term for these leases until January 15, 2022. The Company also has a satellite testing facility in Ahmedabad, India, which occupies 1,108 square feet for a three-year term beginning November 1, 2017. During September 2021, the Company renewed this lease with a new expiration date of August 31, 2022. The base rent is approximately $6,500 per annum. The Company's total short-term lease obligation as of September 30, 2021 is $197,955.

Total rent expense for the fiscal years ended September 30, 2021 and 2020 were $565,597 and $585,189, respectively.

NOTE K – COMMITMENTS AND CONTINGENCIES, continued

Future minimum rental payments (excluding real estate tax and maintenance costs) as of September 30, 2021 are as follows:

For the fiscal year ending September 30,		
2022	$	197,955

Employment and Consulting Agreements

Employment agreements

The employment agreement with Dr. James Hayward, the Company's President and Chief Executive Officer ("CEO"), entered into in July 2016 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, 2020, 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.

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

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

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

Effective May 2, 2018, the Compensation Committee, increased the amount of the Revenue Bonus to $403,623; effective December 27, 2018, to $553,623; and effective December 5, 2019 to $803,623. The revenue targets underlying the Revenue Bonus have not yet been achieved. The Revenue Bonus has no expiration date and may be earned at any time during the CEO's employment if the Revenue Goals are achieved.

On March 2, 2021, the Company entered into an agreement with the CEO, pursuant to which the Company agreed to accelerate the payment of $556,840 of the Revenue Bonus to the CEO in recognition of his contributions to the Company. In exchange for the payment of the Revenue Bonus, the CEO agreed to waive his right to earn any remaining portions of the Revenue Bonus.

NOTE K – COMMITMENTS AND CONTINGENCIES, continued

The CEO voluntarily reduced his salary for the fiscal years ended September 30, 2020 and 2019. As of October 3, 2020, the Company has re-affirmed the employment agreement's annual salary of $400,000, and from that date the CEO's salary will be paid at such rate. On October 19, 2020, the Company awarded the CEO, a one-time discretionary bonus, to be paid in cash, of $250,000, in recognition of his contributions to the Company. For the fiscal year ended September 30, 2021, the CEO earned a $300,000 bonus as the Company's annual revenue was greater than $8 million. On November 1, 2021, this $300,000 bonus was paid to the CEO by granting stock options with a fair value of $300,000 calculated using the Black Scholes Option Pricing Model.

Subsequently, during October 2021, the Board of Directors amended the existing compensatory arrangement with the CEO to increase his salary to $450,000, effective November 1, 2021.

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

The Company attributes net revenues from external customers according to the geographic location of the customer. Net revenues by geographic location of customers are as follows:

	Year Ended September 30,	
	2021	2020
Americas	$ 8,520,336	$ 1,165,320
Europe	359,509	266,701
Asia and other	147,893	499,476
Total	$ 9,027,738	$ 1,931,497

NOTE M — RELATED PARTY TRANSACTIONS

On December 12, 2019, the Company entered into a consulting agreement, with Meadow Hill Place, LLC ("Meadow Hill"), a company wholly owned by Scott L. Anchin ("Mr. Anchin"), a board member, whereby Meadow Hill will provide certain advisory services to the Company. The initial term of the agreement ended on June 12, 2020. The agreement provided for compensation in the form of both cash and equity. Meadow Hill was eligible to receive $125,000 for the initial six month term. In addition, in satisfaction of the equity compensation portion of the agreement, (i) the Company granted an option to purchase 20,834 shares of its common stock to Mr. Anchin on December 12, 2019 at an exercise price equal to $4.26 per share, which vested on June 12, 2020, and (ii) the Company granted an option to purchase 20,786 shares of its common stock to Mr. Anchin on January 2, 2020 at an exercise price equal to $4.43 per share, of which 9,121 vested on July 2, 2020. The consulting agreement was completed on June 12, 2020 in full satisfaction of all obligations. As a result, the agreement was not extended and therefore expired on June 12, 2020. As a result, 11,665 of the options granted on January 2, 2020, which were related to the extension period, did not vest and were cancelled on June 12, 2020.

On each of December 9 and 10, 2020, Dillon Hill Capital, LLC and its affiliate, Dillon Hill Investment Company LLC., a greater than 5% shareholder, exercised 100,000 of their 2019 Warrants, for an aggregate exercise of 200,000 of their 2019 Warrants, resulting in total net proceeds to the Company of approximately $1.1 million. As a result of these exercises, the Company issued to the Investors an aggregate of 100,000 additional replacement warrants, which are substantially similar to the Replacement Warrants described above except that 50,000 of the newly-issued replacement warrants have an exercise price of $6.57 and 50,000 of such replacement warrants have an exercise price of $6.46.

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Applied DNA Sciences, Inc. on Form S-1 (File Nos. 333-233830 and 333-234664), Form S-3 (File Nos. 333-252280, 333-202432, 333-220481, 333-218158, 333-214920, and 333-238557) and S-8 (File Nos. 333-182350, 333-205123, 333-231944 and 333-249365) of our report dated December 9, 2021 which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Applied DNA Sciences, Inc. as of September 30, 2021 and 2020 and for each of the two years in the period ended September 30, 2021, which report is included in this Annual Report on Form 10-K of Applied DNA Sciences, Inc. for the year ended September 30, 2021.

/s/ Marcum LLP

Marcum LLP
Melville, NY
December 9, 2021

Exhibit 31.1

CERTIFICATION

I, James A. Hayward, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: December 9, 2021

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

Exhibit 31.2

CERTIFICATION

I, Beth Jantzen, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: December 9, 2021

/s/ Beth Jantzen

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Applied DNA Sciences, Inc. (the "Company") for the fiscal year ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James A. Hayward, President, Chief Executive Officer and Chairman of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: December 9, 2021

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Applied DNA Sciences, Inc. (the "Company") for the fiscal year ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Beth Jantzen, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Date: December 9, 2021

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