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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, 2022

□ **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, 2022), was approximately $17.2 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, 2022 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 9, 2022, the Registrant had outstanding 12,908,520 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 2023 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, 2022. 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. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements.

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", "designed 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. 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;
- our business strategy and the timing of our expansion plans;
- demand for Therapeutic DNA Production Services;
- demand for DNA Tagging Services
- demand for MDx Testing Services
- our expectations concerning existing or potential development and license agreements for third-party collaborations or joint ventures;
- regulatory approval and compliance for our Therapeutic DNA Production Services;

- the effect of governmental regulations generally;
- our expectations of when regulatory submissions may be filed or when regulatory approvals may be received;
- our expectations concerning product candidates for our technologies; 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 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;
- 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 that have received regulatory clearance or approval;
- economic and industry conditions generally and in our specific markets;
- we may conduct a reverse stock split of our common stock to meet the requirements of Nasdaq, which may adversely impact the market price and liquidity of our common stock;
- 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.

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

Any of the assumptions underlying the forward-looking statements contained in this Annual Report on Form 10-K could prove inaccurate and, therefore, we cannot assure you that any of the results or events 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®, SigNify®, Beacon®, CertainT®, LinearDNA™, Linea™ COVID-19 Diagnostic Assay Kit 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

Applied DNA Sciences is a biotechnology company developing and commercializing technologies to produce and detect deoxyribonucleic acid ("DNA"). Using the polymerase chain reaction ("PCR") to enable both the production and detection of DNA, we operate in three primary business segments: (i) the manufacture of synthetic DNA for use in nucleic acid-based therapeutics ("Therapeutic DNA Production Services"); (ii) the detection of DNA in molecular diagnostics ("MDx") testing services ("MDx Testing Services"); and (iii) the manufacture and detection of DNA for industrial supply chain security services ("DNA Tagging and Security Products and Services").

Our growth strategy is to primarily focus our resources on the further development, commercialization, and customer adoption of our Therapeutic DNA Production Services, including the expansion of our contract development and manufacturing operation ("CDMO") for the manufacture of DNA for use in nucleic acid-based therapies and the development of our own product candidates in veterinary health.

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. On December 17, 2008, we reincorporated from the State of Nevada to the State of Delaware.

Our corporate headquarters are located at the Long Island High Technology Incubator at Stony Brook University in Stony Brook, New York, where we have established laboratories for the manufacture and detection of DNA to support our various business units. In addition, this location also houses our New York State Department of Health ("NYSDOH") Clinical Laboratory Evaluation Program ("CLEP")-permitted, Clinical Laboratory Improvement Amendments ("CLIA")-certified clinical laboratory where we perform MDx testing. The mailing address of our corporate headquarters is 50 Health Sciences Drive, Stony Brook, New York 11790, and our telephone number is (631) 240-8800.

Industry Background and Markets

Therapeutic DNA Production Services

Through our LinearRx, Inc. ("LRx") subsidiary we are developing and commercializing the LinearDNA ("linearDNA") platform. The linearDNA platform enables the rapid, efficient, and large-scale cell-free manufacture of high-fidelity synthetic DNA sequences for use in nucleic acid-based therapeutics. The linearDNA platform enzymatically produces a linear form of DNA we call 'linearDNA' that is an alternative to plasmid-based DNA manufacturing technologies that have supplied the DNA used in biotherapeutics for the past 40 years.

The DNA manufactured via our linearDNA platform may be used by a customer directly as a drug or biological product or it may be incorporated by a customer into a drug or biological product. To date, none of our linearDNA has been incorporated into a drug or biological product approved by any regulatory body. We do not know if our linearDNA will be incorporated into a drug or biological product that will be approved by any regulatory body but believe it has this potential as described herein.

We believe our enzymatic linearDNA platform has numerous advantages over existing cell-based plasmid DNA manufacturing platforms. Plasmid-based DNA manufacturing is based on the complex, costly and time-consuming biological process of amplifying DNA in living cells. Once amplified, the DNA must be separated from the living cells and other process contaminants via multiple rounds of purification, adding further complexity and costs. Unlike plasmid-based DNA manufacturing, the linearDNA platform does not require living cells and instead amplifies DNA via the enzymatic process of PCR. The linearDNA platform is simple, with only four ingredient inputs, and can rapidly produce very large quantities of DNA without the need for complex purification steps.

We believe the key advantages of the linearDNA platform include:

- Speed – Production of linearDNA can be measured in terms of hours, not days and weeks as is the case with plasmid-based DNA manufacturing platforms.
- Scalability – linearDNA production takes place on efficient bench-top instruments, allowing for rapid scalability in a minimal footprint.
- Purity – DNA produced via PCR is pure, resulting in only large quantities of only the target DNA sequence. Unwanted DNA sequences such as plasmid backbone and antibiotic resistance genes, inherent to plasmid DNA, are not present in linearDNA.
- Simplicity – The production of linearDNA is streamlined relative to plasmid-based DNA production. linearDNA requires only four primary ingredients, does not require living cells or complex fermentation systems and does not require multiple rounds of purification.
- Flexibility – DNA produced via the linearDNA platform can be easily chemically modified to suit specific customer applications. In addition, the linearDNA platform can produce a wide range of complex DNA sequences that are difficult to produce via plasmid-based DNA production platforms. These complex sequences include inverted terminal repeats (ITRs) and polyadenylation sequences (poly (A) tail) important to gene therapy and mRNA therapies, respectively.

Preclinical studies have shown that linearDNA is substitutable for plasmid DNA in numerous nucleic acid-based therapies, including:

- therapeutic and prophylactic DNA vaccines;
- DNA templates for *in vitro* transcription to produce ribonucleic acid ("RNA"), including messenger RNA ("mRNA"); and
- adoptive cell therapy manufacturing.

Further, we believe that linearDNA is also substitutable for plasmid DNA in the following nucleic acid-based therapies:

- viral vector manufacturing for *in vivo* and *ex vivo* gene editing;
- Clustered regularly interspaced short palindromic repeats ("CRISPR")-mediated homology-directed repair ("HDR"); and
- non-viral gene therapy.

As of the third quarter of calendar 2022, there were 3,694 gene, cell and RNA therapies in development from preclinical through pre-registration stages, almost all of which use DNA in their manufacturing process. (Source: ASGCT Gene, Cell & RNA Therapy Landscape: Q3 2022 Quarterly Report). Due to what we believe are the linearDNA platform's numerous advantages over legacy plasmid-based DNA manufacturing platforms, we believe this large number of therapies under development represents a substantial market opportunity for linearDNA to supplant plasmid DNA in the manufacture of nucleic acid-based therapies.

Our linearDNA is currently manufactured pursuant to Good Laboratory Practices ("GLP") that we believe are sufficient for pre-clinical discovery and development of nucleic acid-based therapies. In addition, for indirect clinical use of linearDNA (i.e., where linearDNA is a starting material but is not incorporated into the final therapeutic product, as is the case with the production of mRNA or certain viral vectors), we believe that high-quality grade GLP linearDNA is sufficient for clinical and commercial stage customers of our Therapeutic DNA Production Services. For the direct clinical use of our linearDNA (i.e., nucleic acid-based therapies where our linearDNA is incorporated into the final therapeutic product, as in the production of DNA vaccines, adoptive cell therapies and certain gene therapies) we believe clinical and commercial-stage customers of our Therapeutic DNA Production Services will generally require our manufacturing facilities to meet current Good Manufacturing Practices ("cGMP"). We currently do not have any manufacturing facilities that meet cGMP. We will need to develop and maintain manufacturing facilities that meet cGMP to support customers that wish to use our linearDNA for direct clinical use and for indirect clinical use customers who request linearDNA manufactured under cGMP. In the longer term, we believe that the development and maintenance of a cGMP manufacturing facility for linearDNA will benefit the entirety of our Therapeutic DNA Production Services business, in both direct and indirect clinical applications. We are in the design phase for a cGMP manufacturing facility, with expected cGMP manufacturing to begin in the second half of calendar 2023.

Our business strategy for the linearDNA platform is: (i) to utilize our current GLP LinearDNA production capacity to secure CDMO contracts to supply linearDNA to pre-clinical therapy developers, as well as clinical and commercial therapy developers and manufacturers that are pursuing therapeutics that require the indirect clinical use of linearDNA; and (ii) upon our development of cGMP linearDNA production facilities, to secure CDMO contracts with clinical stage therapy developers and commercial manufactures to supply linearDNA for direct clinical use.

In addition, we plan to leverage our Therapeutic DNA Production Services and deep knowledge of PCR to develop and monetize, ourselves or with strategic partners, one or more linearDNA-based therapeutic or prophylactic vaccines for the veterinary health market. Currently, we have in-licensed a therapeutic DNA vaccine candidate against canine lymphoma, which accounts for up to 24% of all cancers in canines. Our lymphoma vaccine candidate was licensed from Takis S.R.L and EvviVax, S.R.L. for exclusive use by the Company in association with our linearDNA platform, and is subject to certain commercialization milestones. We currently seek to commercialize our canine lymphoma vaccine in conjunction with lipid nanoparticle (LNP) encapsulation to facilitate intramuscular ("IM") administration. We have recently demonstrated *in vitro* and *in vivo* (mice studies) expression of generic reporter proteins via linearDNA encapsulated by LNPs. For the *in vivo* study, successful expression of the LNP-encapsulated linearDNA was administered and achieved via IM injection. We believe the linearDNA platform provides a substantial advantage to the development and monetization of a therapeutic DNA vaccine against canine lymphoma.

MDx Testing Services

Through Applied DNA Clinical Labs, LLC ("ADCL"), our clinical laboratory subsidiary, we leverage our expertise in DNA detection via PCR to provide and develop clinical MDx testing services. ADCL is a NYSDOH and CLEP permitted, CLIA-certified laboratory which is currently permitted for virology. In providing MDx testing services, ADCL employs its own or third-party molecular diagnostic tests.

Under our MDx testing services, ADCL currently provides COVID-19 testing for large populations marketed under our safeCircle™ trademark. Leveraging ADCL's customizable high-throughput robotic pooled testing workflow and the CLEARED4 digital health platform owned and operated by CLEARED4 Inc. (the "CLEARED4 Platform"), our safeCircle testing service is an adaptable turnkey large population COVID-19 testing solution that provides for all aspects of COVID-19 testing, including test scheduling, sample collection and automated results reporting. Our safeCircle testing service utilizes high-sensitivity robotically-pooled real-time PCR ("RT-PCR") testing to help mitigate virus spread by quickly identifying COVID-19 infections within a community, school, or workplace. Our safeCircle COVID-19 testing is performed using either the Company's internally developed Linea 2.0 RT-PCR Assay, a NYSDOH conditionally approved laboratory developed test ("LDT") or third-party emergency use authorization ("EUA")-authorized RT-PCR COVID-19 assays. Our safeCircle testing service also incorporates the CLEARED4 Platform to enable large-scale digital test scheduling, in-field sample collection and registration, and results reporting. By leveraging the combination of our robotically-pooled workflows and the CLEARED4 Platform, our safeCircle testing services typically return testing results within 24 to 48 hours. We currently provide safeCircle testing services to higher education institutions, private clients, and businesses located in New York State.

ADCL has also developed PCR-based MDx testing services for the Monkeypox virus, which are currently approved by NYSDOH. These services are designed to run on the same high-throughput platform utilized by our COVID-19 testing services and provides ADCL's with a substantial testing throughput. Demand for these types of services may vary greatly depending upon public health requirements, e.g., Monkeypox testing is now a lower public health priority, and we intend to pursue such opportunities on an opportunistic basis.

In addition to our infectious disease testing services, we are currently validating pharmacogenetics ("PGx") testing services. Our PGx testing services will initially utilize a 120-target PGx panel test to evaluate the unique genotype of a specific patient to help guide individual drug therapy decisions. Our PGx testing services are designed to interrogate DNA targets on over 35 genes and provide genotyping information relevant to certain cardiac, mental health and pain management drug therapies. In addition, PGx testing services have been shown to significantly reduce healthcare costs both for individual patients as well as payors. We believe the economics of complex MDx testing services such as PGx are more favorable to the Company as compared to high-volume, low-complexity MDx tests such as COVID-19 testing. Our PGx testing services will require NYSDOH approval prior to initiating our patient testing services. If approved, we plan to commercialize our PGx testing services by offering PGx testing services to other clinical laboratories, large healthcare systems and self-insured entities. We have completed analytical validation of our PGx testing services and are currently undertaking clinical validation studies that are expected to be completed by the end of calendar year 2022.

Going forward, our business strategy for ADCL is to leverage our deep knowledge of PCR to develop and commercialize high complexity, high value and differentiated MDx testing services that will be offered to other clinical laboratories and healthcare facilities as clinical reference laboratory testing services. We believe operating as a clinical reference laboratory has several advantages when compared to operating as a typical clinical non-reference laboratory, including:

- the ability to leverage our deep expertise in PCR to develop and perform high-value esoteric MDx testing services not performed by conventional clinical non-reference laboratories;
- reduced sample acquisition costs;
- reduced marketing costs; and
- a national customer base that may lead to a larger total addressable market.

The clinical reference laboratory services market is forecasted to have incremental growth of $26.0B between 2020 and 2025 with a 6.71% compound annual growth rate ("CAGR"). We believe that the rapidly increasing number of specialized MDx tests for early disease detection, disease prognosis, disease risk, companion diagnostics and personalized medicine will drive an increase in the demand for highly specialized MDx clinical reference laboratory services.

DNA Tagging and Security Products and Services

By leveraging our expertise in both the manufacture and detection of DNA via PCR, our DNA Tagging and Security Products and Services allow our customers to use non-biologic DNA 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 DNA tag. We believe our DNA tags are not economically feasible nor practical to replicate, and that our disruptive tracking platform offers broad commercial relevance across many industry verticals. The Company's core DNA Tagging and Security Products and Services, which are marketed collectively as a platform under the trademark CertainT®, include:

- SigNature® Molecular Tags, which are short non-biologic DNA taggants produced by the Company's linearDNA platform, provide a methodology to authenticate goods within large and complex supply chains for materials such as cotton, leather, pharmaceuticals, nutraceuticals and other products.
- SigNify® IF portable DNA readers and SigNify consumable reagent test kits provide definitive real-time authentication of the Company's DNA tags in the field, providing a front-line solution for supply chain integrity backed with forensic-level molecular tag authentication. The Company's software platform enables customers to track materials throughout a supply chain or product life.

- fiberTyping®, which uses PCR-based DNA detection to determine a cotton cultivar, and other product genotyping services that utilize PCR-based DNA detection to detect a product's naturally occurring DNA sequences for the purposes of product provenance authentication and supply chain security.

Our DNA Tagging and Security Products and Services are fully developed, highly scalable, and currently used in several commercial applications. To date, our largest commercial application for our DNA Tagging and Security Products and Services is in the tracking and provenance authentication of cotton. Cotton home textile products utilizing our DNA Tagging and Security Products and Services are available in national retail chains including Costco® and Bed Bath & Beyond®.

We believe that the Uyghur Forced Labor Prevention Act ("UFLPA"), signed into law on December 23, 2021, may be helpful to increase demand for our DNA Tagging and Security Products and Services. The UFLPA establishes a rebuttable presumption that any goods mined, produced, or manufactured wholly or in part in the Xinjiang Uyghur Autonomous Region ("XUAR") of the People's Republic of China are not entitled to entry to the United States. The presumption applies unless the importer of record has complied with specified conditions and, by clear and convincing evidence, shown that the goods were not produced using forced labor. On June 17, 2022, an implementation strategy for the UFLPA was published that listed DNA tagging as evidence that importers may present to potentially prove that a good did not originate in XUAR or did not benefit from forced labor. Approximately 20% of the world's cotton garments contain cotton that originated in the XUAR.

Our business plan is to leverage growing consumer and governmental awareness for product traceability and the newly enacted UFLPA to expand our existing partnerships and seek new partnerships for our DNA Tagging and Security Products and Services with a focus on cotton and synthetic fibers. We do not know when and whether our DNA Tagging and Security Products and Services will have increased demand based on the UFLPA or any other track-and-trace-type requirements for any products.

Sales and Marketing

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

Research and Development

For all of our business segments, we believe that our continued development of new and enhanced technologies is essential to our future success.

In our Therapeutic DNA Production Services segment, our research and development efforts are focused on the development and optimization of our linearDNA platform and the development of linearDNA-based vaccines for the veterinary health market. linearDNA platform development and optimization is focused on increased DNA yields, purification workflows and enzyme system optimization. For our linearDNA-based vaccines, our research and development efforts are focused on the development of a cost-effective LNP formulation that can achieve therapeutic antigen expression via linearDNA to facilitate IM administration of linearDNA vaccines.

In our MDx Testing Services segment, our research and development efforts are primarily focused on the development and validation of our PGx testing services. Our PGx testing services will utilize a 120-target PGx panel test to evaluate the unique genotype of a specific patient to help guide individual drug therapy decisions. Our PGx testing services are designed to interrogate DNA targets on over 35 genes and provide genotyping information relevant to certain cardiac, mental health and pain management drug therapies.

Our research and development efforts for our DNA Tagging and Security Products and Services segment are primarily focused on incorporating DNA molecular tags into carriers such as 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.

We incurred approximately $3.9 million and $4.2 million on research and development activities for the fiscal years ended September 30, 2022 and 2021, 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. In addition, we utilize DNA polymerase ("DNAP") in all of our PCR reactions to amplify DNA. DNAP is available from multiple sources. For our Therapeutic DNA Production Services, our services may be optimized for a specific DNAP. Unforeseen discontinuation or unavailability of a certain DNAP produced by a single provider could cause production delays as we modify our product specifications and workflows to accommodate a replacement DNAP.

Manufacturing

For our Therapeutic DNA Production Services and DNA Tagging and Security Products and Services segments, we have the capability to manufacture large quantities of DNA via our linearDNA platform at our facility in Stony Brook. For our MDx Testing Services segment, we also manufacture COVID-19 diagnostic assay kits in our Stony Brook facility. We also have in-house capabilities to complete all authentications for our DNA Tagging and Security Products and Services segment 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 and services, among others:

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 of 2021 (the "Contract"). The initial Contract term was 12 months, had a maximum value not to exceed $35.0 million, and contained no minimum weekly testing commitment. During August 2022 the Contract was extended for an additional twelve-months under the same terms as the original Contract. 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.

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 August 2021, we entered into an exclusive licensing agreement with Takis S.R.L. and Evvivax S.R.L. relating to DNA vaccines for SARS-CoV-2 and canine lymphoma. The license agreement grants the Company exclusive rights

to the DNA vaccine constructs in association with its linearDNA platform, and is subject to certain commercialization milestones to maintain exclusive rights.

Cornell University College of Veterinary Medicine. During September 2021, we entered into a Sponsored Research Agreement with Cornell University College of Veterinary Medicine ("Cornell University") relating to the development of certain linearDNA vaccines against infectious disease. Under this agreement, the Company and Cornell University conducted a SARS-CoV-2 challenge trail in ferrets that showed that a linearDNA vaccine using concomitant electroporation was protective against SARS-CoV-2 infection in ferrets. In addition, during March 2022 the Company and Cornell University entered into an additional Sponsored Research Agreement under which the parties seek to develop several linearDNA/LNP vaccine candidates against veterinary infectious diseases.

Customer Concentration

Our revenues earned from sale of products and services for the fiscal year ended September 30, 2022 includes 58% from one customer within our MDx Testing Services segment. At September 30, 2022, two customers accounted for 89% of our accounts receivable. 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 within our MDx Testing Services segment. At September 30, 2021, two customers accounted for 67% 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., Juno Therapeutics, Inc., Promega Corporation, OriGene Technologies, Inc., Blue Heron Biotech, LLC, Gene Art, GenScript Biotech Corporation, Merck & Co., Inc. and others.

Some of our competitors that operate in the veterinary biologics space include Zoetis, Inc., Merck Animal Health, Boehringer Ingelheim Animal Health USA, Inc., Elanco Animal Health Incorporated, Dechra Pharmaceuticals plc, Invetx, Inc. and Ceva Animal Health LLC.

Some of our competitors that operation in the molecular and genetic diagnostic space include 23andMe, Inc., Laboratory Corporation of America (LabCorp); Quest Diagnostics Inc., Myriad Genetics, Inc., ARUP Laboratories, Sonic Healthcare USA, Everly Well, Inc and, Fulgent Genetics, Inc.

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 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.

Intellectual Property

The proprietary nature of and protection for our various technologies and know-how are important to our business. Our success depends in part on our ability to protect the proprietary nature of our technologies and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek and maintain patent protection in the United States and internationally for our various technologies associated with our three primary business markets. We endeavor to patent or in-license technology, inventions and improvements that we consider important to the development of our business. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position.

Because the development of our Therapeutic DNA Production Services and MDx Testing Services businesses are at an early stage, our intellectual property portfolio with respect to certain technologies associated with these businesses is also at an early stage. As further described below, we have filed or intend to file patent applications on certain technologies associated with these business markets, and as we continue the development of our technologies, we intend to identify additional means of obtaining patent protection that would potentially enhance commercial success.

We cannot be certain that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology. Any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, see "*Risk Factors — Risks Related to Our Intellectual Property*."

As of December 9, 2022, our patent portfolio included the following issued and pending patent applications applicable to each of our three primary business markets:

- Therapeutic DNA Production Services
  - 5 issued patents and 10 pending patent applications in the United States
  - 11 issued foreign patents and 5 pending foreign patent applications
- MDx Testing Services
  - 5 issued patents and 1 pending patent applications in the United States
  - 4 issued foreign patents and 1 pending foreign patent applications
- DNA Tagging and Security Products and Services
  - 28 issued patents and 5 pending patent applications in the United States
  - 47 issued foreign patents and 14 pending foreign patent applications

In addition to patent protection, we also rely on trademarks, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. In our Therapeutic DNA Production Services, we currently rely heavily on trade secret protection. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see "*Risk Factors — Risks Related to Our Intellectual Property*."

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third party patent would require us to alter our development or commercial strategies, or our manufacturing processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products or services may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office, or USPTO, to determine priority of invention. For more information, see "*Risk Factors — Risks Related to Our Intellectual Property*."

Government Approvals of Commercial Non-Biologic Products

We do not require any governmental approvals of our currently commercialized DNA Tagging and Security Product and Services.

Government Regulations for COVID-19 Testing

Surveillance testing is generally not regulated by the FDA and Centers for Medicare & Medicaid Services ("CMS") has stated that CLIA certification is not required to conduct surveillance testing to report non patient-specific results. ADCL is offering its safeCircle™ surveillance testing in compliance with current Centers for Disease Control and Prevention ("CDC"), FDA, CMS and New York State Department of Health recommendations.

In addition, clinical diagnostic testing and the review and approval of LDTs in New York State falls under the jurisdiction of NYSDOH. ADCL is offering all clinical diagnostic testing and LDTs in compliance with NYSDOH regulations. For more information regarding the risks related to our COVID-19 testing services and our LDTs, see "*Risks Related to Regulatory Approval of Our Customer and Collaborator's Pharmaceutical and Biotherapeutic Product Candidates and Other Legal Compliance Matters*"

Government Approvals of Drug and Biologic Products

The DNA manufactured via our linearDNA platform may be used by a customer directly as a drug or biological product or it may be incorporated by a customer into a drug or biological product. We do not plan to seek approval of a drug or licensure of a biological product based on our linearDNA platform, except with respect to the veterinary health market, but the demand for our linearDNA is in part dependent on our customer's ability to seek and obtain approval of a drug or biological product using our technology.

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 ("BLA"), 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

The DNA manufactured via our linearDNA platform may be used by a customer directly as a drug or biological product or it may be incorporated by a customer into a drug or biological product. We do not plan to seek approval of a drug or licensure of a biological product based on our linearDNA platform, except with respect to the veterinary health market, but the demand for our linearDNA is in part dependent on our customer's ability to seek and obtain approval of a drug or biological product using our technology.

In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHS Act, and their 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.

In addition, veterinary DNA vaccines and therapeutics in the United States are subject to review and regulatory approval by the United States Department of Agriculture ("USDA"). The USDA's Center for Veterinary Biologics is responsible for the regulation of animal health vaccines, including certain immunotherapeutics. All manufacturers of animal health biologicals must show their products to be pure, safe, effective and produced by a consistent method of manufacture as defined under the Virus Serum Toxin Act. Post-approval monitoring of products is required. Reports of product quality defects, adverse events or unexpected results are submitted in accordance with the agency requirements.

Preclinical Studies

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. In an Investigational New Drug Application ("IND") a 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.

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 current Good Clinical Practices ("cGCP") requirements. 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 independent Institutional Review Board ("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.

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.

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 comply with cGMP requirements and are 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, or CRL. A CRL 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.

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.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA.

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 Risk Evaluation and Mitigation Systems, or REMS, program.

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.

Veterinary Biologics

The regulatory body in the U.S. for veterinary biologicals is the USDA. The Center for Veterinary Biologics within the Animal and Plant Health Inspection Service in the USDA is responsible for the regulation of animal health biologicals, which includes but is not limited to vaccines, including DNA vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live microorganisms, and diagnostic components of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens or antibodies. All manufacturers of animal health biologicals must show their products to be pure, safe, potent, effective and produced by a consistent method of manufacture as defined under the Virus Serum Toxin Act. Post-approval monitoring of products is required. Reports of product quality defects, adverse events or unexpected results must be maintained and submitted in accordance with USDA requirements.

Laboratory Developed Tests

The FDA is currently exercising enforcement discretion over the regulation of most Laboratory Developed Tests ("LDTs"), such as our Linea 2.0 SARS-CoV-2 Assay and our Monkeypox Virus 1.0 Assay. If the FDA were to begin enforcement, our products 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, *de novo* authorization, or approval of a Premarket Approval Application ("PMA") 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. The *de novo* process provides a marketing pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device. 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, authorization 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.

Most recently in Spring 2022, a version of a bill introduced in 2020 and 2021, the "Verifying Accurate Leading-edge IVCT Development Act of 2020," or VALID Act, was added to the reauthorization bill for the Medical Device User Fee Act ("MDUFA") V but then was removed to permit a more rapid passage of MDUFA V to prevent worker layoffs. The bill proposed a risk-based approach that would have subjected many LDTs to FDA regulation by creating a new in vitro clinical test, or IVCT, category of regulated products. As proposed, the bill would have grandfathered many existing LDTs from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e.g., registration and listing, adverse event reporting). 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 have been established that would have allowed a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs met quality system requirements. If pre-certified, low-risk IVCTs, developed by the laboratory would not have been subject to pre-market review. The new regulatory framework would have included quality control and post-market reporting requirements. The FDA would have had the authority to withdraw approvals for IVCTs for various reasons, including (for example) if there were a reasonable likelihood that the test would cause death or serious adverse health consequences. However, with bill language being removed from MDUFA V, we cannot predict if this (or any other bill) will be enacted in its current (or any other) form and cannot quantify the effect of such proposals on our business.

Clinical Laboratory Improvement Amendments

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

Emergency Use Authorizations

The FDA has the authority to grant an Emergency Use Authorization ("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 a pandemic-health-type situation, such as the current 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 the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act 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 ("ACA"), which require manufacturers of certain drugs and biologics to track and report to 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 CMS, 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 ("FTC"), the Occupational Safety & Health Administration, the Environmental Protection Agency, the United States Department of Agriculture, 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.

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, 2022, we had a total of 69 employees (61 fulltime and 8 part-time), consisting of 4 in executive management, 12 in research and development, 2 in forensics, 3 in quality assurance and compliance, 3 in quality control, 3 in finance, accounting and human resources, 12 in operations/production, 7 in sales and marketing, 1 in shared services, 5 in information services, 2 in product development, 10 in clinical laboratory operations and 5 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, 2022, 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:

- We have produced limited revenue. This makes it difficult to evaluate our future prospects and increase the risk that we will not be successful.
- We may require additional financing which may in turn require the issuance of additional shares of common stock, preferred stock or other debt or equity securities (including convertible securities) and which would dilute the ownership held by or stockholders.
- We have identified a material weakness in our internal control over financial reporting.
- Our operating results could be adversely affected by a reduction in business with our significant customers.
- We may encounter difficulties in managing our growth and these difficulties could impair our profitability.
- Our new emphasis on Therapeutic DNA Production Services may reduce our ability to maintain and expand our existing MDX Testing Services and DNA Tagging and Security Products and Services businesses.
- If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop, commercialize and have our customers adopt our Therapeutic DNA Production Services.

- If we are unable to expand our DNA manufacturing capacity, we could lose revenue and our business could suffer.
- Rapidly changing technology and extensive competition in synthetic biology could make the services or products we are developing obsolete or non-competitive unless we continue to develop new and improved services or products and pursue new market opportunities.
- 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.
- We will need to develop and maintain manufacturing facilities that meet cGMP.
- Pharmaceutical and biologic-related revenue will be dependent on our collaborators' and customers' demand for our manufacturing services.
- Our safeCircle™ COVID-19 testing service could become obsolete or its utility could be significantly diminished.
- We may be unable to consistently manufacture or source our products to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels.
- The markets for drug and biologic candidates and synthetic 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.
- We compete with life science, pharmaceutical and biotechnology companies, some of whom are our customers, who are substantially larger than we are and potentially capable of developing new approaches that could make our products and technology obsolete or develop their own internal capabilities that compete with our products.
- Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand.
- Pharmaceutical and biologic-related revenue is generally dependent on regulatory approval, oversight and compliance.
- 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.
- 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.
- 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.

- If we fail to comply with the continued listing standards of Nasdaq, our securities could be delisted, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.

- 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:

We have produced only limited 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 opportunities to work with customers to develop pharmaceuticals and biologics will require substantial additional funding. Our customers may not be successful in their efforts to create a pipeline of product candidates, to develop commercially successful products, or to develop commercially successful biologic production. If our customers fail to successfully identify, finance and develop product candidates and/or fail to develop commercially successful biologic production incorporating our linearDNA platform, commercial opportunities in pharmaceuticals and biologics may be limited.

We do not plan to market, except with respect to products in the veterinary health market, nor do we have any pharmaceutical or biologic products approved for commercial sale and have not generated any revenue from pharmaceutical or biologic product sales, or manufacturing. Identifying, developing, obtaining regulatory approval and commercializing pharmaceutical and biologic product candidates and biologic production will require substantial additional funding beyond our current available resources, will require substantial funding on the part of our customers, and is prone to the risks of failure inherent in drug or biologic development. Developing product candidates and biologic production is expensive, and we expect to spend substantial amounts as we work with our customers to fund our early-stage research projects, engage in preclinical development of early-stage programs and, in particular, work with our customers to 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 our customers will be able to successfully advance any product candidates through the development process or, if approved, successfully commercialize any product candidates.

Even if our customers receive regulatory approval to market product candidates incorporating our linearDNA platform technology, or if we receive regulatory approval to market any veterinary health products, 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 our customers are able to generate revenue from the sale of any approved pharmaceutical and biologic products or we are able to generate revenue from the sale of any veterinary health 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 linearDNA products and veterinary health 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.

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

We may need to raise funds through either debt or the sale of our shares of our common stock in order to achieve our business goals. Any additional shares issued would further dilute the percentage ownership held by the stockholders. Furthermore, if we raise funds in equity transactions through the issuance of convertible securities which are convertible at the time of conversion at a discount to the prevailing market price, substantial dilution is likely to occur resulting in a material decline in the price of your shares. Our public offerings completed in November 2014, April 2015, December 2018, November 2019 and August 2022, our registered direct offerings during January 2021 and February 2022, our registered direct public offering and concurrent private placement during November 2015, our private placements completed in November 2016, June 2017, and August 2019, and our registered direct offering in December 2017 resulted in dilution to investors and future offerings of securities could result in further dilution to investors.

If we are unable to maintain and implement effective internal controls over financial reporting and disclosure, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

As a public company, we are required to maintain internal control over financial reporting and our disclosure controls and to report any material weaknesses in such internal control and our disclosure controls. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements and disclosure may be materially misstated. We have implemented various systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act. We will need to maintain and enhance these processes and controls as we grow, and we will require additional management and staff resources to do so. Additionally, even if we conclude our internal controls or disclosure controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls or disclosure controls, in which case our management will be unable to conclude that our internal control over financial reporting or disclosure controls are effective. Please see the following risk factor "We have identified a material weakness in our internal control over financial reporting." Even if our management concludes that our internal control over financial reporting and our disclosure controls are effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. In addition, if we lose our status as a "smaller reporting company," we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting.

If we are unable to conclude that our internal control over financial reporting or our disclosure controls are effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results.

We expect that compliance with these requirements will continue to increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will continue to need to divert attention from operational and other business matters to devote substantial time to these public company requirements. We also expect that it will continue to be expensive for us to maintain director and officer liability insurance.

If we fail to maintain an effective system of internal control over financial reporting or our disclosure, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting. This, in turn, could have an adverse impact on trading prices for our common stock. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting or disclosure that are deemed to be material weaknesses, the market price of

our stock could decline, our ability to access the capital markets could be reduced and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

We have identified a material weakness in our internal control over financial reporting.

In connection with the audit of our consolidated financial statements for the fiscal years ended September 30, 2022 and 2021, we identified a material weakness in our internal control over financial reporting (see Item 9A of this report for further information). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness in our case related to the controls around accounting for complex financial instruments, as it relates to the accounting for our outstanding warrants and the related tax impact. If we are unable to remedy this or a similar material weakness that may arise in the future, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price. Furthermore, future 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.

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

Our revenue earned from the sale of product and services for the fiscal year ended September 30, 2022 included an aggregate of 58% of our total revenue from one customer within our MDx Testing Services segment. At September 30, 2022, two customers accounted for an aggregate of 89% of our total accounts receivable. 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 within our MDx Testing Services segment. At September 30, 2021, two customers accounted for an aggregate of 67% 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, 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.

The ongoing military conflict between Russia and Ukraine has caused geopolitical instability, economic uncertainty, financial markets volatility and capital markets disruption. Our business, financial condition and results of operations may be materially adversely affected by any negative impact on the capital markets resulting from the conflict in Ukraine or any other geopolitical tensions.

In late February 2022, Russia invaded Ukraine, significantly amplifying already existing geopolitical tensions among Russia and other countries in the region and in the west, including the United States. Russia's invasion, the responses of countries and political bodies to Russia's actions, the larger overarching tensions, and Ukraine's military response and the potential for wider conflict have resulted in inflation, financial market volatility and capital markets disruption, potentially increasing in magnitude, and could have severe adverse effects on regional and global economic markets and international relations. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial.

Third parties may use our products in ways that could damage our reputation.

After our customers have received our products, we do not have any control over their use and our customers may use them in ways that are harmful to our reputation as a supplier of synthetic DNA products. In addition, while we plan to establish a biosecurity program

designed to ensure that third parties do not obtain our products for malevolent purposes, we cannot guarantee that these preventative measures, once instituted, will eliminate or reduce the risk of the domestic and global opportunities for the misuse of our products. Accordingly, in the event of such misuse, our reputation, future revenue and operating results may suffer.

Our business could be adversely impacted by inflation.

Increases in inflation may have an adverse effect on our business. Current and future inflationary effects may be driven by, among other things, supply chain disruptions and governmental stimulus or fiscal policies as well as the ongoing military conflict between Russia and Ukraine. Continuing increases in inflation could impact the overall demand for our products, our costs for labor, material and services, and the margins we are able to realize on our products, all of which could have an adverse impact on our business, financial position, results of operations and cash flows.

We may encounter difficulties in managing our growth, and these difficulties could impair our profitability.

Currently, we are working simultaneously on multiple projects, expanding our DNA manufacturing capacity as well as targeting several market sectors, including activities in the diagnostics, veterinary and human therapeutics, and the product security sectors. These diversified operations and activities place significant demands on our limited resources and require us to substantially expand the capabilities of our technical, administrative, and operational resources.

If we are unable to manage this growth effectively, our shipments to our customers could be impacted, our time and resources could be diverted from other products and offerings and our business and operating results could suffer. Our ability to manage our operations and costs, including research and development, costs of components, manufacturing, sales and marketing, requires us to continue to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. Failure to attract and retain sufficient numbers of talented employees will further strain our human resources and could impede our growth.

Our new emphasis on Therapeutic DNA Production Services may reduce our ability to maintain and expand our existing MDx Testing Services and DNA Tagging and Security Products and Services businesses.

Our new emphasis on Therapeutic DNA Production Services may divert funding and our limited managerial and other resources from our existing MDX Testing Services and DNA Tagging and Security Products and Services 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 to achieve the revenues and growth we seek in our Therapeutic DNA Production Services. We have yet to achieve substantial revenues and have incurred losses from our Therapeutic DNA Production Services.

If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop our Therapeutic DNA Production Services.

If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop, commercialize and have our customers adopt our Therapeutic DNA Production Services, including the expansion of our CDMO operation for the manufacture of DNA for use in our nucleic acid-based therapies in veterinary health and the development of our customers' nucleic acid-based therapy candidates. In such event, and if we are unable to raise additional capital, we would have to scale back our Therapeutic DNA Production Services which would have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Manufacturing, Development, and Industries:

If we are unable to expand our DNA manufacturing capacity, we could lose revenue and our business could suffer.

In order to expand our manufacturing capacity for our DNA production, including our linearDNA platform, we need to either build additional internal manufacturing capacity, contract with one or more partners, or both. Our technology and the production process for our DNA production are complex, involving specialized parts, and we may encounter unexpected difficulties in the manufacture, improvement or increasing the capacity of our DNA production, and addressing these difficulties may cause us to divert our time and resources from our other product offerings. There is no assurance that we will be able to continue to increase manufacturing capacity

internally or that we will find one or more suitable partners to help us towards this objective, in order to meet the volume and quality requirements necessary for success in our existing and potential markets. Manufacturing and product quality issues may arise as we continue to increase the scale of our production. If our DNA manufacturing equipment and tools do not consistently produce DNA products that meet our customers' performance expectations, our reputation may be harmed, and we may be unable to generate sufficient revenue to become profitable. Any delay or inability in expanding our manufacturing capacity could diminish our ability to develop or sell our DNA products, which could result in lost revenue and materially harm our business, financial condition and results of operations.

Rapidly changing technology and extensive competition in synthetic DNA could make the services or products we are developing obsolete or non-competitive unless we continue to develop and manufacture new and improved services or products and pursue new market opportunities.

The synthetic DNA industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry demands and standards. Our future success will depend on our ability to continually improve the services we are developing and producing, to develop and introduce new services that address the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand, and the utility and value of new products and services developed by us may not be accepted in the markets served by the new services. Our inability to gain market acceptance of existing products and services in new markets or market acceptance of new products and services could harm our future operating results. Our future success also depends on our ability to manufacture these new and improved products and services to meet customer demand in a timely and cost-effective manner, including our ability to resolve manufacturing issues that may arise as we commence production of any new products and services we develop.

In addition, there is extensive competition in the synthetic DNA industry, and our future success will depend on our ability to maintain a competitive position with respect to technological advances. Technological development by others may result in our technologies, as well as products developed using our technologies, becoming obsolete. Our ability to compete successfully will depend on our ability to develop proprietary technologies and services that are technologically superior to and/or are less expensive than our competitors' technologies and products. Our competitors may be able to develop competing and/or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time.

Pharmaceutical and biologic products and services 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.

We will need to develop and maintain manufacturing facilities that meet current Good Manufacturing Practices.

Since a primary focus of our business will be contract manufacturing of synthetic DNA, it will be critical for us to be able to produce sufficient quantities of materials required for the manufacture of our product candidates or the product candidates of our collaborators or customers for preclinical testing and clinical trials, in compliance with applicable regulatory and quality standards. If we are unable to provide such manufacturing supplies or fail to do so on commercially-reasonable terms, we may not be able to successfully produce

sufficient supply of product candidate(s) or we may be delayed in doing so. Such failure or substantial delay could materially harm our business.

Our customers will rely on us for synthetic DNA and other biological materials that are used in their discovery and development programs. These materials can be difficult to produce and occasionally have variability from the product specifications. Any disruption in the supply of these biological materials consistent with our product specifications could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. We may also have lower yields in manufacturing batches, which can increase our costs and slow our development timelines. Improper storage of these materials, by us or any third-party storage facilities, may require us to destroy some of our biological raw materials or product candidates.

We also face risks that we may fail to synthesize and manufacture our customers' product candidates in accordance with their product specifications, and the possibility of termination or nonrenewal of the agreement by our customers at a time that is costly or damaging to us.

In addition, the FDA and other regulatory authorities require that our products be manufactured according to cGMP and similar foreign standards relating to methods, facilities, and controls used in the manufacturing, processing, and packing of the product, which are intended to ensure that biological and drug products are safe and that they consistently meet applicable requirements and specifications.

Pharmaceutical manufacturers are required to register their facilities and list their products manufactured after beginning drug manufacturing and then annually thereafter with the FDA and certain state and foreign agencies. If the FDA or a comparable foreign regulatory authority does not approve our customers' product candidates at any of our proposed contract manufacturer's facilities, or if we fail to maintain a compliance status acceptable to the FDA or a comparable foreign authority, our customers may need to find alternative manufacturing facilities, which would significantly impact our ability to supply our customers' product candidates, if approved. Any discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of such incidents.

If we were unable to provide a solution in time, our customers' clinical trials could be delayed, thereby limiting our commercial activities associated with those products. The sale of our customers' products could contain other defects could adversely affect our business, financial condition, and results of operations. Any failure by us or another third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our customers' candidates and, therefore, affect our business.

Pharmaceutical manufacturers are also subject to extensive pre- and post-marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is being studied or marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. If an FDA inspection of our facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations or a "Form FDA 483". If observations in the Form FDA 483 are not addressed in a timely manner and to the FDA's satisfaction, the FDA may issue a Warning Letter or pursue other forms of enforcement action. Any failure by us or another contract manufacturers to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in enforcement action that could impact our ability to attract and maintain other contract manufacturing arrangements or lead to a shortage of our customers' products and harm our business, including withdrawal of approvals previously granted, seizure, injunction or other civil or criminal penalties. The failure of us or another manufacturer to address any concerns raised by the FDA or foreign regulators could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications, or by foreign regulators in any indication. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, on us as contract manufacturers, as part of the regulatory approval process for products in such countries. The failure by us or other third-party manufacturers to satisfy such requirements could impact our ability to obtain or maintain contract manufacturing arrangements with our customers in one or more countries.

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 research and development ("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.

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

Surveillance testing is not generally regulated by the FDA and CMS has stated that CLIA certification is not required to conduct surveillance testing for non-patient-specific tests. ADCL is offering its safeCircle™ surveillance testing in compliance with current CDC, FDA, CMS and NYSDOH 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 via a NYSDOH conditionally approved LDT. In the event that NYSDOH revokes the conditional approval or declines to fully approve the LDT, ADCL will be required to utilize a third-party EUA-authorized COVID-19 assay and potentially stop utilizing pooled testing.

Further, our COVID-19 testing may become obsolete for a variety of reasons, including an end to the current pandemic, mutations in the genome of the SARS-CoV-2 virus, 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.

We have limited experience producing and supplying our products. We may be unable to consistently manufacture or source our products to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels.

As we continue to scale commercially and develop new products, and as our products incorporate increasingly sophisticated technology, it will become more difficult to ensure our products are produced in the necessary quantities while maintaining quality. There is no assurance that we or our third-party manufacturers will be able to continue to manufacture our products so that our technology consistently achieves the product specifications and produces results with acceptable quality. Any future design issues, unforeseen manufacturing problems, such as contamination of our or our manufacturers' facilities, equipment malfunctions, aging components, quality issues with components and materials sourced from third-party suppliers, or failures to strictly follow procedures or meet specifications, may have a material adverse effect on our brand, business, reputation, results of operations and financial condition and could result in us or our third-party manufacturers losing International Organization for Standardization (ISO) or quality management certifications. If our third-party manufacturers fail to maintain ISO quality management certifications, our customers might choose not to purchase products from us.

In addition, as we scale our commercial operations, we will also need to make corresponding improvements to other operational functions, such as our customer support, service and billing systems, compliance programs and internal quality assurance programs. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that

appropriate personnel will be available. As we develop additional products, we may need to bring new equipment online, implement new systems, technology, controls and procedures and hire personnel with different qualifications.

An inability to manufacture products and components that consistently meet specifications, in necessary quantities, at commercially acceptable costs and without significant delays, may have a material adverse effect on our business, results of operations, financial condition and prospects.

We must continue to secure and maintain sufficient and stable supplies of components and raw materials.

Certain disruptions in supply of, and changes in the competitive environment for, components and raw materials integral to the manufacturing of our products may adversely affect our profitability. We use a broad range of materials and supplies in our products. A significant disruption in the supply of these materials could decrease production and shipping levels, materially increase our operating costs and materially and adversely affect our revenues and profit margins. Shortages of materials or interruptions in transportation systems, labor strikes, work stoppages, war, acts of terrorism or other interruptions to or difficulties in the employment of labor or transportation in the markets in which we purchase materials, components and supplies for the production of our products, in each case, may adversely affect our ability to maintain production of our products and achieve profitability. Unforeseen discontinuation or unavailability of certain components, such as enzymes (e.g. DNAP) or nucleotides, each of which we currently primarily source from single supplier, could cause production delays as we modify our product specifications to accommodate replacement components. If we were to experience a significant or prolonged shortage of critical components from any of our suppliers and could not procure the components from other sources, we would be unable to manufacture our products and ship them to our customers in a timely fashion, or at all, which would adversely affect our sales, margins and customer relations.

The markets for our drug and biologic candidates and synthetic 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 synthetic 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., Juno Therapeutics, Inc., Promega Corporation, OriGene Technologies, Inc., Blue Heron Biotech, LLC, Gene Art, GenScript Biotech Corporation, and others.

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 other forms of therapeutic 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 linearDNA 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 other forms of therapeutic DNA developed by our competitors may render our potential drug and biologic candidates and linearDNA uneconomical or obsolete, and we may not be successful in marketing any drug and biologic candidates and linearDNA 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**.**

The market for our MDx Testing Services is very competitive, and we may be unable to continue to compete effectively in this industry in the future.

The principal market for molecular diagnostics testing services is intensely competitive. We compete with many existing testing service providers 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 testing services that are more effective than the testing services that we have or may develop and may be more successful than us in producing and marketing their existing testing services. Some of our competitors that operate in the molecular diagnostics testing markets include: 23andMe, Inc., Laboratory Corporation of America (LabCorp); Quest Diagnostics Inc., Myriad Genetics, Inc., ARUP Laboratories, Sonic Healthcare USA, Everly Well, Inc., and Fulgent Genetics, Inc.

Our MDx Testing Services provide higher education institutions, private clients, and businesses located in New York State with COVID-19 testing services, including test scheduling, sample collection and automated results reporting. It is unclear whether we will be able to maintain and grow the number of customers who will avail themselves of our testing services, or how regularly we will be able to obtain a flow of business from existing customers. If we are unable to increase sales of our testing services or to successfully develop, validate and commercialize other diagnostic tests and services, our MDx Testing Services may not produce sufficient revenues to become profitable.

We compete with life science, pharmaceutical and biotechnology companies, some of whom are our customers, who are substantially larger than we are and potentially capable of developing new approaches that could make our products and technology obsolete or develop their own internal capabilities that compete with our products.

The market for biologics components products and services in the biopharmaceutical development, life science research, and diagnostics space is intensely competitive, rapidly evolving, significantly affected by new product introductions and other market activities by industry participants and subject to rapid technological change. We also expect increased competition as additional companies enter our market and as more advanced technologies become available. We compete with other providers of outsourced biologics components products and services. We also compete with the in-house discovery, development and commercial manufacturing functions of pharmaceutical and biotechnology companies. Many of our potential competitors, which in some cases are also our customers, are large, well-capitalized companies with significantly greater resources and market share than we have. They may undertake their own development of products that are substantially similar to or compete with our products and they may succeed in developing products that are more effective or less costly than any that we may develop. These competitors may be able to spend more aggressively on product and service development, marketing, sales and other initiatives than we can. Many of these competitors also have:

- broader name recognition;
- longer operating histories and the benefits derived from greater economies of scale;
- larger and more established distribution networks;

- additional product and service lines and the ability to bundle products and services to offer higher discounts or other incentives to gain a competitive advantage;
- more experience in conducting research and development, manufacturing and marketing;
- more experience in entering into collaborations or other strategic partnership arrangements; and
- more financial, manufacturing and human resources to support product development, sales and marketing and patent and other intellectual property litigation.

These factors, among others, may enable our competitors to market their products and services at lower prices or on terms more advantageous to customers than we can offer. Competition may result in price reductions, reduced gross margins and loss of market share, any of which could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. Additionally, our current and future competitors, including certain of our customers, may at any time develop additional products and services that compete with our products and new approaches by these competitors may make our products, technologies and methodologies obsolete or noncompetitive. We may not be able to compete effectively against these organizations.

In addition, to develop and market our new products, services, technologies and methodologies successfully, we must accurately assess and meet customers' needs, make significant capital expenditures, optimize our development and manufacturing processes to predict and control costs, hire, train and retain the necessary personnel, increase customer awareness and acceptance of such services, provide high quality services in a timely manner, price our products and services competitively and effectively integrate customer feedback into our business planning. If we fail to create demand for our new products, services or technologies, our future business could be harmed.

The animal health industry is highly competitive.

The animal health industry is highly competitive. Our competitors include standalone animal health businesses, the animal health businesses of large pharmaceutical companies, specialty animal health businesses and companies that mainly produce generic products. We believe many of our competitors are conducting R&D activities in areas in which we are developing products. Several new start-up companies also compete in the animal health industry. These competitors may have access to greater financial, marketing, technical and other resources. As a result, they may be able to devote more resources to developing, manufacturing, marketing and selling their products, initiating or withstanding substantial price competition or more readily taking advantage of acquisitions or other opportunities. Further, consolidation in the animal health industry could result in existing competitors realizing additional efficiencies or improving portfolio bundling opportunities, thereby potentially increasing their market share and pricing power, which could lead to an increase in competition. In addition to competition from established market participants, new entrants to the animal health medicines and vaccines industry could substantially reduce our market share, render our products obsolete or disrupt our business model.

To the extent that any of our competitors are more successful with respect to any key competitive factor, our business, financial condition and results of operations could be materially adversely affected. Competitive pressure could arise from, among other things, more favorable safety and efficacy product profiles, limited demand growth or a significant number of additional competitive products being introduced into a particular market, price reductions by competitors, the ability of competitors to capitalize on their economies of scale, the ability of competitors to produce or otherwise procure animal health products at lower costs than us and the ability of competitors to access more or newer technology than us.

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

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

In addition, research, development, and commercialization of our Therapeutic DNA Production Services and veterinary biologic products are inherently risky. We cannot give any assurance that any future customers and/or collaborators of our Therapeutic DNA Production Services will receive regulatory approval for their pharmaceutical and biotherapeutic product candidates. In addition, we cannot give any assurance that any of our own veterinary 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 all or 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 developed independently, compromised by third parties, or disclosed, 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 ("USPTO") 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.

Moreover, the scope, validity and enforceability of granted claims can be challenged in a variety of proceedings. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, outside of the context of litigation per se. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, derivation and pre- and post-grant opposition proceedings.

Furthermore, the courts have held that patent claims that recite laws of nature are not patent eligible, but patent claims that recite sufficient additional features that provide practical assurance that claimed processes are genuine inventive applications of those laws may be patent eligible. But what constitutes a "sufficient" additional feature is the subject of uncertainty. The USPTO has published and continues to revise and publish guidelines for patent examiners to apply when examining claims for patent eligibility as the case law continues to evolve. Patent eligibility is also an area of the law under continual development in other jurisdictions around the world.

In addition, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

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 Customer and Collaborator's Pharmaceutical and Biotherapeutic Product Candidates and Other Legal Compliance Matters:

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

Our Therapeutic DNA Production Services 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 FTC, as well as state, local, and foreign authorities, also exercise ongoing review and control of the manufacturing, packaging, labeling, advertising, sale, distribution, and monitoring of pharmaceutical and biologic products. If

our or our customers' 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.

In addition, veterinary DNA vaccines and therapeutics in the United States are subject to review and regulatory approval by the USDA. The USDA's Center for Veterinary Biologics is responsible for the regulation of animal health vaccines, including certain immunotherapeutics. All manufacturers of animal health biologicals must show their products to be pure, safe, effective and produced by a consistent method of manufacture as defined under the Virus Serum Toxin Act. Post-approval monitoring of products is required. Reports of product quality defects, adverse events or unexpected results are submitted in accordance with the agency requirements.

Revenue from our Therapeutic DNA Production Services will be highly dependent on our collaborators' and customers' success in obtaining regulatory approval and commercializing their products.

The DNA produced via our Therapeutic DNA Production Services may be incorporated into our customers' 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 an NDA or BLA. 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, USDA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If we or our customers are ultimately unable to obtain regulatory approval for products incorporating our Therapeutic DNA Production Services, we will be unable to generate product revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA, USDA 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 submitted by one of our customers or by us with respect to the veterinary health market. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our customers' data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for, or plan to obtain regulatory approval for any product candidate (except with respect to the veterinary health market), and it is possible that none of our, or our customers' existing product candidates or any product candidates that we or our customers may seek to develop in the future will ever obtain regulatory approval. Applications for our and our customers' 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 failing to obtain regulatory approval to market any of such product candidates, which would significantly harm our business, results of operations, and prospects.

Our or our customers' 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 or our customers' product candidates could cause 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 or our customers' 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 or our customers may be required to change the way the product is manufactured, be forced to suspend manufacturing the product or required to create a REMS. In addition, our or our customers' reputation may suffer. Any of these events could prevent us or our customers 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 our customers obtain regulatory approval for a product candidate, our Therapeutic DNA Production Services will remain subject to extensive regulatory scrutiny.

If any of our customers' 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 our customers receive for our products 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. Any new legislation addressing drug or biologic safety issues could result in delays in product development or commercialization, or increased costs to assure manufacturing 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. 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. 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 manufacturing changes to verify the safety and efficacy of our customers' products in general. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval and thereby affect the need for our manufacturing services.

In addition, veterinary DNA vaccines and therapeutics in the United States are subject to review and regulatory approval by the USDA. The USDA's Center for Veterinary Biologics is responsible for the regulation of animal health vaccines, including certain immunotherapeutics. All manufacturers of animal health biologicals must show their products to be pure, safe, effective and produced by a consistent method of manufacture as defined under the Virus Serum Toxin Act. Post-approval monitoring of products is required. Reports of product quality defects, adverse events or unexpected results are submitted in accordance with the agency requirements.

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, our customer 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 or our customers' ability to continue to manufacture the product(s). Any government investigation of alleged violations of law could require our customers or 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 customers' ability to commercialize and generate

revenue from our customers' products and demand for our synthetic DNA for their 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 related to the demand for those customers' products or our products in the case of the veterinary health market.

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 our post-approval manufacturing 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 our customers or we are not able to achieve and maintain regulatory compliance, we may not be permitted to continue manufacturing synthetic DNA products for our customers' 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 MDx Testing Services are currently subject to enforcement discretion by the FDA. While FDA has issued various guidance documents proposing a framework to regulate LDTs, the FDA appears to be waiting for a legislative solution.

In this regard, most recently, the "Verifying Accurate Leading-edge IVCT Development Act of 2020," or VALID Act, was introduced in March 2020, then in June 2021, and Spring 2022. A modified version of the VALID Act was added to the reauthorization bill for the Medical Device User Fee Act ("MDUFA") V but then was removed to permit a more rapid passage of MDUFA V to prevent worker layoffs. The bill proposed a risk-based approach that would have subjected many LDTs to FDA regulation by creating a new in vitro clinical test, or IVCT, category of regulated products. As proposed, the bill would have grandfathered many existing LDTs from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would have required such tests to comply with other regulatory requirements (e.g., registration and listing, adverse event reporting). To market a high-risk IVCT, reasonable assurance of analytical and clinical validity for the intended use would have needed to be established. Under VALID, a precertification process would have been established that would have allowed 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, developed by the laboratory would not have been subject to pre-market review. The new regulatory framework would have included quality control and post-market reporting requirements. The FDA would have had the authority to withdraw approvals for IVCTs for various reasons, including (for example) if there were a reasonable likelihood that the test would cause death or serious adverse health consequences. However, with bill language being removed from MDUFA V, we cannot predict if this (or any other bill) will be enacted in its current (or any other) form and cannot quantify the effect of such proposals on our business.

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.

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 customer's product candidates, if our customers 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 from any customer. 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, customers 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, customers 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 our customers obtain FDA approval of any of their products and begin commercializing those products in the United States, our potential exposure under such laws may increase significantly, and our costs associated with compliance with such laws as a result of our relationship with our customers may also increase. 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 our customers may obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including 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 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, 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 customers' 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. We have a limited number of personnel and expect to continue to have a limited number of personnel for the foreseeable future.

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, 2022, 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. 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 9, 2022, we had 12,908,520 shares of common stock issued and outstanding, outstanding options to purchase 1,061,810 shares of common stock, outstanding warrants to purchase 7,313,963 shares of common stock, and 2,767,568 shares available for grant under our 2005 and 2020 Equity Incentive Plans. The issuance of shares upon exercise of our outstanding options and warrants will cause immediate and substantial dilution to our stockholders and any sale thereof may depress the market price of our common stock.

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.

If we fail to comply with the continuing listing standards of Nasdaq, our securities could be delisted, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.

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, which provide, among other things, that a company may be delisted if the bid price of its stock drops below $1.00 for a period of 30 consecutive business days.

We may in the future decide to enact a reverse stock split to comply with Nasdaq's minimum bid price requirement. However, even if we enact such a reverse stock split, there can be no assurance that we would be able to maintain compliance with Nasdaq's minimum bid price or other listing requirements. If we were unable to meet these requirements, our common stock could be delisted from Nasdaq. The effect of a reverse stock split on the market price of our common stock cannot be predicted with any certainty, and the history of similar reverse stock split combinations for companies in like circumstances is varied. It is possible that the per share price of the common stock after the reverse stock split will not rise in proportion to the reduction in the number of shares of the common stock outstanding resulting from the reverse stock split, effectively reducing our market capitalization, and there can be no assurance that the market price per post-reverse split share will either exceed or remain in excess of the Nasdaq prescribed minimum bid price for a sustained period of time. The market price of our common stock may vary based on other factors that are unrelated to the number of shares outstanding, including our future performance.

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.

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

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

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 originally 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. During November 2019, we extended this lease until January 15, 2020. 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, extending the term for these leases until January 15, 2022. On February 1, 2022, we entered into a new lease agreement for the same facility for a one-year period, expiring January 31, 2023. The base rent during the additional twelve-month period is $589,056 per annum. We also have a satellite testing facility in Ahmedabad, India, which occupies 1,108 square feet for a three-year term beginning November 1, 2017. During August 2022, we renewed this lease with a new expiration date of July 31, 2023. The base rent is approximately $6,500 per annum.

ITEM 3. LEGAL PROCEEDINGS.

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

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

Our common stock is listed on The Nasdaq Capital Market under the symbol "APDN". 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 9, 2022, we had 126 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. RESERVED.

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

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

Introduction

We are a biotechnology company developing and commercializing technologies to produce and detect deoxyribonucleic acid ("DNA"). Using the polymerase chain reaction ("PCR") to enable both the production and detection of DNA, we operate in three primary business markets: (i) the manufacture of synthetic DNA for use in nucleic acid-based therapeutics ("Therapeutic DNA Production Services"); (ii) the detection of DNA in molecular diagnostics testing services ("MDx Testing Services"); and (iii) the manufacture and detection of DNA for industrial supply chain security services ("DNA Tagging and Security Products and Services").

Our growth strategy is to primarily focus our resources on the further development, commercialization, and customer adoption of our Therapeutic DNA Production Services, including the expansion of our contract development and manufacturing operation ("CDMO") for the manufacture of synthetic DNA for use in nucleic acid-based therapies and the development of our own product candidates in veterinary health

Therapeutic DNA Production Services

Through our LinearRx, Inc. ("LRx") subsidiary we are developing and commercializing the linearDNA ("linearDNA") platform. The linearDNA platform enables the rapid, efficient, and large-scale cell-free manufacture of high-fidelity DNA sequences for use in nucleic acid-based therapeutics. The linearDNA platform enzymatically produces a linear form of DNA we call 'linearDNA' that is an alternative to plasmid-based DNA manufacturing technologies that have supplied the DNA used in biotherapeutics for the past 40 years.

We believe our enzymatic linearDNA platform has numerous advantages over existing cell-based plasmid DNA manufacturing platforms. Plasmid-based DNA manufacturing is based on the complex, costly and time-consuming biological process of amplifying DNA in living cells. Once amplified, the DNA must be separated from the living cells and other process contaminants via multiple rounds of purification, adding further complexity and costs. Unlike plasmid-based DNA manufacturing, the linearDNA platform does not require living cells and instead amplifies DNA via the enzymatic process of PCR. The linearDNA platform is simple, with only four ingredient inputs, and can rapidly produce very large quantities of DNA without the need for complex purification steps.

We believe the key advantages of the linearDNA platform include:

- Speed – Production of linearDNA can be measured in terms of hours, not days and weeks as is the case with plasmid-based DNA manufacturing platforms.
- Scalability – linearDNA production takes place on efficient bench-top instruments, allowing for rapid scalability in a minimal footprint.
- Purity – DNA produced via PCR is pure, resulting in only large quantities of only the target DNA sequence. Unwanted DNA sequences such as plasmid backbone and antibiotic resistance genes, inherent to plasmid DNA, are not present in linearDNA.
- Simplicity – The production of linearDNA is streamlined relative to plasmid-based DNA production. linearDNA requires only four primary ingredients, does not require living cells or complex fermentation systems and does not require multiple rounds of purification.

- Flexibility – DNA produced via the linearDNA platform can be easily chemically modified to suit specific customer applications. In addition, the linearDNA platform can produce a wide range of complex DNA sequences that are difficult to produce via plasmid-based DNA production platforms. These complex sequences include inverted terminal repeats (ITRs) and polyadenylation sequences (poly (A) tail) important to gene therapy and messenger RNA ("mRNA") therapies, respectively.

Preclinical studies have shown that linearDNA is substitutable for plasmid DNA in numerous nucleic acid-based therapies, including:

- therapeutic and prophylactic DNA vaccines;
- DNA templates for *in vitro* transcription to produce ribonucleic acid ("RNA"), including mRNA; and
- adoptive cell therapy manufacturing.

Further, we believe that linearDNA is also substitutable for plasmid DNA in the following nucleic acid-based therapies:

- viral vector manufacturing for *in vivo* and *ex vivo* gene editing;
- Clustered regularly interspaced short palindromic repeats ("CRISPR")-mediated homology-directed repair ("HDR"); and
- non-viral gene therapy.

As of the third quarter of calendar 2022, there were 3,694 gene, cell and RNA therapies in development from preclinical through pre-registration stages, almost all of which use DNA in their manufacturing process. (Source: ASGCT Gene, Cell & RNA Therapy Landscape: Q3 2022 Quarterly Report). Due to what we believe are the linearDNA platform's numerous advantages over legacy plasmid-based DNA manufacturing platforms, we believe this large number of therapies under development represents a substantial market opportunity for linearDNA to supplant plasmid DNA in the manufacture of nucleic acid-based therapies.

Our linearDNA is currently manufactured pursuant to Good Laboratory Practices ("GLP") that we believe are sufficient for pre-clinical discovery and development of nucleic acid-based therapies. In addition, for indirect clinical use of linearDNA (i.e., where linearDNA is a starting material but is not incorporated into the final therapeutic product, as is the case with the production of mRNA or certain viral vectors), we believe that high-quality grade GLP linearDNA is sufficient for clinical and commercial stage customers of our Therapeutic DNA Production Services. For the direct clinical use of our linearDNA (i.e., nucleic acid-based therapies where our linearDNA is incorporated into the final therapeutic product, as in the production of DNA vaccines, adoptive cell therapies and certain gene therapies) we believe clinical and commercial stage customers of our Therapeutic DNA Production Services will generally require our manufacturing facilities to meet current Good Manufacturing Practices ("cGMP"). We currently do not have any manufacturing facilities that meet cGMP. We will need to develop and maintain manufacturing facilities that meet cGMP to support customers that wish to use our linearDNA for direct clinical use and for indirect clinical use customers who request linearDNA manufactured under cGMP. In the longer term, we believe that the development and maintenance of a cGMP manufacturing facility for linearDNA will benefit the entirety of our Therapeutic DNA Production Services business, in both direct and indirect clinical applications.

Our business strategy for the linearDNA platform is (i) to utilize our current GLP linearDNA production capacity to secure CDMO contracts to supply linearDNA to pre-clinical therapy developers, as well as clinical and commercial therapy developers and manufacturers that are pursuing therapeutics that require the indirect clinical use of linearDNA; and (ii) upon our development of cGMP linearDNA production facilities, to secure CDMO contracts with clinical stage therapy developers and commercial manufactures to supply linearDNA for direct clinical use.

In addition, we plan to leverage our Therapeutic DNA Production Services and deep knowledge of PCR to develop and monetize, ourselves or with strategic partners, one or more linearDNA-based therapeutic or prophylactic vaccines for the veterinary health market. Currently, we have in-licensed a therapeutic DNA vaccine candidate against canine lymphoma, which accounts for up to 24% of all cancers in canines. Our lymphoma vaccine candidate was licensed from Takis S.R.L and EvviVax, S.R.L. for exclusive use by the Company in association with our linearDNA platform, and is subject to certain commercialization milestones. We currently seek to commercialize our canine lymphoma vaccine in conjunction with lipid nanoparticle ("LNP") encapsulation to facilitate IM administration. We have recently demonstrated *in vitro* and *in vivo* (mice studies) expression of generic reporter proteins via linearDNA

encapsulated by LNPs. For the *in vivo* study, successful expression of the LNP-encapsulated linearDNA was administered and achieved via IM injection. We believe the linearDNA platform provides a substantial advantage to the development and monetization of a therapeutic DNA vaccine against canine lymphoma.

MDx Testing Services

Through Applied DNA Clinical Labs, LLC ("ADCL"), our clinical laboratory subsidiary, we leverage our expertise in DNA detection via PCR to provide and develop clinical molecular diagnostics ("MDx") testing services. ADCL is a New York State Department of Health ("NYSDOH") Clinical Laboratory Evaluation Program ("CLEP") permitted, Clinical Laboratory Improvement Amendments ("CLIA")-certified laboratory which is currently permitted for virology. In providing MDx testing services, ADCL employs its own or third-party molecular diagnostic tests.

Under our MDx testing services, ADCL currently provides COVID-19 testing for large populations marketed under our safeCircle™ trademark. Leveraging ADCL's customizable high-throughput robotically-pooled testing workflow and the Cleared4 digital health platform owned and operated by Cleared4 Inc. (the "Cleared4 Platform"), our safeCircle testing service is an adaptable turnkey large population COVID-19 testing solution that provides for all aspects of COVID-19 testing, including test scheduling, sample collection and automated results reporting. Our safeCircle testing service utilizes high-sensitivity robotically-pooled real-time PCR ("RT-PCR") testing to help mitigate virus spread by quickly identifying COVID-19 infections within a community, school, or workplace. Our safeCircle COVID-19 testing is performed using either the Company's internally developed Linea 2.0 RT-PCR Assay, a NYSDOH conditionally approved laboratory developed test ("LDT") or third-party emergency use authorization ("EUA")-authorized RT-PCR COVID-19 assays. Our safeCircle testing service also incorporates the Cleared4 Platform to enable large-scale digital test scheduling, in-field sample collection and registration, and results reporting. By leveraging the combination of our robotically-pooled workflows and the Cleared4 Platform, our safeCircle testing services typically return testing results within 24 to 48 hours. We currently provide safeCircle testing services to higher education institutions, private clients, and businesses located in New York State.

ADCL has also developed PCR-based MDx testing services for the Monkeypox virus, which are currently approved by NYSDOH. These services are designed to run on the same high-throughput platform utilized by our COVID-19 testing services and provides ADCL with a substantial testing throughput

In addition to our infectious disease testing services, we are currently validating pharmacogenetics ("PGx") testing services. Our PGx testing services will utilize a 120-target PGx panel test to evaluate the unique genotype of a specific patient to help guide individual drug therapy decisions. Our PGx testing services are designed to interrogate DNA targets on over 35 genes and provide genotyping information relevant to certain cardiac, mental health and pain management drug therapies. We believe the economics of complex MDx testing services such as PGx are more favorable to the Company as compared to high volume, low complexity MDx tests such as COVID-19 testing. Our PGx testing services will require NYSDOH approval prior to initiating our patient testing services. If approved, we plan to commercialize our PGx testing services by offering PGx clinical reference laboratory testing services to other clinical laboratories and healthcare facilities nationwide.

Going forward, our business strategy for ADCL is to leverage our deep knowledge of PCR to develop and commercialize high complexity, high value and differentiated MDx testing services that will be offered to other clinical laboratories and healthcare facilities as clinical reference laboratory testing services. We believe operating as a clinical reference laboratory has several advantages when compared to operating as a typical clinical non-reference laboratory, including:

- the ability to leverage our deep expertise in PCR to develop and perform high-value esoteric MDx testing services not performed by conventional clinical non-reference laboratories;
- reduced sample acquisition costs;
- reduced marketing costs; and
- a national customer base that may lead to a larger total addressable market.

The clinical reference laboratory services market is forecasted to have incremental growth of $26.0B between 2020 and 2025 with a 6.71% compound annual growth rate ("CAGR"). We believe that the rapidly increasing number of specialized MDx tests for early disease detection, disease prognosis, disease risk, companion diagnostics and personalized medicine will drive an increase in the demand for highly specialized MDx clinical reference laboratory services.

DNA Tagging and Security Products and Services

By leveraging our expertise in both the manufacture and detection of DNA via PCR, our DNA Tagging and Security Products and Services allow our customers to use non-biologic DNA 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 DNA tag. We believe our DNA tags are not economically feasible nor practical to replicate, and that our disruptive tracking platform offers broad commercial relevance across many industry verticals. The Company's core DNA Tagging and Security Products and Services, which are marketed collectively as a platform under the trademark CertainT®, include:

- SigNature® Molecular Tags, which are short non-biologic DNA taggants produced by the Company's linearDNA platform, provide a methodology to authenticate goods within large and complex supply chains for materials such as cotton, leather, pharmaceuticals, nutraceuticals and other products.

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

- fiberTyping®, which uses PCR-based DNA detection to determine a cotton cultivar, and other product genotyping services that utilize PCR-based DNA detection to detect a product's naturally occurring DNA sequences for the purposes of product provenance authentication and supply chain security.

Our DNA Tagging and Security Products and Services are fully developed, highly scalable, and currently used in several commercial applications. To date, our largest commercial application for our DNA Tagging and Security Products and Services is in the tracking and provenance authentication of cotton. Cotton home textile products utilizing our DNA Tagging and Security Products and Services are available in national retail chains including Costco® and Bed Bath & Beyond®.

We believe that the Uyghur Forced Labor Prevention Act ("UFLPA"), signed into law on December 23, 2021, may be helpful to increase demand for our DNA Tagging and Security Products and Services. The UFLPA establishes a rebuttable presumption that any goods mined, produced, or manufactured wholly or in part in the Xinjiang Uyghur Autonomous Region ("XUAR") of the People's Republic of China are not entitled to entry to the United States. The presumption applies unless the importer of record has complied with specified conditions and, by clear and convincing evidence, shown that the goods were not produced using forced labor. On June 17, 2022, an implementation strategy for the UFLPA was published that listed DNA tagging as evidence that importers may present to potentially prove that a good did not originate in XUAR or did not benefit from forced labor. Approximately 20% of the world's cotton garments contain cotton that originated in the XUAR.

Our business plan is to leverage growing consumer and governmental awareness for product traceability and the newly enacted UFLPA to expand our existing partnerships and seek new partnerships for our DNA Tagging and Security Products and Services with a focus on cotton and synthetic fibers.

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 our validated COVID-19 pooled testing, and our COVID-19 Surveillance Testing, which are part of our MDx testing services business. We also expect future growth in revenues to be derived from our Therapeutic DNA Production Services and our MDx testing services. 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. We have continued to incur expenses in expanding our business to meet current and anticipated future demand. We have limited sources of liquidity.

Comparison of the Fiscal Year Ended September 30, 2022 to the Fiscal Year Ended September 30, 2021

Revenues

Product revenues

For the twelve-month periods ended September 30, 2022 and 2021, we generated $1,882,804 and $3,295,849 in revenues from product sales, respectively. Product revenue decreased by $1,413,045 or 43% for the twelve-month period ended September 30, 2022 as compared to the prior fiscal year. Revenues decreased by $1,323,610 in sales of our MDx test kits and supplies, of which $1,266,895 was attributable to sales pursuant to our contract with Stony Brook University Hospital. The decrease also relates to a decrease of approximately $163,000 in the textiles market for the shipment of DNA concentrate used by customers to protect the supply chain.

Service revenues

For the twelve-month periods ended September 30, 2022 and 2021, we generated $759,138 and $937,735 in service revenues, respectively. Service revenue decreased by $178,597 or 19% for the twelve-month period ended September 30, 2022 as compared to the prior fiscal year. The decrease in service revenues is related to a decrease of approximately $258,000 for research and development projects in our Therapeutic DNA production segment.

Clinical laboratory service revenues

For the twelve-month periods ended September 30, 2022 and 2021, we generated $15,526,735 and $4,794,154 in revenues from clinical laboratory testing services, respectively. Clinical laboratory service revenue increased by $10,732,581 or 224% for the twelve-month period ended September 30, 2022 as compared to the prior fiscal year. The increase in revenue is primarily due to a full twelve months of our contract with the City University of New York which resulted in an increase of $9,319,884 year over year.

Costs and Expenses

Gross Profit

Gross profit for the twelve-month period ended September 30, 2022 increased by $570,734 or 13% from $4,482,906 for the twelve-month period ended September 30, 2021 to $5,053,640 for the twelve-month period ended September 30, 2022. The gross profit percentage was 28% and 50% for the twelve-month periods ended September 30, 2022 and 2021, respectively. The decline in gross profit percentage was the result of a significant portion of our clinical laboratory revenue coming from our screening testing contracts where we also provide and staff the testing centers, as these contracts have higher costs associated with them as compared to our surveillance testing contracts. To a lesser extent, the decline is due to product sales mix, as sales during the twelve-month period ended September 30, 2021 included MDx 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 current fiscal year.

Selling, General and Administrative

Selling, general and administrative expenses for the twelve-month period ended September 30, 2022 increased by $2,251,988 or 18% to $15,097,360 from $12,845,372 in the twelve-month period ended September 30, 2021. The increase is primarily attributable to an increase in stock-based compensation expense of $615,000 relating to officer stock option grants that vested immediately, as well as to the annual non-employee board of director grants that vest one-year from the date of grant. The remainder of the increase relates to an increase in insurance expense of approximately $413,000, primarily related to an increase in our Directors and Officers insurance policy premiums and payroll of approximately $809,000. The increase in total payroll is primarily due to an increase of $500,000 for a bonus accrual for the CEO, in accordance with his employment agreement, and was also due to the twelve-month period ended September 30, 2021 having a reversal of an accrual of approximately $300,000 for an accrued bonus that was forgiven by the CEO. To a lesser extent, the increase is due to an increase of approximately $240,000 in bad debt expense for the twelve-month period ended at September 30, 2022 to fully reserve for an outstanding customer balance that was deemed to be uncollectible.

Research and Development

Research and development expenses for the twelve-month period ended September 30, 2022 decreased by $238,391 or 6% to $3,926,043 from $4,164,434 in the twelve-month period ended September 30, 2021. This decrease is primarily due to decreased purchases relating to our clinical laboratory build out as well as for research projects related to genetic sequencing and isotopic research analysis projects during the period ended September 30, 2022.

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* income, net**

Interest income, net for the fiscal year ended September 30, 2022, decreased to $7,200 from $13,675 in the same period of 2021.

Other expense, net

Other expense, net for the twelve-month periods ended September 30, 2022 and 2021, was $47,305 and $8,756, respectively.

Loss on extinguishment of convertible notes payable

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.

Transaction cost allocated to warrant liabilities

Transaction cost allocated to warrant liabilities for the twelve-month period ended September 30, 2022 was $1,668,112. These transaction costs represent the portion of the closing costs from both the February and August 2022 financing transactions that was allocated to the warrants issued in those transactions.

Unrealized gain on change in fair value of the Common Warrants

Unrealized gain on change in fair value of Common Warrants for the twelve-month period ended September 30, 2022, of $17,999,521 relates to the change in fair value of the Common Warrants issued as part of the February and August 2022 Offerings (see Note H of the accompanying consolidated financial statements). The gain on change in fair value represents the difference between the fair value of the Common Warrants on the issuance date compared to the fair value as of September 30, 2022. The primary driver of this change is the decline in our stock price during the period.

Gain on extinguishment of 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 plus accrued interest.

Loss on issuance of warrants

The loss on issuance of warrants of $10,591,600 for the twelve-month period ended September 30, 2022 relates to the August 2022 financing transaction and is the result of the fair value of the warrants being greater than the cash received from the financing.

Net Loss

Net loss decreased $6,008,380, or 42% to $8,270,059 for the fiscal year ended September 30, 2022 compared to $14,278,439 for the fiscal year ended September 30, 2021, 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, 2022, we had working capital of $15,757,821. For the fiscal year ended September 30, 2022, we used cash in operating activities of $8,976,706 consisting primarily of our loss of $8,270,059 net with non-cash adjustments of $1,290,480 in depreciation and amortization charges, $2,518,665 in stock-based compensation expense, $1,668,112 in public offering costs incurred, $10,591,600 in loss on issuance of warrants, $17,999,521 in unrealized gain on change in fair value of common warrants, and $269,451 of bad debt expense. Additionally, we had a net increase in operating assets of $258,488 and a net decrease in operating liabilities of $1,213,054. Cash used in investing activities was $489,553, for the purchase of property and equipment. Cash provided by financing activities was $18,126,596, which included net proceeds from public offerings of $14,426,521, and warrant exercises of $3,700,075.

We have recurring net losses. We have incurred a net loss of $8,270,059 for the fiscal year ended September 30, 2022. 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. Through September 30, 2022, we have dedicated most of our financial resources to commercialization of our MDx Testing Services, specifically our COVID-19 Testing Services, as well as to research and development efforts focused on the development of our Therapeutic DNA Productions Services, as well as, advancing our intellectual property, and general and administrative activities.

As discussed in Note H of the accompanying consolidated financial statements, on August 8, 2022, we closed on a public offering of 3,000,000 shares of Common Stock and warrants, at a purchase price of $4.00 per share. The net proceeds, after deducting the placement agent's fees and other offering expenses were approximately $10.7 million. Also, we received $3.7 million in proceeds from the exercise of 900,000 Series B Warrants.

We have alleviated the substantial doubt of a going concern through the cash received from the August 2022 public offering and the warrant exercises, discussed above, as well as collection of our accounts receivable. We estimate that we will have sufficient cash and cash equivalents to fund operations for the next twelve months from the date of filing of this annual report.

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

We expect capital expenditures to be less than $3,000,000 in fiscal 2023. Our primary investments are expected to be in laboratory equipment related to our Therapeutic DNA Production segment's research and development activities.

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

Critical Accounting Estimates and 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.
- Warrant Liabilities

Critical Accounting 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, recoverability of long-lived assets, including the values assigned to property and equipment, fair value calculations for 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

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.

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 product revenues are accounted for/recognized 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. For those customers with a fixed monthly fee, the revenue is recognized over-time as the services are provided.

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.

Warrant Liabilities

The Company evaluated the Common Warrants and the Series A and Series B Warrants (collectively the "Warrants") in accordance with ASC 480 "Distinguishing Liabilities from Equity" and ASC 815-40, "Derivatives and Hedging — Contracts in Entity's Own Equity" and concluded that due to the terms of the warrant agreements, the instrument does not qualify for equity treatment. As such, the Warrants were recorded as a liability on the consolidated balance sheet and measured at fair value at inception and at each reporting date in accordance with ASC 820, "Fair Value Measurement", with changes in fair value recognized in the consolidated statement of operations in the period of change.

Recent Debt and Equity Financing Transactions

Fiscal 2022

Registered Direct Public Offering

On February 24, 2022, we closed a registered direct offering (the "Offering") in which, pursuant to the Securities Purchase Agreement dated February 21, 2022, by and between the Company and an institutional investor, the Company issued and sold 748,200 shares of the Company's Common Stock ("Share") and 748,200 pre-funded warrants ("Pre-Funded Warrants") to purchase shares of the Company's Common Stock. The Pre-Funded Warrants have an exercise price of $0.0001 per share and were immediately exercisable and can be exercised at any time after their original issuance until such Pre-Funded Warrants are exercised in full. Each Share was sold at an offering price of $2.80 and each Pre-Funded Warrant was sold at an offering price of $2.7999. Pursuant to the Securities Purchase Agreement, in a concurrent private placement (together with the Registered Direct Offering, the "Offerings"), the Company issued unregistered warrants ("Common Warrants") to purchase up to 1,496,400 shares of Common Stock. Each Common Warrant has an exercise price of $2.84 per share, is exercisable six months from the date of issuance and will expire five years from the initial exercise date on August 24, 2027. The gross proceeds of the offering, before deducting placement agent fees and other offering expenses, were approximately $4.2 million. On June 9, 2022, all of the 748,200 Pre-Funded Warrants were exercised.

After deducting underwriting discounts and commissions and other expenses related to the offering, the aggregate net proceeds were approximately $3.7 million.

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

The exercise price and number of the shares of Common Stock issuable upon the exercise of a 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. The Common Warrants are recorded as a liability in the consolidated balance sheet and were recorded at fair value and will be marked to market at each period end. The fair value of the Common Warrants upon issuance was $3,350,400. The fair value of the warrants as of September 30, 2022 was $1,477,000, which resulted in a gain in the change in fair value of Common Warrants of $1,873,400 for the twelve-month periods ended September 30, 2022. Additionally, the Company allocated $391,335 of transaction costs to the warrant liabilities which is included in the consolidated statement of operations for the twelve-month period ended September 30, 2022.

As a result of this financing, the exercise price of the 458,813 remaining warrants issued during November 2019, 159,000 warrants issued during October 2020 and 100,000 warrants issued during December 2020 was all reduced to an exercise price of $2.80 per share in accordance with the adjustment provision contained in their respective warrant agreements. The incremental change in fair value of these warrants as a result of the triggering event was $110,105 and is recorded as a deemed dividend in the consolidated statement of operations for the twelve-month period ended September 30, 2022.

Public Offering

On August 8, 2022, we closed on a public offering of 3,000,000 shares of our common stock (or common stock equivalents in lieu thereof), together with Series A warrants to purchase up to 3,000,000 shares of our common stock and Series B warrants to purchase up to 3,000,000 shares of our common stock at a combined offering price to the public of $4.00 per share (or $3.9999 per common stock equivalent with an exercise price of $0.0001) and associated warrants, priced at a premium to market under Nasdaq rules. The Series A warrants have an exercise price of $4.00 per share, are exercisable immediately upon issuance, and expire five years following the date of issuance. The Series B warrants have an exercise price of $4.00 per share, are exercisable immediately upon issuance, and expire thirteen months following the date of issuance. The net proceeds to us from the offering, were approximately $10.7 million, after deducting the placement agent's fees and other offering expenses payable by us.

Warrant Exercises

During August 2022, 925,000 of the Series B warrants were exercised for total net proceeds of $3,700,000.

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 agreed 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.

Product Research and Development

We anticipate spending approximately $4,000,000 for product research and development activities during the next twelve months.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Inflation

The effect of inflation on our revenue and operating results was not significant during the fiscal years ended September 30, 2022 and 2021.

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.

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, 2022, 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, 2022. 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, 2022, our disclosure controls and procedures were not effective because of a material weakness in our internal control over financial reporting as of September 30,2022. The material weakness is further described below.

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, 2022. 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 not effective as of September 30, 2022 due to the material weakness detailed below.

Material Weakness in Internal Control Over Financial Reporting

In connection with the audit of our consolidated financial statements for the fiscal year ended September 30, 2022, and 2021, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. For the fiscal year ended September 30, 2022, the material weakness related to the controls around the accounting for complex financial instruments, as it relates to the accounting for our outstanding warrants and the related tax impact. Nonetheless, we have concluded that this material weakness does not require a restatement of or change in our consolidated financial statements for any prior interim period. We also developed a remediation plan for this material weakness which is described below.

Remediation of Material Weakness

We are committed to maintaining a strong internal control environment and implementing measures designed to help ensure that this material weakness is remediated as soon as possible. We believe we have made progress towards remediation and continue to implement our remediation plan for the current material weakness in internal control over financial reporting. Specifically, we intend to identify practices and/or procedures to expand and improve the review process for complex financial instruments and the related tax impact that is performed by both our personnel, as well as by the third-party professionals with whom we consult regarding complex accounting and tax applications. We will consider the material weakness remediated after the applicable controls operate for a sufficient period of time, and management has concluded, through testing, that the controls are operating effectively.

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.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information called for by Item 10 will be included in our definitive proxy statement for the 2023 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, 2022. The relevant portions of such definitive proxy statement are incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by Item 11 will be included in our definitive proxy statement for the 2023 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, 2022. The relevant portions of such definitive proxy statement are incorporated herein by reference.

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

The information called for by Item 12 will be included in our definitive proxy statement for the 2023 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, 2022. The relevant portions of such definitive proxy statement are incorporated herein by reference.

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

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. As of September 30, 2022, Dillon Hill Capital, LLC and its affiliate, Dillon Hill Investment Company, LLC, are no longer a greater than 5% shareholder.

The information called for by Item 13 will be included in our definitive proxy statement for the 2023 Annual Meeting of Stockholders, or will be included in an amendment thereto, which will be filed with the SEC within 120 days after September 30, 2022. The relevant portions of such definitive proxy statement are incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by Item 14 will be included in our definitive proxy statement for the 2023 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, 2022. 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, 2022 and 2021 and for the years ended September 30, 2022 and 2021, 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 14, 2022

/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 14, 2022
/s/ BETH M. JANTZEN Beth M. Jantzen	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	December 14, 2022
/s/ **ROBERT CATELL** Robert Catell	Director	December 14, 2022
/s/ **JOSEPH D. CECCOLI** Joseph D. Ceccoli	Director	December 14, 2022
/s/ **SCOTT L. ANCHIN** Scott L. Anchin	Director	December 14, 2022
/s/ **YACOV A. SHAMASH** Yacov A. Shamash	Director	December 14, 2022
/s/ **SANFORD R. SIMON** Sanford R. Simon	Director	December 14, 2022
/s/ **ELIZABETH M. SCHMALZ** Elizabeth M. Schmalz	Director	December 14, 2022

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	10-K	4.1	001-36745	12/9/2021	
4.2	Form of Purchase Warrant	8-K	4.1	001-36745	12/20/2017	
4.3	Common Stock Purchase Warrant	8-K	4.1	001-36745	12/21/2018	
4.4	Form of common warrant certificate (included in the Warrant Agreement, dated November 15, 2019)	8-K	4.2	001-36745	11/18/2019	
4.5	Form of Indenture	S-3	4.1	333-238557	05/21/2020	
4.6	Form of Common Stock Purchase Warrant	8-K	10.3	001-36745	10/14/2020	
4.7	Form of Pre-Funded Common Stock Purchase Warrant	8-K	4.1	001-36745	2/23/2022	
4.8	Form of Common Stock Purchase Warrant	8-K	4.2	001-36745	2/23/2022	
4.9	Form of Series A Warrant	8-K	4.1	001-36745	8/9/2022	
4.10	Form of Series B Warrant	8-K	4.2	001-36745	8/9/2022	
4.11	Form of Prefunded Warrant	8-K	4.3	001-36745	8/9/2022	
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†	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	

10.8	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
10.9	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
10.10	Second Amendment to Warrant Agreement dated November 2, 2016	8-K	10.4	001-36745	11/2/2016
10.11	Registration Rights Agreement dated November 2, 2016	8-K	10.3	001-36745	11/2/2016
10.12*	License Agreement with Himatsingka America, Inc. dated June 23, 2017	10-Q	10.1	001-36745	8/10/2017
10.13	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
10.14	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
10.15	Registration Rights Agreement, dated November 29, 2018	8-K	10.2	001-36745	12/6/2018
10.16	Securities Purchase Agreement, dated November 29, 2018	8-K	10.3	001-36745	12/6/2018
10.17	Registration Rights Agreement, dated August 31, 2018	8-K/A	10.2	001-36745	12/10/2018
10.18	Securities Purchase Agreement, dated August 31, 2018	10-K	10.45	001-36745	12/18/2018
10.19+	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
10.20	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
10.21	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
10.22	Asset Purchase Agreement, dated July 29, 2019 by and between LineaRX, Inc. and Vitatex Inc.	8-K	10.1	001-36745	8/12/2019
10.23	Form of Subscription Agreement between investors and Applied DNA Sciences, Inc., dated August 22, 2019.	8-K	10.1	001-36745	8/26/2019
10.24	Underwriting Agreement entered into by and between Applied DNA	8-K	1.1	001-36745	11/14/2019

	Sciences, Inc. and Maxim Group LLC, as Representative of the Underwriters listed in Schedule I hereto, dated November 13, 2019.				
10.25	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
10.26†	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
10.27	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
10.28	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
10.29	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
10.30	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
10.31	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
10.32	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
10.33	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
10.34	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
10.35+	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	10-K	10.46	001-36745	12/17/2020
10.36	Animal Clinical Trial Agreement, dated September 14, 2020, between Applied	10-K	10.47	001-36745	12/17/2020

	DNA Sciences, Inc., Evvivax S.R.L. and Veterinary Oncology Services, PLLC					
10.37	Letter Agreement dated March 2, 2021, by and between the Company and Dr. James Hayward	8-K	10.1	001-36745	3/4/2021	
10.38	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	
10.39	Form of Securities Purchase Agreement	8-K	10.2	001-36745	01/11/2021	
10.40	Form of Placement Agency Agreement by and between Applied DNA Sciences, Inc. and Roth Capital Partners, LLC, dated February 21, 2022	8-K	10.2	001-36745	2/23/2022	
10.41	Form of Securities Purchase Agreement	8-K	10.1	001-36745	2/23/2022	
10.42	Form of Securities Purchase Agreement, dated August 4, 2022, by and between Applied DNA Sciences, Inc. and certain purchasers	8-K	10.1	001-36745	8/9/2022	
10.43	Office Lease Renewal Letter Agreement, dated February 1, 2022, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc.					Filed
10.44	Laboratory Lease Renewal Letter Agreement, dated February 1, 2022, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc.					Filed
10.45+	Contract Number T212206, dated August 3, 2021, by and between The City University of New York and Applied DNA Clinical Labs, LLC.					Filed
10.46+	First Amendment to Contract No. T212206, dated December 16, 2021, by and between The City University of New York and Applied DNA Clinical Labs, LLC.					Filed
10.47+	Second Amendment to Contract No. T212206, dated July 19, 2022, by and between The City University of New York and Applied DNA Clinical Labs, LLC.					Filed
14.1	Code of Business Conduct and Ethics.					Filed
21.1	Subsidiaries of Applied DNA Sciences, Inc.	10-K	21.1	001-36745	12/17/2020	
23.1	Consent of Marcum LLP					Filed
31.1	Certification of Chief Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					Filed

31.2	Certification of Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed
32.1	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	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	Inline XBRL Instance Document	Filed
101 SCH	Inline XBRL Taxonomy Extension Schema Document	Filed
101 CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed
101 DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed
101 LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed
101 PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101)	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 is the type that the Company treats as private or confidential. The omissions have been indicated by bracketed asterisks ("[***]").

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

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, 2022 and 2021, the related consolidated statements of operations, equity and cash flows for each of the two years in the period ended September 30, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2022, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

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 our 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 14, 2022

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

SEPTEMBER 30, 2022 AND 2021

	September 30, 2022	September 30, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,215,285	$ 6,554,948
Accounts receivable, net of allowance of $330,853 and $29,821 at September 30, 2022 and 2021, respectively	3,067,544	2,804,039
Inventories	602,244	1,369,933
Prepaid expenses and other current assets	1,058,056	568,881
Total current assets	19,943,129	11,297,801
Property and equipment, net	2,222,988	3,023,915
Other assets:		
Deposits	98,997	95,040
Total assets	$ 22,265,114	$ 14,416,756
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 3,621,751	$ 2,991,343
Deferred revenue	563,557	281,000
Total current liabilities	4,185,308	3,272,343
Long term accrued liabilities	31,467	31,467
Common Warrant liability	5,139,400	—
Total liabilities	9,356,175	3,303,810
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, 2022 and 2021, respectively	—	—
Series A Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2022 and 2021, respectively	—	—
Series B Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2022 and 2021, respectively	—	—
Common stock, par value $0.001 per share; 200,000,000 shares authorized as of September 30, 2022 and 2021, 12,908,520 and 7,486,120 shares issued and outstanding as of September 30, 2022 and 2021, respectively	12,909	7,488
Additional paid in capital	305,399,008	295,228,272
Accumulated deficit	(292,500,088)	(284,122,092)
Applied DNA Sciences, Inc. stockholders' equity:	12,911,829	11,113,668
Noncontrolling interest	(2,890)	(722)
Total equity	12,908,939	11,112,946
Total liabilities and equity	$ 22,265,114	$ 14,416,756

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	2022	2021
Revenues		
Product revenues	$ 1,882,804	$ 3,295,849
Service revenues	759,138	937,735
Clinical laboratory service revenues	15,526,735	4,794,154
Total revenues	18,168,677	9,027,738
Cost of product revenues	2,116,717	1,566,656
Cost of clinical laboratory service revenues	10,998,320	2,978,176
Total cost of revenues	13,115,037	4,544,832
Gross profit	5,053,640	4,482,906
Operating expenses:		
Selling, general and administrative	15,097,360	12,845,372
Research and development	3,926,043	4,164,434
Impairment losses	-	821,741
Total operating expenses	19,023,403	17,831,547
LOSS FROM OPERATIONS	(13,969,763)	(13,348,641)
Interest income, net	7,200	13,675
Loss on extinguishment of convertible notes payable	—	(1,774,662)
Unrealized gain on change in fair value of warrants classified as a liability	17,999,521	—
Gain on extinguishment of notes payable	—	839,945
Transaction costs related to warrant liabilities	(1,668,112)	—
Loss on issuance of warrants	(10,591,600)	—
Other expense, net	(47,305)	(8,756)
Loss before provision for income taxes	(8,270,059)	(14,278,439)
Provision for income taxes	—	—
NET LOSS	(8,270,059)	(14,278,439)
Less: Net (income) loss attributable to noncontrolling interest	2,168	(8,003)
NET LOSS attributable to Applied DNA Sciences, Inc.	(8,267,891)	(14,286,442)
Deemed dividend related to warrant modifications	110,105	—
NET LOSS attributable to common stockholders	$ (8,377,996)	$ (14,286,442)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.93)	$ (2.07)
Weighted average shares outstanding-basic and diluted	8,967,704	6,916,999

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
FOR THE YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	Common Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Total
Balance, October 1, 2021	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
Exercise of warrants	1,674,200	1,673	3,698,402	—	—	3,700,075
Derecognition of warrant liability	—	—	2,802,879	—	—	2,802,879
Stock based compensation expense	—	—	2,518,665	—	—	2,518,665
Common stock issued in public offering, net of offering costs	3,748,200	3,748	740,685	—	—	744,433
Options issued in settlement of accrued bonus	—	—	300,000	—	—	300,000
Deemed dividend - warrant repricing	—	—	110,105	(110,105)	—	—
Net loss	—	—	—	(8,267,891)	(2,168)	(8,270,059)
Balance, September 30, 2022	12,908,520	$ 12,909	$ 305,399,008	$ (292,500,088)	$ (2,890)	$ 12,908,939

See the accompanying notes to the consolidated financial statements

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE YEARS ENDED SEPTEMBER 30, 2022 AND 2021

	Twelve Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (8,270,059)	$ (14,278,439)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,290,480	844,438
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)
Public offering costs incurred	1,668,112	—
Loss on issuance of warrants	10,591,600	—
Unrealized gain on change in fair value of the warrants classified as a liability	(17,999,521)	—
Stock-based compensation	2,518,665	1,668,003
Provision for bad debts	269,451	28,629
Change in operating assets and liabilities:		
Accounts receivable	(532,957)	(2,638,350)
Inventories	767,689	(872,566)
Prepaid expenses and other current assets and deposits	(493,220)	30,415
Accounts payable and accrued liabilities	930,497	94,711
Deferred revenue	282,557	(230,036)
Net cash used in operating activities	(8,976,706)	(13,387,955)
Cash flows from investing activities:		
Purchase of property and equipment	(489,553)	(2,548,695)
Net cash used in investing activities	(489,553)	(2,548,695)
Cash flows from financing activities:		
Net proceeds from exercise of warrants	3,700,075	2,613,929
Net proceeds from issuance of common stock and warrants	14,426,521	13,756,507
Repayment of convertible notes	—	(1,665,581)
Net cash provided by financing activities	18,126,596	14,704,855
Net increase (decrease) in cash and cash equivalents	8,660,337	(1,231,795)
Cash and cash equivalents at beginning of period	6,554,948	7,786,743
Cash and cash equivalents at end of period	$ 15,215,285	$ 6,554,948
Supplemental Disclosures of Cash Flow Information:		
Cash paid during period for interest	$ —	$ —
Cash paid during period for income taxes	$ —	$ —
Non-cash investing and financing activities:		
Interest paid in kind	$ —	$ 28,329
Deemed dividend warrant modifications	$ 110,105	$ —
Property and equipment acquired, and included in accounts payable	$ —	$ 181,807
Issuance of stock options for payment of accrued bonus	$ 300,000	$ —
Issuance of warrants in settlement of convertible notes payable	$ —	$ 1,074,118
Fair value of warrants exercised	$ 2,802,879	$ —
Fair value of warrants issued	$ 25,939,000	$ —

See the accompanying notes to the consolidated financial statements

NOTE A – NATURE OF THE BUSINESS

Applied DNA Sciences, Inc. ("Applied DNA" or the "Company") is a biotechnology company developing technologies to produce and detect deoxyribonucleic acid ("DNA"). The Company uses the polymerase chain reaction ("PCR") to enable both the production and detection of DNA, for use in three primary markets: (i) the manufacture of DNA for use in nucleic acid-based therapeutics ("Therapeutic DNA Production Services"); (ii) the detection of DNA in molecular diagnostics testing services ("MDx Testing Services"); and (iii) the manufacture and detection of DNA for industrial supply chain security services ("DNA Tagging and Security Products and Services"). Under its MDx Testing Services, the Company's wholly owned subsidiary, Applied DNA Clinical Labs, LLC ("ADCL"), is offering a high-throughput turnkey solution for population-scale COVID-19 testing marketed as safeCircle™. safeCircle utilizes the Company's COVID-19 Diagnostic Tests and is designed to look for infection within defined populations or communities utilizing high throughput testing methodologies (the "COVID-19 Testing Services").

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.

NOTE B – LIQUIDITY AND MANAGEMENT'S PLAN

The Company has recurring net losses, which have resulted in an accumulated deficit of $292,500,088 as of September 30, 2022. The Company incurred a net loss of $8,270,059 and generated negative operating cash flow of $8,976,706 for the twelve-month period ended September 30, 2022. At September 30, 2022, the Company had cash and cash equivalents of $15,215,285 and working capital of $15,757,821.

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. Through September 30, 2022, the Company has dedicated most of its financial resources to commercialization of its MDx Testing Services, specifically its COVID-19 Testing Services, as well as to research and development efforts, primarily in the Therapeutic DNA Production segment, including the development and validation of its own technologies as well as, advancing its intellectual property, and general and administrative activities.

As discussed in Note H, on August 8, 2022, the Company closed on a public offering of 3,000,000 shares of Common Stock and warrants, at a purchase price of $4.00 per share. The net proceeds, after deducting the placement agent's fees and other offering expenses were approximately $10.7 million. Also, the Company received $3.7 million in proceeds from the exercise of 925,000 Series B Warrants.

The Company has alleviated the substantial doubt of a going concern through the cash received from the August 2022 public offering and the warrant exercises, discussed above, as well as collection of its accounts receivable. The Company estimates that it will have sufficient cash and cash equivalents to fund operations for the next twelve months from the date of filing of this annual report.

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

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES

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, recoverability of long-lived assets, including the values assigned to property and equipment, fair value calculations for 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 product revenues are accounted for/recognized 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.

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

Revenue Recognition, continued

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. For those customers with a fixed monthly fee, the revenue is recognized over-time as the services are provided.

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.

Disaggregation of Revenue

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

	Fiscal Years Ended: September 30,	
	2022	2021
Research and development services (over-time)	$ 592,001	$ 799,718
Clinical laboratory testing services (point-in-time)	10,398,782	4,231,654
Clinical laboratory services (over-time)	5,127,953	562,500
Product and authentication services (point-in-time):		
Supply chain	887,061	1,003,248
Asset marking	534,594	458,409
MDx test kits and supplies	628,286	1,972,209
Total	$ 18,168,677	$ 9,027,738

Contract balances

As of September 30, 2022, 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.

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

Revenue Recognition, continued

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

	Balance sheet classification	October 1, 2021	September 30, 2022	$ change
Contract liabilities	Deferred revenue	$ 281,000	$ 563,557	$ (282,557)

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

For the fiscal year ended September 30, 2022, the Company recognized $31,061 of revenue that was included in contract liabilities as of October 1, 2021.

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, 2022 and 2021, cash equivalents were $15,215,285 and $6,554,948, respectively.

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, 2022 and 2021, the Company has an allowance for doubtful accounts of $330,853 and $29,821, 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.

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

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, 2022 and 2021, the Company incurred losses from operations. Based upon these results and the trends in the Company's performance projected for fiscal year 2022, 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, 2022 and 2021. Tax years 2017 through 2020 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:

	September 30,	
	2022	2021
Computer equipment	$ —	$ —
Lab equipment	4,059,754	3,565,057
Furniture	—	—
Vehicles	108,361	108,361
Leasehold improvements	124,825	124,825
Total	4,292,940	3,798,243
Accumulated depreciation	2,069,952	774,328
Property and equipment, net	$ 2,222,988	$ 3,023,915

As of September 30, 2022 and 2021, there was $127,935 and $6,580 of construction in progress, respectively that was included in lab equipment. Depreciation expense for the fiscal years ended September 30, 2022 and 2021 were $1,290,480 and $767,025, respectively.

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

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Events relating to recoverability may include significant unfavorable changes in business conditions, recurring losses, or a forecasted inability to achieve break-even operating results over an extended period. The Company evaluates the recoverability of long-lived assets based upon forecasted undiscounted cash flows. Should impairment in value be indicated, the carrying value of long-lived assets will be adjusted, based on estimates of future discounted cash flows resulting from the use and ultimate disposition of the asset. 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. Such intangible assets were 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, 2022 and 2021, 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, 2022 and 2021 are as follows:

	2022	2021
Warrants	7,313,963	745,268
Options	1,063,055	487,377
	8,377,018	1,232,645

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.

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

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, 2022 and 2021, the Company had cash and cash equivalents of approximately $14.6 million and $6.0 million in excess of the FDIC insurance limit, respectively.

The Company's revenues earned from sale of products and services for the fiscal year ended September 30, 2022 included an aggregate of 58% from one customer within the MDx Testing Services segment.

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 within the MDx Testing Services segment.

Two customers accounted for 89% of the Company's accounts receivable at September 30, 2022 and two customers accounted for an aggregate of 67% of the Company's total accounts receivable at September 30, 2021.

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, 2022 and 2021, the Company incurred research and development expenses of 3,926,043 and $4,164,434, respectively.

Advertising

The Company follows the policy of charging the costs of advertising to expense as incurred. The Company charged to operations $293,395 and $283,621, as advertising costs for the fiscal years ended September 30, 2022 and 2021, respectively.

Goodwill and Other Intangible Assets

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

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

The Company evaluates goodwill for impairment at least annually. The Company qualitatively and quantitatively determines whether, more likely than not, the fair value exceeds the carrying amount of a reporting unit. There are numerous assumptions and estimates underlying the quantitative assessments including future earnings, long-term strategies, and the Company's annual planning and forecasts. If these planned initiatives do not accomplish the targeted objectives, the assumptions and estimates underlying the quantitative assessments could be adversely affected and have a material effect upon the Company's financial condition and results of operations. As of September 30, 2021, as a result of the qualitative analysis performed, the Company has recorded a non-cash impairment charge of $821,741 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.

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

Warrant Liabilities

The Company evaluated the Common Warrants and the Series A and Series B Warrants (collectively the "Warrants) in accordance with ASC 480 "Distinguishing Liabilities from Equity" and ASC 815-40, "Derivatives and Hedging — Contracts in Entity's Own Equity" and concluded that due to the terms of the warrant agreements, the instruments do not qualify for equity treatment. As such, the Warrants were recorded as a liability on the consolidated balance sheet and measured at fair value at inception and at each reporting date in accordance with ASC 820, "Fair Value Measurement", with changes in fair value recognized in the consolidated statement of operations in the period of change.

Offering Costs

The Company complies with the requirements of the ASC 340-10-S99-1 and SEC Staff Accounting Bulletin ("SAB") Topic 5A - "Expenses of Offering". Offering costs consist principally of professional and underwriting fees incurred. Accordingly, in relation to the registered direct offering and the public offering (See Note H), offering costs in the aggregate of $1,766,170 were incurred, of which $98,058 was charged to additional paid in capital, and $1,668,112 was allocated to the liability classified warrants, and are included in other expense in the accompanying consolidated statement of operations for the twelve-month period ended September 30, 2022.

Segment Reporting

The Company has three reportable segments. (1) Therapeutic DNA Production Services (2) MDx Testing Services, and (3)DNA Tagging and Security Products and Services. Resources are allocated by our CEO, COO, CFO and CLO whom, collectively the Company has determined to be our Chief Operating Decision Maker (CODM). The following is a brief description of our reportable segments.

Therapeutic DNA Production Services — Segment operations consist of the manufacture of DNA for use in nucleic acid-based therapeutics.

MDx Testing Services— Segment operations consist of performing and developing clinical molecular diagnostic tests and clinical laboratory testing services. Under our MDx testing services, ADCL provides COVID-19 testing for large populations marketed under its safeCircle™ trademark. It also includes the sales of our MDx test kits and related supplies.

DNA Tagging and Security Products and Services — Segment operations consist of the manufacture and detection of DNA for industrial supply chain security services.

The accounting policies of the segments are the same as those described in the "Summary of Accounting Policies" above. The Company evaluates the performance of its segments and allocates resources to them based on revenues and operating income (losses). Operating income (loss) includes intersegment revenues, as well as a charge allocating all corporate headquarters costs. Since each vertical has shared employee resources, payroll and certain other general expense such as rent, and utilities were allocated based on an estimate by management of the percentage of employee time spent in each vertical. Segment assets are not reported to, or used by, the CODM to allocate resources to, or assess performance of, the segments and therefore, total segment assets have not been disclosed.

Fair Value of Financial Instruments

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

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

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

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

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

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

For fair value measurements categorized within Level 3 of the fair value hierarchy, the Company's accounting and finance department, which reports 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, 2022, there were no transfers between Levels 1, 2 and 3 of the fair value hierarchy.

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, 2022 and 2021:

	2022	2021
Raw materials	$ 471,947	$ 786,938
Work in progress	55,817	—
Finished goods	74,480	582,995
Total	$ 602,244	$ 1,369,933

NOTE E – INTANGIBLE ASSETS

Intangible assets at September 30, 2021 are as follows:

	2021
Customer relationships (10-year useful life)	$ 621,000
Intellectual property (5-15 years)	917,350
	1,538,350
Less:	
Accumulated amortization	1,001,995
Impairment losses	536,355
Intangible assets, net	$ —

Total amortization expense charged to operations for the fiscal year ended September 30, 2022 and 2021 were $0 and $68,976, respectively.

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, 2022 and 2021 are as follows:

	2022	2021
Accounts payable	$ 1,744,105	$ 2,010,410
Accrued salaries payable	1,458,661	655,240
Other accrued expenses	418,985	325,693
Total	$ 3,621,751	$ 2,991,343

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.

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 were $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 had an initial 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.

NOTE G – NOTES PAYABLE, continued

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 had an original exercise price of $6.57 and 50,000 of such replacement warrants have an original 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 February 24, 2022, the Company closed a registered direct offering (the "Offering") in which, pursuant to the Securities Purchase Agreement dated February 21, 2022, by and between the Company and an institutional investor, the Company issued and sold 748,200 shares of the Company's Common Stock ("Share") and 748,200 pre-funded warrants ("Pre-Funded Warrants") to purchase shares of the Company's Common Stock. The Pre-Funded Warrants have an exercise price of $0.0001 per share and were immediately exercisable and can be exercised at any time after their original issuance until such Pre-Funded Warrants are exercised in full. Each Share was sold at an offering price of $2.80 and each Pre-Funded Warrant was sold at an offering price of $2.7999. Pursuant to the Securities Purchase Agreement, in a concurrent private placement (together with the Registered Direct Offering, the "Offerings"), the Company issued unregistered warrants ("Common Warrants") to purchase up to 1,496,400 shares of Common Stock. Each Common Warrant has an exercise price of $2.84 per share, is exercisable six months from the date of issuance and will expire five years from the initial exercise date on August 24, 2027. The gross proceeds of the offering, before deducting placement agent fees and other offering expenses, were approximately $4.2 million. On June 9, 2022, all of the 748,200 Pre-Funded Warrants were exercised.

After deducting underwriting discounts and commissions and other expenses related to the offering, the aggregate net proceeds were approximately $3.7 million.

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

The exercise price and number of the shares of Common Stock issuable upon the exercise of the Common Warrant will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the Warrant Agreement. The Common Warrants are recorded as a liability in the consolidated balance sheet and were recorded at fair value and will be marked to market at each period end. The fair value of the Common Warrants upon issuance was $3,350,400. The fair value of the warrants as of September 30, 2022 was $1,477,000, which resulted in an unrealized gain in the change in fair value of Common Warrants of $1,873,400 for the twelve-month period ended September 30, 2022. Additionally, the Company allocated $391,335 of transaction costs to the warrant liabilities which is included in the consolidated statement of operations for the twelve-month period ended September 30, 2022.

As a result of this financing, the exercise price of the 458,813 remaining warrants issued during November 2019, 159,000 warrants issued during October 2020 and 100,000 warrants issued during December 2020 was all reduced to an exercise price of $2.80 per share in accordance with the adjustment provision contained in their respective warrant agreements. The incremental change in fair value of these warrants as a result of the triggering event was $110,105 and is recorded as a deemed dividend in the consolidated statement of operations for the twelve-month period ended September 30, 2022.

NOTE H – CAPITAL STOCK, continued

On August 8, 2022, the Company closed on a public offering (the "August 2022 Offering") of 3,000,000 shares of its common stock (or common stock equivalents in lieu thereof), together with Series A warrants to purchase up to 3,000,000 shares of its common stock and Series B warrants to purchase up to 3,000,000 shares of its common stock at a combined offering price to the public of $4.00 per share (or $3.9999 per common stock equivalent with an exercise price of $0.0001) and associated warrants, priced at a premium to market under Nasdaq rules. The Series A warrants have an exercise price of $4.00 per share, are exercisable immediately upon issuance, and expire five years following the date of issuance. The Series B warrants have an exercise price of $4.00 per share, are exercisable immediately upon issuance, and expire thirteen months following the date of issuance. The gross proceeds to the Company from the offering were approximately $12 million, before deducting the placement agent's fees and other offering expenses payable by the Company.

After deducting placement agent's fees and commissions and expenses, other expenses related to the August 2022 Offering, the aggregate net proceeds were approximately $10.7 million.

Subject to limited exceptions, a holder of a Series A or B Warrant 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 Series A or B 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. The Common Warrants are recorded as a liability in the consolidated balance sheet and were recorded at fair value and will be marked to market at each period end (see Note I). Additionally, the Company allocated $ 1,276,777 of transaction costs to the warrant liabilities which is included in the consolidated statement of operations for the twelve-month period ended September 30, 2022.

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 the placement agent"). Net proceeds, after deducting underwriting discounts and commissions, and other offering expenses, were approximately $13.8 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, 2021	745,268	$ 6.44
Granted	9,142,413	3.31
Exercised	(1,854,200)	(2.00)
Cancelled or expired	(719,518)	(6.16)
Balance, September 30, 2022	7,313,963	$ 3.68

Series A Warrants

The Series A warrants are recorded as a liability in the consolidated balance sheet were recorded at fair value and will be marked to market at each period end. The fair value of the Series A Warrants upon issuance and as of September 30, 2022, was $ 13,414,000 and $2,883,000, respectively, which resulted in an unrealized gain in the change in fair value of Series A Warrants of $10,531,000 for the twelve-month period ended September 30, 2022.

Series B Warrants

The Series B warrants are recorded as a liability in the consolidated balance sheet and were recorded at fair value and will be marked to market at each period end. The fair value of the Series B Warrants upon issuance was $9,174,600. During the twelve-month period ended September 30, 2022, there were 925,000 Series B Warrants exercised, with a fair value upon exercise of $2,802,879. The fair value of the remaining Series B Warrants as of September 30, 2022, was $779,400. These changes in fair value resulted in an unrealized gain in the change in fair value of the Series B Warrants of $5,566,365 for the twelve-month period ended September 30, 2022.

Stock Options

During June 2020, the Board of Directors and subsequently during September 2020, the holders of a majority of the Company's 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.

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.

NOTE I – STOCK OPTIONS AND WARRANTS, continued

Stock Options, continued

Transactions involving stock options issued are summarized as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value	Weighted Average Contractual Life (years)
Outstanding at October 1, 2021	487,377	$ 40.26		
Granted	588,187	5.94		
Exercised	—	—		
Cancelled or expired	(12,509)	99.63		
Outstanding at September 30, 2022	1,063,055	20.49		
Vested at September 30, 2022	840,012	24.57	—	7.67
Non-vested at September 30, 2022	223,043	5.53	—	9.08

For the twelve-month period ended September 30, 2022, the Company granted 361,552 options to officers of the Company. These options have a ten-year term and vest immediately. Also, during the twelve-month period ended September 30, 2022, 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.

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.

The fair value of options granted during the fiscal years ended September 30, 2022 and 2021 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:

	2022	2021
Stock price	$ 5.55	$ 6.43
Exercise price	$ 594	$ 6.43
Expected term	5.16	5.10
Dividend yield	—	—
Volatility	143 %	141 %
Risk free rate	1.18 %	0.47 %

The Company recorded $2,518,665 and $1,668,003 as stock compensation expense within selling, general and administrative for fiscal years ended September 30, 2022 and 2021, respectively. As of September 30, 2022, unrecorded compensation cost related to non-vested awards was $125,118 which is expected to be recognized over a weighted average period of approximately 0.20 years. The weighted average grant date fair value per share for options granted during the fiscal years ended September 30, 2022 and 2021 was $0.84 and $5.72, respectively.

NOTE J – INCOME TAXES

The income tax provision (benefit) for the fiscal years ended September 30, 2022 and 2021 consists of the following:

	2022	2021
Federal:		
Current	$ —	$ —
Deferred	(2,781,000)	(1,423,000)
	(2,781,000)	(1,423,000)
State and local:		
Current	—	—
Deferred	(852,000)	(26,000)
	(852,000)	(26,000)
Foreign:		
Current	—	—
Deferred	11,000	18,000
	—	—
Change in valuation allowance	3,622,000	1,431,000
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, 2022 and 2021 as follows:

	2022	2021
Statutory federal income tax rate	21.00 %	21.00 %
Statutory state and local income tax rate (1%, as of September 30, 2021 and 2020), net of federal benefit	6.20 %	1.52 %
Stock based compensation	(5.01)%	(11.54)%
Permanent differences related to warrants	14.60 %	— %
Other permanent differences	1.70 %	(0.56)%
Federal R&D Credit	3.83 %	— %
Change in deferred tax rate	1.56 %	(0.41)%
Change in valuation allowance	(43.88)%	(10.01)%
Effective tax rate	0.00 %	0.00 %

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

	September 30,	
	2022	2021
Deferred tax assets (liabilities):		
Stock based compensation	$ 847,000	$ 650,000
Depreciation and amortization	113,000	247,000
Net operating loss carry forward	22,872,000	20,115,000
Impairment of intangibles	205,000	187,000
Tax credits	2,055,000	1,566,000
Other	397,000	99,000
Less: valuation allowance	(26,489,000)	(22,864,000)
Net deferred tax asset	$ —	$ —

NOTE J – INCOME TAXES, continued

As of September 30, 2022, the Company has approximately $94,315,000 of Federal and $45,746,000 of State net operating loss "NOL" carryforwards available. The Federal NOL of $60,374,000 begins 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, and as a result of the August 2022 public offering. The annual limitation ranges between $94,000 and $1,528,742 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 $3,622,000.

The Company has Federal research and development credits of approximately $1,552,000 that will begin to expire after 2034. The Company also has state investment tax credits of $457,000 that will begin to expire after 2029.

On August 16, 2022, President Biden signed the Inflation Reduction Act, which is effective for tax years beginning on or after January 1, 2023 and includes a corporate minimum tax on certain corporations and a one percent excise tax on stock repurchases. We do not anticipate this legislation will have a material impact on our consolidated financial statements.

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 originally expired on May 31, 2016, with the option to extend the lease for two additional three-year periods. The Company exercised its option to extend the lease for one additional three-year period ending May 31, 2019. 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. On February 1, 2022, the Company entered into a new lease agreement for the same facility for an one-year term, expiring January 31, 2023. The base rent during the additional twelve-month period is $589,056 per annum. 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 August 2022, the Company renewed this lease with a new expiration date of July 31, 2023. The base rent is approximately $6,500 per annum. The Company's future minimum rental payments (excluding real estate tax and maintenance costs as of September 30, 2022 are $199,665 and are considered short-term lease obligations).

Total rent expense for the fiscal years ended September 30, 2022 and 2021 were $587,346 and $565,597, respectively.

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. The initial term was from July 1, 2016 through June 30, 2017, with automatic one-year renewal periods. On July 28, 2017, the employment agreement was renewed for a successive one-year term and the employment agreement has been renewed for successive one-year terms, most recently as of June 30, 2021. Under the employment agreement, the CEO is eligible for a special aggregate cash incentive bonus of up to $800,000, $300,000 of which is payable if and when annual revenue reaches $8 million, plus an additional $100,000 payable for each additional $2 million of annual revenue in excess of $8 million. Pursuant to the contract, the CEO's annual salary was $400,000. The Board of Directors, acting in its discretion, may grant annual bonuses to the CEO. The CEO will be entitled to certain benefits and perquisites and will be eligible to participate in retirement, welfare and incentive plans available to the Company's other employees.

NOTE K – COMMITMENTS AND CONTINGENCIES, continued

Employment agreements, continued

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.

On October 29, 2021, the Board of Directors amended the existing compensatory arrangement with the CEO to increase his salary to $450,000, effective November 1, 2021. Effective March 7, 2022 the CEO voluntarily reduced his salary to $225,000. The CEO's salary was restored back to $450,000 on September 3, 2022 and the CEO was paid a one-time payment of $110,343, which represents the reduction in his salary from March 7, 2022 through September 3, 2022. As of September 30, 2022 the CEO's annual salary was $450,000.

In accordance with the terms of his employment agreement, for the twelve-month period ended September 30, 2022, the CEO earned a $800,000 bonus as the Company's year to date revenue was greater than $18 million. The bonus was not paid as of September 30, 2022 and is included in accounts payable and accrued liabilities in the consolidated balance sheet.

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 – SEGMENT AND GEOGRAPHIC AREA INFORMATION

As detailed in Note C above, the Company has three reportable segments. (1) Therapeutic DNA Production Services (2) MDx Testing Services, and (3)DNA Tagging and Security Products and Services. Resources are allocated by our CEO, COO, CFO and CLO whom, collectively the Company has determined to be our Chief Operating Decision Maker (CODM).

Information regarding operations by segment for the twelve- month period ended September 30, 2022 is as follows:

	Therapeutic DNA Production	MDx Testing Services	DNA Tagging and Security Products	Consolidated
Revenues:				
Product revenues	$ —	$ 628,286	$ 1,254,518	$ 1,882,804
Service revenues	439,355	—	319,783	759,138
Clinical laboratory service revenues	—	15,979,631	—	15,979,631
Less intersegment revenues	—	(452,896)	—	(452,896)
Total revenues	439,355	16,155,021	1,574,301	18,168,677
Gross profit	439,355	4,827,672	(213,387)	5,053,640
Loss from segment operations (a)	(4,497,699)	(464,894)	(4,652,786)	(9,615,379)

Information regarding operations by segment for the twelve- month period ended September 30, 2021 is as follows:

	Therapeutic DNA Production	MDx Testing Services	DNA Tagging and Security Products	Consolidated
Revenues:				
Product revenues	$ —	$ 1,943,697	$ 1,352,152	$ 3,295,849
Service revenues	559,319	—	378,416	937,735
Clinical laboratory service revenues	—	5,090,794	—	5,090,794
Less intersegment revenues	—	(296,640)	—	(296,640)
Total revenues	559,319	6,737,851	1,730,568	9,027,738
Gross profit	559,318	3,327,080	596,508	4,482,906
Loss from segment operations (a)	(5,214,221)	(274,250)	(4,823,348)	(10,311,819)

Reconciliation of segment loss from operations to corporate loss:

	2022	2021
Loss from operations of reportable segments	$ (9,615,379)	$ (10,311,819)
General corporate expenses (b)	(4,354,384)	(3,036,822)
Interest income (expense), net	7,200	13,675
Unrealized gain on change in fair value of warrants	17,999,521	—
Transaction costs related to warrant liabilities	(1,668,112)	—
Loss on issuance of warrants	(10,591,600)	—
Loss on extinguishment of convertible notes payable	—	(1,774,662)
Gain on extinguishment of notes payable	—	839,945
Other expense, net	(47,305)	(8,756)
Consolidated loss before provision for income taxes	$ (8,270,059)	$ (14,278,439)

(a) Segment operating loss consists of net sales less cost of sales, specifically identifiable research and development, and selling, general and administrative expenses.

(b) General corporate expenses consists of Selling, general and administrative expenses that are not specifically identifiable to a segment.

NOTE L – SEGMENT AND GEOGRAPHIC AREA INFORMATION, continued

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,	
	2022	2021
Americas	$ 17,544,444	$ 8,520,336
Europe	448,847	359,509
Asia and other	175,386	147,893
Total	$ 18,168,677	$ 9,027,738

NOTE M — RELATED PARTY TRANSACTIONS

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. As of September 30, 2022, Dillon Hill Capital, LLC and its affiliate, Dillon Hill Investment Company, LLC, are no longer a greater than 5% shareholder.

NOTE N – FAIR VALUE OF FINANCIAL INSTRUMENTS

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

The following table presents the fair value of the Company's financial instruments as of September 30, 2022 and summarizes the significant unobservable inputs in fair value measurement of Level 3 financial assets and liabilities as of September 30, 2022. The Company did not have any assets or liabilities categorized as Level 1 or 2 as of September 30, 2022.

	Fair value at September 30, 2022	Valuation Technique	Unobservable Input	Range	Weighted Average
Liabilities:					
Common Warrants	$ 1,477,000	Monte Carlo simulation	Annualized volatility	146.72% - 174.63 %	160.00 %
Series A Warrants	$ 2,883,000	Monte Carlo simulation	Annualized volatility	146.72% - 174.63 %	160.00 %
Series B Warrants	$ 779,400	Monte Carlo simulation	Annualized volatility	146.72% - 174.63 %	170 %

The change in fair value of the Common Warrants for the twelve-month period ended September 30, 2022 is summarized as follows:

	Common Warrants
Fair value at issuance, February 24, 2022	$ 3,350,400
Change in fair value	(1,873,400)
Fair Value at September 30, 2022	$ 1,477,000

The change in fair value of the Series A and Series B Warrants for the twelve-month period ended September 30, 2022 is summarized as follows:

	Series A Warrants	Series B Warrants
Fair value at issuance August 8, 2022	$ 13,414,000	$ 9,174,600
Fair value of warrants exercised	—	(2,828,835)
Change in fair value	(10,531,000)	(5,566,365)
Fair Value at September 30, 2022	$ 2,883,000	779,400

LIHTI | LONG ISLAND HIGH TECH INCUBATOR

Beth Jantzen, CPA
Chief Financial Officer
Applied DNA Sciences, Inc.
50 Health Sciences Drive
Stony Brook, NY 11790

February 1, 2022

Dear Ms. Jantzen,

In accordance with your Lease dated June 14, 2013, the Long Island High Technology Incubator, Inc. hereby renews your lease for a period of one year.

The Term of the renewal is February 1, 2022 to January 31, 2023. Applied DNA Sciences, Inc. occupies approximately 30,000/sf space in 50 Health Sciences Drive, Stony Brook, NY 11790. Your new rent will be $42,488/mo; $509,856 per annum.

All other conditions set forth in the lease remain in effect for the renewal Term. Please note that rent is due by the 5th day of the month. Any rent received after the 15th will be subject to a late fee.

Please sign and return the agreement to our office indicating your acceptance. Upon receipt, LIHTI's Executive Director, Anil Dhundale, PhD will sign the renewal and we will deliver to you the fully executed agreement. We look forward to your continued success in the months ahead. Thank you.

Best regards,

/s/Anil Dhundale, PhD
Anil Dhundale, PhD
Executive Director
Long Island High Technology Incubator, Inc.

2/1/2022
Date

/s/ Beth Jantzen, CPA
Beth Jantzen, CPA
Chief Financial Officer
Applied DNA Sciences, Inc.

2/1/2022
Date

LIHTI | NGIil't INCUBATOR

Beth Jantzen, CPA
Chief Financial Officer
Applied DNA Sciences, Inc.
50 Health Sciences Drive
Stony Brook, NY 11790

February 1, 2022

Dear Ms. Jantzen,

In accordance with your Lease dated November 1, 2015, the Long Island High Technology Incubator, Inc. hereby renews your lease for a period of one year.

The Term of the renewal is February 1, 2022 to January 31, 2023. Applied DNA Sciences, Inc. occupies 2,200/sf of laboratory space in 25 Health Sciences Drive, Stony Brook, NY 11790. Your rent will remain $6,600/mo.; $79,200 per annum.

All other conditions set forth in the Lease remain in effect for the renewal Term. Please note that rent is due by the 5th day of the month. Any rent received after the 15th will be subject to a late fee.

Please sign and return the agreement to our office indicating your acceptance. Upon receipt, LIHTI's Executive Director, Anil Dhundale, PhD will sign the renewal and we will deliver to you the fully executed agreement. We look forward to your continued success in the months ahead. Thank you.

/s/ Anil Dhundale, PhD
Anil Dhundale, PhD
Executive Director
Long Island High Technology Incubator, Inc.

2/1/2022
Date

/s/ Beth Jantzen, CPA
Beth Jantzen, CPA
Chief Financial Officer
Applied DNA Sciences, Inc.

2/1/2022
Date

Portions of this exhibit have been omitted because the information is both not material and is the type that the Company treats as private or confidential. The omissions have been indicated by bracketed asterisks ("[***]").

Contract Number T212206
by and between
The City University of New York
and
Applied DNA Clinical Labs, LLC

This is a services contract ("Contract" or "Agreement") by and between The City University of New York, located at 205 East 42nd Street, New York, New York 10017 ("College" or "University" or "Client"), and Applied DNA Clinical Labs, LLC, located at 25 Health Sciences Drive, Suite 120, Stony Brook, New York 11790 ("Contractor" or "Company"). In consideration of the mutual covenants and agreements herein made, the parties hereby agree as follows:

1. This Contract is entered into following the issuance of University's Request for Proposal, UCO 832 released June 22, 2021 ("RFP") and evaluation of proposals received in response to the RFP. This Contract incorporates herein the RFP, including all attachments and exhibits attached thereto and all addenda to the RFP issued by the University, and the Contractor's Proposal in response to the RFP.

2. The University engages Contractor to provide for a period of one (1) year from July 21, 2021 through July 20, 2022 ("Term") the COVID-19 Testing and Related Services described in the scope of work under the terms and conditions set forth herein.

3. The amount payable under this Contract during the Term shall not exceed [***] dollars ([***]), and the University shall not be required to pay to Contractor under this Contract any sums in excess of such amount unless such amount has been increased by an amendment to this Contract signed by both parties.

Unit pricing under this Contract (the "Unit Prices") are set forth in the table below:

	Weekly Tests Scenarios		
Type of Test	**25,000 20% testing	**40,000 30% testing	**65,000 50% testing
*Unit price per PCR Test: Administered by Contractor	[***]	[***]	[***]
*Unit price per PCR Test: Self-Administered under supervision of Contractor	[***]	[***]	[***]
*Unit price per PCR Drop Off Test	[***]	[***]	[***]

* Unit price includes all costs associated, as applicable, for conducting/administering, collecting, sending sample to laboratory, retrieving results and uploading/sharing results with and with the tested individual and any other related costs in providing the services in accordance with the scope herein. Contractor will not charge, and University will not pay any charges or costs that are additional to the prices included in the unit prices as set forth above.

** These numbers are estimates and do not in any way represent a guaranteed testing volume or a commitment from Client. Client will pay only for actual tests administered, self-administered, and used.

4. The following documents constitute the Contract (collectively "Contract Documents"), listed in order of precedence in the event of a conflict between or among the Contract Documents: NYS Appendix A, these signature pages and the contract terms and conditions attached, the RFP including addenda issued, and the Contractor's Proposal.

IN WITNESS WHEREOF, the parties hereto, by their duly authorized representatives, have executed this Contract as of the last day signed below.

Instruction to Contractor: *Sign in the presence of a notary; have Certificate of Acknowledgment (next page) completed and signed.*	**Applied DNA Clinical Labs, LLC** EIN: [***] By: /s/ James A. Hayward (signature of authorized representative) Name: James A. Hayward (print name of authorized representative) Title: President and CEO (print title of authorized representative)

AGENCY APPROVALS –Contract Number: C212206–Covid-19 Testing and Related Services

In addition to the acceptance of this Contract, the University certifies that original copies of this signature page will be attached to all exact copies of this Contract.

Contract Preparer's Name and Signature: _____

Approved as to Form /s/ Marina Ho/RHo Office of the General Counsel The City University of New York Date: 8/2/2021	THE CITY UNIVERSITY OF NEW YORK By: /s/ Derek Davis Derek Davis, General Counsel and Senior Vice Chancellor of Legal Affairs Its Duly Authorized Officer Date: August 3, 2021

Approved as to Form NEW YORK STATE ATTORNEY GENERAL N/A	Approved NEW YORK STATE COMPTROLLER N/A

CERTIFICATE OF ACKNOWLEDGMENT OF THE CONTRACTOR – INDIVIDUAL, CORPORATION, PARTNERSHIP, or LIMITED LIABILITY COMPANY:
STATE OF[***])
) ss:
COUNTY OF[***])

On the [***] day of [***] in the year 2021, before me, the undersigned, [***], personally known to me or proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to the within instrument and acknowledged to me that s/he executed the same in her/his capacity, and that by her/his signature on the instrument, the individual, or the person upon behalf of which the individual acted, executed the instrument; and further that.
[Mark an X in the appropriate box and complete the accompanying statement.]

- o (If an individual): he executed the foregoing instrument in his/her name and on his/her own behalf.
- o (If a corporation): he is the _____ of _____, the corporation described in said instrument; that, by authority of the Board of Directors of said corporation, he is authorized to execute the foregoing instrument on behalf of the corporation for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said corporation as the act and deed of said corporation.
- o (If a partnership): he is the _____ of _____, the partnership described in said instrument; that, by the terms of said partnership, he is authorized to execute the foregoing instrument on behalf of the partnership for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said partnership as the act and deed of said partnership.
- o (If a limited liability company): he is a duly authorized member of [***] LLC, the limited liability company described in said instrument; that he is authorized to execute the foregoing instrument on behalf of the limited liability company for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said limited liability company as the act and deed of said limited liability company.

Notary Stamp

[***] [***]
Notary Public or Commissioner of Deeds Registration No.

Contract Terms and Conditions

Contractor shall provide to The City University of New York ("University") the labor, materials, and equipment to provide the Work as set forth in the COVID Testing Services, in accordance with these contract terms and conditions, New York State Appendix A (October 2019), and the University's Purchase Order terms and conditions.

Contractor shall provide all labor ("Services"), materials, including personal protective equipment and collection supplies (items that Contractor supplies to College and are used in the provision of Services shall be referred to as "Materials"), and tools and equipment (items that belong to Contractor that Contractor uses to perform the Services shall be referred to as "Equipment"). The Services, Equipment, and Materials shall be referred to collectively as "Work." Contractor shall provide the Work in locations to be identified by the College ("Sites") as set forth herein.

All terms used herein but not defined herein shall have the meaning set forth elsewhere in this document.

Section 1 - Contractor Requirements

1.1 During any absence of Contractor's Representative, Contractor shall designate an alternate Contractor's Representative under the same terms and conditions.

1.2 Contractor only shall assign competent personnel who are qualified to provide the Services. If Contractor's Representative is notified in writing that, in the reasonable opinion of College, any worker, employee, or agent of Contractor or its subcontractors is incompetent or otherwise unacceptable, then Contractor shall promptly replace such worker, employee, agent, or subcontractor and shall not assign such person or entity to this Contract again.

1.3 None of the provisions of this Contract are intended to create and none shall be deemed or construed to create, any relationship between the parties other than that of independent entities contracting solely for the purposes set forth herein. This Contract is not intended, and shall not be construed, to create a venture, partnership, association; trustee-beneficiary relationship, principal-agent relationship, or fiduciary relationship, between the parties.

1.4 Contractor shall not employ or use any labor, materials, or means whose employment or use during the course of this Contract may or in any way cause or result in strikes, work stoppages, delays, suspension of work, or similar actions by: (1) employees or agents of College; or (2) any of the trades working in or about the buildings and premises where Work is being performed; or (3) College or its subcontractors pursuant to other agreements or contracts, on or at the University, College, or any other building or premises owned or operated by the City or the State, and/or their respective agencies, departments, boards, or authorities. Any violation by Contractor of this requirement may be considered proper and sufficient cause for declaring Contractor to be in default under this Contract, and for the University, the City, or the State or any or all of them to take such action against it or any such other action as it or they may deem proper.

1.5 Contractor shall have and maintain in good standing, all required licenses, permits, certificates, and the like. Contractor shall deliver copies of all such documents to the College Representative before commencement of the Services and upon request from College.

1.6 Contractor shall execute all Work in strict conformance with all applicable statutes and regulations concerning the administration of the Services, including those concerning the qualifications of any worker, employee, or agent of Contractor and its subcontractors. Contractor will ensure that every worker, employee, or agent of Contractor and of its subcontractors (collectively, "Contractor's Personnel") is competent, qualified, and skilled to perform the services for which they are responsible. Contractor will not knowingly permit any Contractor's Personnel to perform the Services who does not possess the requisite qualifications to perform such Services, or who has any record of failure to properly perform the Services in accordance with applicable standards or guidelines or any similar situation that may reasonably suggests the Contractor's Personnel is incapable of performing the Services. Prior to assigning Contractor's Personnel to perform the Services, Contractor must conduct a thorough check of the Contractor's Personnel to ensure said Contractor's Personnel's qualifications and satisfactory performance history. Contractor also must conduct similar periodic assessments of the Consultant's Personnel during the Term of this Contract. Contractor shall ensure that all contracts with subcontractors impose these obligations on the subcontractors, and Contractor shall monitor its subcontractors' compliance with such obligations.

1.7 Contractor acknowledges and agrees that no change in or modification to or discharge of this Contract, in any form whatsoever, shall be valid or enforceable unless it is in writing and signed by an authorized representative of the party to be charged therewith.

1.8 Contractor shall maintain all records and reports required by Contract, by Law, by best practices, and by industry standards. Immediately upon request from College, Contractor shall provide access to all such records and reports for College review.

1.9 Contractor acknowledges and agrees that in work of this character, it is impossible either to show all details in advance or to forecast all exigencies precisely. The Contract is to be taken, therefore, as indicating the anticipated amount of work and its nature.

1.10 Contractor shall at all times and in all respects follow best practices and highest industry standards that are applicable to its work. Where no specific requirements are given, Contractor shall conform the Work to the latest applicable standards and provide and install materials that conform to the standards of nationally recognized associations that sponsor the particular type of work involved.

1.11 The language of the Contract is directed at Contractor unless specifically stated otherwise. The Contract language and attachments are complementary, and what is called for by one shall be as binding as if called for by all. In the event of conflicting provisions, Contractor is obligated to seek clarification from College as soon as Contractor becomes aware of any conflicting provisions; in general, however, Contractor is obligated to provide the most expensive option, and the more specific provision will take precedence over the less

specific; the more stringent will take precedence over the less stringent; and the more expensive item will take precedence over the less expensive item.

1.12 Contractor shall comply with all applicable laws, regulations, rules, orders--including executive orders, requirements, and the like of federal, state, and local governments, courts, governmental authorities, legislative bodies, boards, agencies, commissions, and the like ("Law(s)") with respect to this Contract. If there is a conflict between or among any laws and specific requirements of this Contract, then Contractor shall comply with the most stringent Law in each instance.

1.13 By noting any specific Laws with particularity in this Contract or in any other prior or future communication, Contractor is not relieved of any obligation to comply with all Laws, and the University does not waive any rights it may have with respect to such compliance.

1.14 Contractor will protect the confidentiality and information of all students, employees, visitors, and guests tested by Contractor, tested by a party other than Contractor, and relating to vaccination status in connection with the Work. Records generated by Contractor shall be the property of the University. Contractor shall not release any records other than testing results to the University and individual testing participants as required under the Services. Contractor shall treat all records as confidential and treat all records so as to comply with all federal and New York State laws and regulations regarding the confidentiality of patient records. The foregoing shall not restrict Contractor from submitting COVID-19 testing records or results to New York State or federal agencies in compliance with applicable Laws.

1.15 The Services will require Contractor to have access to certain personally identifiable information regarding the University's students. The University hereby appoints Contractor as its agent for the sole purpose of assuming duties in connection with the processing of student records relating to the Services that would otherwise be provided by the University. As an agent of the University, Contractor is subject to and shall comply with the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) ("FERPA") and its prohibitions against disclosure of personally identifiable information regarding students to third parties, except where permitted by the regulations of the United States Department of Education. Contractor shall not disclose personally identifiable information or other information which under FERPA would be deemed a part of the University's student's education record, as such education record is defined under 20 U.S.C. § 1232g(a)(4)(A)(i), (ii), except as is consented to in writing by such student or is otherwise permitted or required by law or regulation. The foregoing shall not restrict Contractor from submitting COVID-19 testing related personally identifiable information to New York State or federal agencies in compliance with applicable Laws.

1.16 HIPAA Compliance. Contractor shall comply with applicable provisions of the Administrative Simplification Section of the Health Insurance Portability and Accountability Act of 1996 as codified at 42 U.S.C. § 1320d through d-8 ("HIPAA"), and the requirements of any regulations promulgated thereunder including, without limitation, the federal privacy regulation as contained in 45 C.F.R. part 164 (the "Federal Privacy

Regulations"), the federal security standards as contained in 45 C.F.R. Part 142 (the "Federal Security Regulation"), and Subtitle D of the Health Information Technology for Economic and Clinical Health Act ("HITECH"). Contractor shall not use or further disclose any protected health information, as defined in 45 CFR 164.504, or individually identifiable health information, as defined in 42 U.S.C. § 1320d (collectively the "Protected Health Information"), concerning a patient other than as permitted by this Contract and the requirements of HIPAA or regulations promulgated under HIPAA including, without limitation, the Federal Privacy Regulations, the Federal Security Regulations, and HITECH. The foregoing shall not restrict Contractor from submitting COVID-19 testing related individually identifiable health information to New York State or federal agencies in compliance with applicable Laws.

1.17 Contractor shall assist the University in its compliance with any federal, state, and municipal health and safety laws, including, but not limited to HIPAA and FERPA regulatory requirements, to the extent applicable.

1.18 Contractor shall ensure that its personnel, staff, and subcontractors practice all CDC-recommended, NYS-recommended, NYC-recommended, and University-recommended social distancing/physical distancing, facial covering, and proper hygiene practices so as to minimize COVID-19 transmission risk.

Section 2 – Work Rules

2.1 Contractor shall provide Services at the Sites only as required by the University.

2.2 Contractor shall require its employees and its subcontractors' employees to contact and check in with the College's Public Safety Office and College Representative at the start of each day when they arrive on College's premises whenever they are scheduled to be at a Site.

2.3 Contractor's employees shall wear and display prominently on their persons identification cards that include the individual's photograph and Contractor's name and the individual's first and last names in clear, easily legible type at all times while on College or University property.

2.4 Contractor shall ensure that its employees and agents follow all University and College rules and regulations.

2.5 Contractor shall contact the College Representative or its designee to arrange for access to the Site, delivery of Materials or Equipment, and use of College facilities and equipment.

2.6 Contractor shall request and obtain approval from College at least seventy-two (72) hours in advance for use of freight elevators or the receiving platform.

2.7 Contractor shall supply all Services and Equipment necessary to provide delivery of all Materials to the Site. Contractor shall deliver all Materials to the Site at the time needed. Contractor shall be responsible for all Materials or Equipment left at the Site or anywhere

on University/College's premises. Contractor acknowledges and agrees that College will not provide any staging or storage areas on College's campus unless Contractor obtains prior written approval from the University/College in advance for same.

2.8 Contractor shall coordinate its Work in and around the Site(s) and with any other contractors or suppliers that may be providing services in the vicinity so as to prevent duplication of effort, disruption of College's schedule, and any damage. Contractor shall protect from damage all property at College while delivering Materials and while performing the Work.

2.9 Contractor shall execute and complete all Work to the full satisfaction and approval of College.

2.10 Contractor shall remove from College's premises and properly label, package, and dispose of all debris caused or created by the Work, including all medical waste, at Contractor's expense on a daily basis.

2.11 Contractor shall ensure that the Sites are left in a first-class condition, broom clean, and ready for use by the University/College each time a shift is completed.

Section 3 – Assignment Prohibited

3.1 Contractor shall not assign or transfer this Agreement, or any of the rights, obligations or remedies of Contractor hereunder, without the prior written consent of the University in each instance. Any purported assignment or transfer in violation of this Article will be void. Contractor acknowledges and agrees that no assignment shall be effective unless and until Contractor, upon receiving any necessary University's written consent (and unless it was theretofore delivered to the University) causes a duly executed copy of the assignment to be delivered to the University within ten (10) days after execution thereof. Any such assignment of this Agreement shall contain an assumption by the assignee of all of the terms, covenants and conditions of this Agreement to be performed by Contractor.

Section 4 – Guarantees and Accreditation

4.1 Contractor shall guarantee that all Services and Work have been executed as required herein.

4.2 Contractor certifies that it and its employees and its subcontractors' employees have the background, training, experience, and necessary licenses and certifications to perform properly the services to be delivered under this Contract and that all such licenses and certifications will be kept current and in good standing. Contractor acknowledges that the University, in entering into this Contract, reasonably expects Contractor to be aware of and that it will comply with all applicable safety standards and necessary safety procedures and practices to be able to perform the services to be delivered under this Contract without injury to the University, the University's constituents, including its students and employees, and any third parties.

4.3 Contractor's COVID-19 testing facility is and shall remain duly licensed under applicable law. Contractor shall provide documentation of such credentials to the University upon request. Contractor's laboratory and any laboratory that Contractor uses, shall comply with applicable standards under the Clinical Laboratory Improvement Amendments of 1988, the College of American Pathologists, and the New York State Clinical Laboratory Evaluation Program.

Section 5 – Termination

5.1 The University may terminate the Contract for cause at any time if:

a. Contractor does not provide any of the information or documents as required under the terms of this Contract; or

b. Contractor misstates, conceals, or fails to disclose any material information in this Contract, or in any written statement or oral examination or hearing, in connection with this Contract; or

c. Contractor fails to advise University within five (5) Business Days if there is any change in the facts or information provided by Contractor after the date Contractor signs this Contract; or

d. the University determines that Contractor has violated any Law(s) or University regulations; or that College is not responsible as "responsible" is defined in the New York State Finance Law; or

e. the University finds that the certification filed by Contractor in accordance with New York State Finance Law §139-k was intentionally false or intentionally incomplete; or

f. on thirty (30) days' written notice to Contractor, for any reason or no reason.

Upon such finding, the University may exercise its termination right by providing written notification to Contractor in accordance with the written notification terms of the Contract.

5.2 The University may terminate the Contract for its convenience, without cause, by providing Contractor with at least thirty (30) days' prior written notice. Such right to terminate shall apply to all or a portion of the Work of the Contract. If the Contract is terminated by University under this Section 5.2 or Section 5.1(f), above, University shall pay Contractor for all Work actually performed through the effective termination date of the Contract.

5.3 Upon the termination of this Contract, neither party shall have any further obligation hereunder with respect to such matters, except for (i) obligations accruing prior to the date of termination, and (ii) obligations, promises or covenants contained herein that are expressly made to extend beyond the term of this Contract.

Section 6 – Payment

6.1 Contractor shall submit invoices to the College's Accounts Payable Department at a time interval and in a format approved by College.

6.2 Contractor shall provide sufficient and appropriate documentation with invoices. College reserves the right to request additional information at any time.

6.3 Contractor shall not submit invoices to College to be paid for any Goods or Services until it has received Acceptance from College.

6.4 College will pay Contractor the Unit Prices set forth in the Contract.

Section 7 - Responsibility for Injuries to Persons or Property

7.1 The term Indemnified Parties, whenever, referred to in this Contract shall consist of the following parties including their officers, employees and agents:

a. The City University of New York ("CUNY");
b. the College, a constituent entity of CUNY ("College");
c. The State of New York;
d. The City of New York; and
e. The Dormitory Authority of the State of New York ("DASNY").

7.2 Contractor shall indemnify and save harmless the Indemnified Parties to the fullest extent permitted by law, from loss and liability upon any and all claims and expenses, including, but not limited to, attorneys' fees, on account of such injuries to persons occurring on account of, or in connection with, the performance of the Work or such damage to property occurring on account of, or in connection with, the performance of the Work, excepting bodily injuries and property damage to the extent caused by the sole negligence of College or CUNY.

7.3 The term "loss and liability," as used herein, shall be deemed to include, but not be limited to, liability for the payment of workers' compensation benefits under the Workers' Compensation Law of the State of New York and/or similar statutes.

7.4 CUNY has hired Contractor, and is relying upon Contractor for its ability, capabilities, and expertise in performing the Work. The approval of College or CUNY of the methods of doing the Work or the failure of College or CUNY to call attention to improper or inadequate methods or to require a change in methods or to direct Contractor to take any particular precautions or to refrain from doing any particular thing shall not excuse Contractor in case of any such injury to person or damage to property.

7.5 n/a

7.6 n/a

7.7 Contractor's Responsibilities

7.7.1 Contractor shall be responsible for (1) all injuries (including death) to persons, including, but not limited to, employees of Contractor and Subcontractors and Indemnified Parties and (2) damage to property, including, but not limited to, property of the Indemnified Parties, Contractor or its subcontractors. The liability hereunder shall be limited to such injuries or damage occurring on account of, or in connection with, the performance of the Work, whether or not the occurrence giving rise to such damage happens at the Site or

whether or not sustained by persons or to property while at the Site, but shall exclude injuries to such persons or damage to such property to the extent such was caused by the negligence of College or CUNY.

7.7.2 Contractor's liability hereunder includes any injury (including death) or damage to property related to the performance of, including the failure to perform, any Work.

7.7.3 Contractor expressly acknowledges that it has reviewed the Contract Documents and if the work is to be considered to be complete without fault or negligence on the part of Contractor, then it will be necessary that the Work will not cause any damage to the foundations, walls or other parts of adjacent, abutting or overhead buildings, above or underground utility pipes, conduits and cables, and/or other similar structures.

Section 8 – Notices, Contact Persons

8.1 Unless the applicable provisions of this Agreement expressly provide that notices may be given telephonically and/or via email, all notices, demands, requests, submissions or other communications which are required to be given by one party to the other party under this Agreement (herein referred to collectively as "notices") must be in writing and must be sent either by certified mail, return receipt requested, or by hand delivery or electronically (tagged for "High Importance" or otherwise noted as such in the caption, with Request for Delivery Receipt) at the receiving party(ies)' addresses set forth below, excluding default notices, termination and cancellation notices, and notices of change of address. Any default notices, termination or cancellation notices may only be sent electronically (tagged for "High Importance" or otherwise noted as such in the caption, with Request for Delivery Receipt), if simultaneously such notice is also sent by certified mail, return receipt requested, or hand-delivered at the receiving party's addresses set forth below in order to be effective.

To Contractor:
Applied DNA Clinical Labs, LLC
25 Health Sciences Drive
Stony Brook, New York 11790
Attention: Judy Murrah, COO
Phone: 631-240-8800
Email: judy.murrah@adnas.com

To CUNY:
The City University of New York

Phone:
Email address:

and to:
The City University of New York
205 East 42nd Street
New York, New York 10017
Attention: General Counsel

Phone: (646) 664-9200
Email address: ogc@cuny.edu

Either party may change its addresses (including its electronic mail addresses) as set forth herein by notice to the other in the manner provided for herein. Notice will be deemed given and received as of five (5) days after the date of mailing in the case of certified mail or when personally delivered or when receipt is rejected in the case of hand delivery or on the date of transmittal in the case of electronic mail (tagged for "High Importance" or otherwise noted as such in the caption, with electronic Request for Delivery Receipt or other confirmation of receipt).

8.2 The University will provide a contact list for each Site, as applicable for routine administrative and day-to-day maintenance and repair matters, as well as COVID-19 communications and security matters. The above shall not be in lieu of any formal notice required or desired to be given under this Agreement, which notice shall be given in accordance with Section 8.1.

Section 9 – Insurance

9.1 Except as otherwise provided herein, Contractor shall procure, at its sole cost and expense, and shall maintain in force at all times during this Contract until delivery of the completed project, policies of insurance set forth below, written by companies with an A.M. Best Company rating of A-7 or better, as approved by CUNY. Contractor shall deliver to College certificates of insurance as evidence of such policies at least (10) ten days prior to commencement of Services at the Site and such certificates shall indicate that the insurance shall not be diminished or canceled without at least 30 days prior written notice to the University. The coverage afforded under the policies shall apply on a primary and not on an excess or contributing basis with any policies which may be available to the University. Except as otherwise provided, policies written on a "claims-made" basis are not acceptable. At least (2) two weeks prior to the expiration of the policies, Contractor shall provide evidence of renewal or replacement policies of insurance, with terms and limits no less favorable than expiring policies to CUNY. Contractor shall be responsible for all claim expense and loss payments within the deductible or self-insured retention. All required policies must include a waiver of subrogation in favor of all the Indemnified Parties set forth in Section 7.1. These requirements apply to any subcontractors or agents that Provider uses in the performance of the work and services provided hereunder and it is Provider's responsibility to assure that subcontractors and agents comply with such requirements.

9.2 Commercial General Liability insurance policy (I.S.O. Form CG 00 01 11 96 or equivalent approved by CUNY) in the Contractor's name with limits of liability of $1,000,000 each occurrence and $2,000,000 aggregate basis for injuries to persons (including death) and damage to property. If the policy is subject to an aggregate limit the aggregate limit must apply on a per location or per project basis and if such aggregate is likely to be exceeded, then Contractor shall be required to provide replacement insurance.

Such policies shall include:

- Contractual coverage for liability assumed by the Contractor;
- Independent Contractors Coverage; and
- Additional Insured Endorsement (latest I.S.O. Form CG 20 10 or equivalent approved by CUNY) naming all the Indemnified Parties set forth in Section 7.1 of this Attachment as additional insureds on a primary and non-contributory basis.

9.3 Business Automobile Liability Insurance Policy (I.S.O. Form CA 00 01 07 97 or equivalent approved by CUNY) in the Contractor's name with limits of liability in the amount of $1,000,000 each accident for claims for bodily injuries (including death) to persons and for damage to property arising out of the ownership, maintenance or use of any owned, hired or non-owned motor vehicle. If the policy is subject to an aggregate limit, replacement insurance will be required if it is likely such aggregate will be exceeded.

9.4 Contractor, at its sole cost and expense, shall maintain malpractice liability insurance covering the acts and omissions (on an occurrence basis) of Contractor with respect to the provision of the Services hereunder. Coverage will be no less than $2 million per occurrence and $5 million in the annual aggregate. Prior to providing any Services hereunder, Contractor shall provide the University with one or more certificates evidencing such coverage. Contractor shall provide the University with certificates evidencing any renewals or replacements thereof.

9.5 Workers' Compensation Insurance (including Employer's Liability Insurance with limits of not less than $2,000,000) meeting the statutory limits of New York State.

9.6 Any additional insurance policies necessary to obtain required permits or otherwise comply with applicable law, ordinances, or regulations regarding the performance of the Work.

9.7 Riders to Policies
The following riders shall be made part of the insurance policies described in this Section:

1. Notice of accident shall be given to the Insurer as soon as practicable but no later than one hundred twenty (120) days after notice to CUNY and the DDCM Chief of Contracts and College Representative of such accident.

2. The presence of representatives of CUNY or College on the Site shall not invalidate this policy.

3. Violation of any of the terms of any other policy issued by the Insurer to the Design Consultant or any subconsultant shall not invalidate this policy.

9.8 Contractor shall supply Certificates of Insurance as evidence of coverage for the policies required by this Contract. If requested by CUNY, Contractor shall deliver to CUNY within ten (10) days of the notice of award of the contract, a copy of such policies. The Certificate of Insurance submitted must: (1) be provided on a Certificate of Insurance Form; (2) be signed by an authorized representative of the insurance carrier or producer; (3) disclose any deductible, self-insured retention, aggregate limit or any exclusions to the policy that materially change the coverage; (4) indicate the Additional Insureds and Named Insureds

required herein; (5) reference the Contract by number and title on the face of the certificate; and (6) expressly reference the inclusion of all required endorsements.

9.9 If, at any time during the period of this Contract, insurance as required is not in effect, or proof thereof is not provided to CUNY, CUNY shall have the option to: (i) direct Contractor to suspend work at no additional cost or extension of time due on account thereof; or (ii) treat such failure as an event of default.

Section 10 - Liabilities

10.1 Any claim made by Contractor arising out of any act or omission by any officer, agent, or employee of CUNY or College in the execution or performance of this Contract shall be made against CUNY and not against the officer, agent, or employee.

10.2 Contractor shall require each subcontract professional or subconsultant to agree in its contract not to make any claim against CUNY, or their respective officers, agents or employees, by reason of such contract, or any acts or omissions of CUNY, Contractor, or their respective officers, agents, or employees.

10.3 Nothing in this Contract shall be construed to give any person, including any subcontractors or suppliers, other than CUNY and Contractor any legal or equitable right, remedy or claim under this Contract. The Contract shall be held to be for the sole and exclusive benefit of CUNY and Contractor.

Section 11 – Miscellaneous

11.1 The parties acknowledge and agree that due to the coronavirus COVID-19 pandemic, all Contract terms and conditions are subject to change and Contractor shall use all reasonable efforts to cooperate with the College and to complete the Work timely.

11.2 Advertisements, Promotion, Marketing

11.2.1 Contractor shall not use any name, logo, trademark or picture of the University of the College in any advertisement or in any other written or oral communication without the University's prior written consent, except that Contractor may provide the name and address of the College Campus as the location for the use permitted under this Agreement. The foregoing notwithstanding, the University acknowledges that Contractor may have to make certain public disclosures and public filings relating to the Contract that contain the University's name to comply with U.S. Securities and Exchange Commission rules and regulations and other applicable securities Laws.

11.2.2 Contractor shall not post, exhibit, or allow to be posted or exhibited any signs, advertisements, show bills, lithographs, posters, cards or flyers of any description on any part of the Premises, or at any other location on the College Campus, without prior written approval of the University. Notwithstanding the foregoing, Contractor may erect temporary signage at the Premises (and subject to the discretion of the Colleges elsewhere on the College Campuses) containing its logo and signage to identify the COVID-19 testing site and remind invitees of social distancing and other requirements. Contractor and each College shall work cooperatively with respect to the size, content, type, methods of attachment and locations in which such signage may be placed, and such signage shall constitute COVID-19 Related Improvements for purposes of this Agreement.

11.3 All Services and Work provided by Contractor shall be in compliance with applicable laws, including those laws prohibiting discrimination on any basis.

11.4 The invalidity or unenforceability of any provision of this Contract shall in no way affect the validity or enforceability of any other provision of this Contract.

11.5 This Contract, including schedules, attachments, and appendices, is intended to by the parties as a final expression of their contractual agreement and as a complete statement of the terms thereof and shall supersede all previous understandings and agreements, whether written or oral.

11.6 No course of dealing between Contractor and the University and no delay by a party in exercising its rights under this Contract shall operate as a waiver of any of the rights of such party hereunder, and no express waiver shall affect any condition, covenant, rule, or regulation other than the one specified in such waiver and only for the time and in the manner specifically stated in such waiver.

11.7 Except as expressly set forth herein, this Contract may not be modified except in a writing duly executed by the parties.

Section 12 – Subcontracting

12.1 Contractor may subcontract to the vendors it has identified in its Proposal for the responsibilities and obligations identified in its Proposal. Any changes to subcontractors or to the responsibilities and obligations identified in its Proposal are subject to review and approval by the University; approval by the University will be exercised in its sole discretion.

12.2 Contractor's use of subcontractors shall not diminish Contractor's obligations to complete the Work in accordance with the Contract. Contractor shall control and coordinate the Work of its subcontractors. Contractor shall inform its subcontractors and suppliers of all the terms, conditions, and requirements of the Contract and require subcontractors and suppliers to comply with same. There shall be no relationship between the University and any of Contractor's subcontractors or suppliers.

Section 13 – Contractor's Representative, Response Time

13.1 Contractor shall designate a competent employee to be responsible for the Work, to coordinate all of the Services to be rendered, and to represent Contractor with authority to act for Contractor ("Contractor's Representative"); Contractor's Representative shall respond to College and act as the liaison between the College and Contractor for purposes of administration of the Contract and shall have full decision-making authority on behalf of Contractor and the authority to obligate Contractor. Contractor's Representative shall be subject to the approval of the University and shall not be changed during the Term without prior written permission of the University.

13.2 Contractor shall identify its Contractor's Representative and provide Contractor's Representative's name and contact telephone number(s) within three (3) days of notice to proceed. Contractor shall also provide a telephone number where Contractor's Representative can be reached in the event of an emergency.

13.3 During the Term, Contractor's Representative shall respond to calls from the College and the University via phone within two hours.

13.4 Contractor's Representative shall be available to respond to College's calls on a 24/7, 365 days-per-year basis via phone; Contractor acknowledges and agrees that a telephone answering service does not meet this requirement.

13.5 During any absence of Contractor's Representative, Contractor shall designate an alternate Contractor's Representative under the same terms and conditions.

13.6 Contractor shall ensure that College shall have access at all times to an individual with full authority to make decisions on behalf of Contractor. Nothing in this section shall be deemed to preclude College or University from discussing any matters relating to the Contract with any other member of Contractor's organization.

* * * * *

Portions of this exhibit have been omitted because the information is both not material and is the type that the Company treats as private or confidential. The omissions have been indicated by bracketed asterisks ("[***]").

First Amendment to Contract No. T212206
by and between
Applied DNA
and
The City University of New York

This First Amendment to Contract No. T212206 ("First Amendment") is effective as of September 16, 2021 by and between Applied DNA Clinical Labs, LLC, located at 25 Health Sciences Drive, Suite 120, Stony Brook, New York 11790 ("Contractor" or "Company") and The City University of New York, located at 205 East 42nd Street, New York, New York 10017
("College" or "University" or "Client").

WHEREAS, Contractor and CUNY are parties to Contract T212206 effective as of July 21, 2021 for the provision of COVID-19 testing and related services as set forth in the agreement.

WHEREAS, the evolution of COVID-19 pandemic has forced CUNY to continuously revisit and adjust its requirements to ensure a safe environment, including the need to shift from a testing- centric program to a vaccination-centric program and to move from focus on a targeted population to a holistic community approach.

WHEREAS, the science indicates that CUNY needs an integrated management system to reliably and accurately track, monitor, and validate testing and vaccination activity for the entire CUNY population of approximately 325,000 persons.

WHEREAS, such integrated managements system must include customer support and technology services to manage the system and necessary staff to support testing services, random surveillance testing process management, and vaccination customer support, and

WHEREAS, Contractor is able to provide such an integrated management system and related support services to track, monitor, and validate testing and vaccination activity for the entire University population of approximately 325,000 individuals through the adoption of the Cleared4 platform at a reasonable price.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein made, Contractor and CUNY hereby agree to amend the Contract as follows:

I. Contractor shall support configuration and implementation and provide post-implementation customer support services for an expanded Cleared4 platform featuring the following features (as set forth below, "Additional Services"):

   A. Expand the Cleared4 platform from supporting only the on-campus weekly testing population to the full community of students, employees and affiliated individuals in CUNY and Research Foundation campuses and administrative offices, now including:
      1. All students living on-campus or off-campus, approximately 260,000
      2. All direct faculty and staff of the University, approximately 35,000

3. Employees in auxiliary, athletics, associations, foundations; adult and continuing education faculty, staff, and students, approximately 5,000
4. Locations at 28 campuses and associated buildings covered by 19 testing sites
5. Expanded hours to cover workers on overnight shifts at a minimum of 5 of the test sites (at least 1 per Borough)

B. Expand system configuration beyond weekly testing (above) to manage the policies, data and reporting related to vaccinations and other compliance policies
   1. System configuration is expanded to enable upload and verification of vaccination and testing records and the granting / removal of campus access on a real-time basis for approximately 60-70% of the population
      i. Maintain reference list of industry-approved vaccinations
      ii. Enable testing site staff to have access to individual testing eligibility status based on vaccination record status
   2. Allow self-registration for contractors and visitors with submission and maintenance of vaccination records and/or third-party PCR testing records prior to admission to campus, approximately 35,000 one-time and regular visitors
      i. Records are kept active for a prescribed time period with the ability for archival according to CUNY policies
      ii. Sponsors of contractors and visitors throughout the University are trained to manage the invitation and record verification process
   3. Allow submission and maintenance by campus liaisons of third-party COVID testing records of any CUNY individual as needed for medical clearances or testing of symptomatic individuals, approximately 25-50 per week
   4. Provide full diagnostic lab reports on a limited, ad hoc basis

C. Develop, implement and support the algorithms, reporting and processes for random surveillance testing
   1. Current campus weekly screening comprises primarily students exempt for vaccination mandates and employees who have not submitted evidence of vaccination, approximately 17,000 individuals
      i. Allow for status changes of individuals from one category to the other
   2. Collaborate with CUNY Administration and School of Public Health to develop statistically significant algorithms for random surveillance testing of the CUNY on-campus population
      i. Approximately 5-10% of each location's on-campus population, resulting in the entire population being tested in a 10-to-20-week period
      ii. For a population of 170,000 on campus regularly or as-needed, approximately 8,000 email invitations per week are distributed
   3. Develop and configure systems to support the identification of the on-campus population with ability real-time to adjust any individual's status

4. Develop and configure systems to support the identification of a random pool of individuals notified for testing each week
5. Allow for the resulting indication of compliance / non-compliance to the policy within individuals' records and to determine campus access

D. Maintain Customer Support help desk staff operating 6 days x 8 hours per day to support additional functionality for testing and vaccination evidence, as well as to support requests directly from CUNY staff or program participants during expanded site hours of operation (from ~200 to ~400 site-hours), approximately 2 FTEs

E. Maintain IT Support for managing configuration of the software platform, interfacing with lab information systems, reporting and user training, approximately 2 FTEs
1. Daily, weekly and ad hoc metrics reporting
2. Direct contact with over 100 campus liaisons and program managers
3. Software development to support testing policy administration at each site with trained staff, approximately 60 to 80 FTEs

II. The University will pay Contractor [***] per month (which is based on approximate population of 325,000 individuals at [***] per person per month) for the Additional Services from September 16, 2021 through July 20, 2022. and Contractor and CUNY hereby agree to re-affirm the Contract as follows:

III. The maximum amount payable to Contractor under the Contract during the Term shall not exceed [***] dollars ([***]), and CUNY shall not be required to pay to

[continued on following page]

Contractor any sums in excess of such amount unless and until such amount shall have been increased by an amendment between the parties and approved by the Attorney General and the Office of the State Comptroller.

The parties hereby agree and affirm all other terms and conditions of the Contract.

IN WITNESS WHEREOF, the parties hereto, by their duly authorized representatives, have executed this First Amendment.

Instruction to Contractor: *Sign in the presence of a notary; have Certificate of Acknowledgment (next page) completed and signed.*	**Applied DNA Clinical Labs, LLC** EIN: [***] By: /s/ Beth Jantzen (signature of authorized representative) Name: Beth Jantzen (print name of authorized representative) Title: CFO (print title of authorized representative)

AGENCY APPROVALS –Contract Number: C212206–Covid-19 Testing and Related Services

Approved as to Form /s/ Marina Ho/ RH Office of the General Counsel The City University of New York Date: 12/16/2021	THE CITY UNIVERSITY OF NEW YORK By: /s/ Derek Davis Derek Davis, General Counsel and Senior Vice Chancellor of Legal Affairs Its Duly Authorized Officer Date December 16, 2021

In addition to the acceptance of this Contract Amendment, the University certifies that original copies of this signature page will be attached to all exact copies of this Contract Amendment.

Contract Preparer's Name and Signature: _____

Approved as to Form NEW YORK STATE ATTORNEY GENERAL N/A	Approved NEW YORK STATE COMPTROLLER N/A

CERTIFICATE OF ACKNOWLEDGMENT OF THE CONTRACTOR – INDIVIDUAL, CORPORATION, PARTNERSHIP, or LIMITED LIABILITY COMPANY:
STATE OF[***])

) ss:

COUNTY OF[***])

On the [***] day of [***] in the year 2021, before me, the undersigned,

[***], personally known to me or proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to the within instrument and acknowledged to me that s/he executed the same in her/his capacity, and that by her/his signature on the instrument, the individual, or the person upon behalf of which the individual acted, executed the instrument; and further that.

[Mark an X in the appropriate box and complete the accompanying statement.]

- o (If an individual): he executed the foregoing instrument in his/her name and on his/her own behalf.
- o (If a corporation): he is the _____ of _____, the corporation described in said instrument; that, by authority of the Board of Directors of said corporation, _he is authorized to execute the foregoing instrument on behalf of the corporation for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said corporation as the act and deed of said corporation.
- o (If a partnership): she is the_____ of _____, the partnership described in said instrument; that, by the terms of said partnership, he is authorized to execute the foregoing instrument on behalf of the partnership for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said partnership as the act and deed of said partnership.
- o (If a limited liability company): she is a duly authorized member of Applied DNA Clinical Labs, LLC

LLC, the limited liability company described in said instrument; that she is authorized to execute the foregoing instrument on behalf of the limited liability company for purposes set forth therein; and that, pursuant to that authority, she executed the foregoing instrument in the name of and on behalf of said limited liability company as the act and deed of said limited liability company.

	Notary Stamp
[***]	[***]
Notary Public or Commissioner of Deeds	Registration No.

Exhibit 10.47

Portions of this exhibit have been omitted because the information is both not material and is the type that the Company treats as private or confidential. The omissions have been indicated by bracketed asterisks ("[***]").

Second Amendment to Contract No. T212206
by and between
Applied DNA and
The City University of New York

This Second Amendment to Contract No. T212206 ("Second Amendment") is effective as of July 18, 2022 by and between Applied DNA Clinical Labs, LLC, located at 25 Health Sciences Drive, Suite 120, Stony Brook, New York 11790 ("Contractor" or "Company") and The City University of New York, located at 205 East 42nd Street, New York, New York 10017 ("College" or "University" or "Client").

WHEREAS, Contractor and CUNY are parties to Contract T212206 effective as of July 21, 2021 for the provision of COVID-19 testing and related services for the period of one year from July 21, 2022 through July 20, 2022.

WHEREAS, Contractor and CUNY are parties to First Amendment to Contract T212206 effective as of September 16, 2021 for Contractor to provide Additional Services (Contract T212206 and the First Amendment to Contract T212206 collectively known as the "Contract") ;

WHEREAS, The COVID-19 public health emergency has required the University to take various actions to protect the health, safety, and welfare of the University's faculty, staff, and students, due to the unprecedented nature of the pandemic and its impact on the mission of the University; and

WHEREAS, Given the potential of surges in cases from Omicron variants or other highly transmissible COVID-19 variants and the growing in-person presence of faculty, students, and staff on campus, the University has a demonstrated need of continued COVID-19 mitigation measures; and

WHEREAS, Surveillance testing of faculty, staff, student, and visitor populations who may have COVID-19 but may be asymptomatic continues to be a means of mitigating potential outbreaks of COVID-19 on college and university campuses; and

WHEREAS, With the return of faculty, staff, and students to campus, it is critical that the University continue to have services available for asymptomatic testing in order to protect the health, safety, and welfare of the campus community; and

WHEREAS, The University and Applied DNA Clinical Labs, LLC entered into a one-year contract effective July 20, 2021 for such surveillance testing services to all 25 University campuses and all University Offices, at a cost not to exceed [***]; and

WHEREAS, Applied DNA Clinical Labs, LLC has met the terms of the contract for such surveillance testing services to all 25 University campuses and all University Offices, at a cost that has not exceed[***].

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein made, Contractor and CUNY hereby agree to amend the Contract as follows:

I. The term of the Contract is hereby extended for one year for the period from July 21, 2022 through July 20, 2023 and the Term of the Contract is July 21, 2021 through July 20, 2023. and to re-affirm as follows:
II. The maximum amount payable to Contractor under the Contract during the Term shall not exceed [***] dollars (]***]), and CUNY shall not be required to pay to Contractor any sums in excess of such amount unless and until such amount shall have been increased by an amendment between the parties and approved by the Attorney General and the Office of the State Comptroller.

The parties hereby agree and affirm all other terms and conditions of the Contract as amended by the First Amendment.

(continued on following page)

IN WITNESS WHEREOF, the parties hereto, by their duly authorized representatives, have executed this First Amendment.

Instruction to Contractor: *Sign in the presence of a notary; have Certificate of Acknowledgment (next page) completed and signed.*	**Applied DNA Clinical Labs, LLC** EIN: [***] By: /s/ James A. Hayward (signature of authorized representative) Name: James A. Hayward (print name of authorized representative) Title: CEO (print title of authorized representative)

AGENCY APPROVALS –Contract Number: C212206–Covid-19 Testing and Related Services

Approved as to Form /s/ Marina Ho/RH Office of the General Counsel The City University of New York Date: 7/19/2022	THE CITY UNIVERSITY OF NEW YORK By: /s/ Derek Davis Derek Davis, General Counsel and Senior Vice Chancellor of Legal Affairs Its Duly Authorized Officer Date: 7/19/2022

In addition to the acceptance of this Contract Amendment, the University certifies that original copies of this signature page will be attached to all exact copies of this Contract Amendment.

Contract Preparer's Name and Signature: _____

Approved as to Form NEW YORK STATE ATTORNEY GENERAL N/A	Approved NEW YORK STATE COMPTROLLER N/A

CERTIFICATE OF ACKNOWLEDGMENT OF THE CONTRACTOR – INDIVIDUAL, CORPORATION, PARTNERSHIP, or LIMITED LIABILITY COMPANY:

STATE OF[***])
) ss:
COUNTY OF [***])

On the [***] day of [***] in the year 2022, before me, the undersigned, [***], personally known to me or proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to the within instrument and acknowledged to me that s/he executed the same in her/his capacity, and that by her/his signature on the instrument, the individual, or the person upon behalf of which the individual acted, executed the instrument; and further that.

[Mark an X in the appropriate box and complete the accompanying statement.]

- o (If an individual): he executed the foregoing instrument in his/her name and on his/her own behalf.
- o (If a corporation): he is the_____ of_____, the corporation described in said instrument; that, by authority of the Board of Directors of said corporation, he is authorized to execute the foregoing instrument on behalf of the corporation for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said corporation as the act and deed of said corporation.
- o (If a partnership): he is the_____ of_____, the partnership described in said instrument; that, by the terms of said partnership, he is authorized to execute the foregoing instrument on behalf of the partnership for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said partnership as the act and deed of said partnership.
- o (If a limited liability company): he is a duly authorized member of _____ LLC, the limited liability company described in said instrument; that he is authorized to execute the foregoing instrument on behalf of the limited liability company for purposes set forth therein; and that, pursuant to that authority, he executed the foregoing instrument in the name of and on behalf of said limited liability company as the act and deed of said limited liability company.

Notary Stamp

[***]
Notary Public or Commissioner of Deeds

[***]
Registration No.

CODE OF BUSINESS CONDUCT AND ETHICS

1. General Principles

The purpose of this code is to describe our standards of ethics and business conduct.

It is the intent of Applied DNA Sciences, Inc. (the Company) to conduct its business with integrity and ethics which applies to all employees, officers and directors.

It is the intent of Applied DNA Sciences, Inc. (the Company) to conduct its business with integrity and ethics which applies to all employees, officers and directors. As representatives of the Company, we should each be personally committed to demonstrating a high standard of business conduct. This includes obeying the spirit and letter of all applicable laws and regulations and avoiding activities that may be, or appear to be, illegal, unethical or improper.

2. Compliance with Laws and Company Code of Business Conduct and Ethics

All company employees, officers and directors are expected and directed to comply with all laws and the Company's Code of Business Conduct and Ethics (the Code).

Each employee, officer and director has an obligation to behave according to ethical standards that comply with the Company's policy provided in this Code, as well as the letter and spirit of applicable laws, rules and regulations. It is everyone's responsibility to know and understand legal and policy requirements as they apply to his or her Company responsibilities.

3. Accuracy of Company Records

Each officer and employee must help maintain the integrity of the Company's financial and other records.

Management, directors, audit committee members, shareholders, creditors, governmental entities and others depend on Company's business records for reliable and accurate information. The Company's books, records, accounts and financial statements must appropriately and accurately reflect the Company's transactions and conform to applicable legal requirements and the Company's system of internal controls. In particular, the Company is committed to fair, accurate, timely and understandable disclosure in all reports filed with the Securities and Exchange Commission (SEC) and in other public communications, and each person subject to this Code is required to provide truthful and timely information in support of this commitment.

4. Securities Trading Policies

Company's Policy on Insider Trading and Disclosure.

Never trade securities on the basis of confidential information acquired in the course of your Company duties or while you are at the workplace.

There are times when employees, officers or directors possess information about the Company, its

subsidiaries or affiliates or about a company with which the Company does business that is not known to the investing public. Such insider information may relate to, among other things, strategies, plans of the Company. new products or processes, mergers, acquisitions or dispositions of business or securities, problems facing the Company, sales, profitability, negotiations relating to significant contracts or business relationships, significant litigation or financial information.

If any information is of the type that a reasonable investor would consider important in reaching an investment decision, the Company employee, officer or director who possesses such information must not buy or sell Company securities, nor provide the information to others, until such information becomes public. Use of material, non-public information in the above manner is not only unethical, but also illegal. An employee, officer or director who is unsure how the law applies in a given instance should seek guidance before he or she trades. Each officer, director and employee shall at all times comply with the Company's policy on Insider Trading and Disclosure and all applicable laws.

5. Contact with Government Officials

The Company complies with all applicable laws, rules and regulations relating to lobbying or attempting to influence government officials.

Bribery, kickbacks or other improper or illegal payments have no place in the Company's business. In addition, information provided to governments must be accurate and interactions with government officials must be honest and ethical. All activities that might constitute lobbying or attempts to influence government officials must first be reviewed with and approved by legal counsel.

Before doing business with foreign, national, state or local government, an employee or officer must know the applicable rules. An employee who is in doubt should not interpret the rules by him or herself, but should discuss the matter with his or her supervisor or an Executive Vice President.

6. Conflicts of Interest

Each employee, officer and director must avoid any situation in which his or her personal interests conflict with or interfere with the Company's interests.

Each employee and officer owes the Company a duty of loyalty. Employees and officers must make business decisions solely in the best interests of the Company. Conflicts may arise when an employee or officer receives improper personal benefits as a result of the person's position with the Company or gains personal enrichment through access to confidential information. A conflict situation can also arise when an employee or officer takes actions or has interests that may make it difficult to perform his or her Company work objectively and effectively. For that reason, all employees and officers must exercise great care not to allow their personal interests to potentially conflict with the Company's interests.

Employees, officers or directors having any pre-existing financial interest, including but not limited to equity and debt ownership, in a transaction between the Company and a supplier, partner or customer (including, for example, an indirect interest through a relative or significant other), must disclose that interest and that interest must be approved in writing by the Company's Compliance Officer. For any future or pending financial interests, employees and officers must notify and request approval from the Company's Compliance Officer.

Each employee, officer and director shall act with honesty and integrity, avoiding conflicts of interest between personal and professional relationships. The following is a non-exhaustive list of examples of prohibited conflicts of interest for employees and officers of the Company.

- Selling competitive services, consulting with or employment in any capacity with a competitor, supplier or customer of the Company.
- Having a substantial equity, debt, or other financial interest in any supplier or customer.
- Having a financial interest in any transaction involving the purchase or sale by the Company of any product, material, equipment, services or property.
- Misusing the Company's confidential or proprietary information, including the unauthorized disclosure or use of such information.
- Taking, misappropriating or using materials, equipment or other assets of the Company for any unauthorized or undisclosed purpose.
- Receiving loans or guarantees of obligations from the Company without Board of Director authorization.

The following applies to directors:

- **Policy**. A director owes certain fiduciary duties, including the duties of loyalty, diligence, and confidentiality, to the Company, which require that a director act in good faith on behalf of the Company and to exercise the powers conferred in the Company's and its shareholder's interest and not for their own or others' interest.
- **Disclosure**. A director shall promptly disclose to the Company's board of directors (the Board) any personal or outside interest, relationship or responsibility (financial, professional or otherwise) held by the director with respect to any potential or actual transaction, agreement or other matter which is or may be presented to the Board for consideration, even if such interest, relationship or responsibility has otherwise generally been disclosed to the Company or the Board.
- **Board Action**. For any potential conflict, the Board, with the abstention of the interested director, may decide whether such director may participate in any reporting, discussion or vote on the issue that gave rise to the potential conflict. The Company shall withhold any information on such issues from the Board materials distributed to the applicable director and take all such other action necessary to effectuate this policy.

- **Recusal**. Any director with such an interest, relationship or responsibility which conflicts with the interest of the Company or its shareholders, shall recuse himself or herself from any reporting, discussions and vote on the issue that gave rise to the conflict and, if necessary, from the Board meeting, or applicable part thereof.
- **Resignation**. In circumstances where a director has a significant, ongoing and irreconcilable conflict, and where such personal or outside interest, relationship or responsibility significantly impedes the director's ability to carry out his or her fiduciary responsibility to the Company, resignation from the Board or the conflicting interest may be appropriate and/or required.

7. Political Contributions and Related Policies

Generally, Company funds or resources may not be used to make a political contribution to any political candidate or political party.

Exceptions to the basic policy are allowed only where such contributions are permitted by law such as through a bona fide Political Action Committee. Company policy does not permit the use of any Company facilities or resources by employees, officers or directors for political campaigning, political fundraising or partisan political purposes. A decision by an employee, officer or director to contribute any personal time, money or other resources to a political campaign or political activity must be totally voluntary.

8. Business Courtesies and Gratuities

The Company's policy is not to offer or accept kickbacks or bribes, or gifts of substantial value.
Company employees, officers and directors may only exchange non-monetary and modestly valued gifts that promote goodwill with our business partners and do not improperly influence others. We will accept only approved and widely available discounts and do not encourage, accept or exchange gratuities or payments for providing services to others.

Business courtesies such as meals, transportation and entertainment provided to a customer must be modest in amount and related to a legitimate business purpose (e.g., explanation or demonstration of Company products, application of products, service capabilities, or training). Such courtesies must not violate the law, regulations, or reasonable customs of the market place. If you have any questions about whether any business courtesies, gratuities or gifts are inappropriate, please contact your supervisor or an Executive Vice President.

9. Company Opportunities

Do not use a Company opportunity for personal gain.

Employees, officers and directors owe a duty to the Company to advance its legitimate interests when the opportunity to do so arises. Employees, officers and directors are prohibited (without the specific consent of the Board or an appropriate committee thereof) from (1) taking for themselves personally opportunities that are discovered through the use of Company property, information or their position,

(2) using Company property, information or their position for personal gain, or (3) competing with the Company directly or indirectly.

10. Intellectual Property and Confidential Information

The Company invests substantial resources in developing proprietary intellectual property and confidential information.

Confidential information is information that is not generally known or readily available to others. It includes non-public information that might be of value to competitors if it were disclosed. It must not be shared with others outside the Company except pursuant to approved business relationships or when required by law. Confidential information includes, but is not limited to, intellectual property and trade secrets, contents of proposals, business plans, marketing and sales programs, customer and prospective programs, customer information and lists, pricing and policies, financial information not otherwise disclosed, and any other information which the Company deems confidential. All information from a client and all data produced for a client is strictly confidential.

Every Company employee, officer and director is obligated to protect the Company's confidential information as well as that of its customers, suppliers and third parties who disclose information to the

Company in confidence. Company employees, officers and directors must not accept confidential information from a third party, including competitors, unless specifically authorized to do so by an authorized supervisor or officer of the Company and following an appropriate grant of rights from such third party.

11. Protection and Proper Use of Company Assets

Our shareholders trust us to manage Company assets appropriately.

Collectively, employees, officers and directors have a responsibility for safeguarding and making proper and efficient use of the Company's assets. Each of us has an obligation to protect the Company's property from loss, damage, misuse, theft, embezzlement or destruction. We seek to ensure that Company equipment, supplies and other assets are used for legitimate business purposes unless otherwise specifically authorized, and to protect all tangible and intangible Company property.

12. Fair Dealing with Competitors, Customers and Suppliers

Respect the rights of customers and suppliers.

The Company's success depends on building productive relationships with our customers and suppliers based on integrity, ethical behavior and mutual trust. In addition, customers have individual needs and expectations representing unique opportunities for mutual success.

The Company bases its supplier relationships on fundamental concepts of integrity, fairness, and mutual respect.

The Company strives to outperform its competition fairly and honestly. The Company seeks and develops competitive advantages through superior performance, not through unethical or illegal business practice. Each Company employee, officer and director should endeavor to deal fairly with the

Company's customers, suppliers and competitors. No one should take unfair advantage through manipulation, concealment, abuse of privileged information, misrepresentation of material facts or any other intentional unfair dealing.

13. Personal Behavior in the Workplace

The Company is committed to providing equal opportunity in employment and will not tolerate illegal discrimination or harassment.

The Company strives to enhance and support the diversity of its employee group. All are expected to deal with each other in an atmosphere of trust and respect in a manner consistent with the Company's core values and comply with all policies disseminated by the Company covering such behavior.

14. Public Disclosure of Code and Waivers

Waivers to the Code granted only by Board of Directors.

The existence and content of this Code will be disclosed to shareholders and may be available on the Company's website. It is expected that waivers of this Code rarely, if ever, would be acceptable. Any waiver of a provision of this Code for executive officers or directors may be granted only by the Board, with only the independent members voting, and such waiver must be promptly disclosed to shareholders.

15. Accountability for Adherence to the Code

Violations may lead to Termination.

Each employee, officer and director must accept responsibility for adherence to this Code. Violations of this Code may lead to serious sanctions including, for an employee, discipline up to and including immediate termination, at the sole discretion of the Company. The Company may, in addition, seek civil recourse against an employee, officer or director and/or refer alleged criminal misconduct to law enforcement agencies.

16. Reporting Suspected Illegal or Unethical Behavior

The Company maintains an open door policy and an anonymous method for employees to raise concerns and to encourage the reporting of suspected violations of law or this Code without fear of retribution or retaliation.

If you have questions about an ethical situation, you are encouraged to talk with your supervisor about any behavior you believe may be illegal or unethical. You will be assured confidentiality, to the limit of the law. If you do not feel it is appropriate to discuss the issue with these persons, you can report concerns or potential violations anonymously by sending an anonymous letter addressed to the Company.

It is against the Company's policy to retaliate against any employee, officer or director for good faith reporting of violation of this Code. If you feel you have been retaliated against for raising your good faith reporting, you should immediately contact your supervisor.

17. Coordination with Other Company Policies

All other Policies remain in effect.

The provisions of this Code are in addition to, and do not modify, replace or supersede, the Company's other policies or procedures including, but not limited to the Company's other statements of policy or procedure, whether written or oral.

Additionally, this Code is not intended to be and does not constitute a contract of employment between the Company and its employees. If you are an employee and do not have an Employment Agreement with the Company, you are an employee at-will. This means that you have the option of resigning from your employment at any time, for any reason, with or without prior notice. Conversely, the Company has the same option to terminate your employment at any time, for any reason or no reason, with or without prior notice.

ACKNOWLEDGEMENT

I have read, understand, and agree to comply with the foregoing policies, rules, and conditions governing Applied DNA Sciences, Inc. Code of Business Conduct and Ethics. Furthermore, I understand that this policy can be amended at any time.

***Employee Signature*_____*Date:*_____**

***Print Name*_____**

Please sign and keep this acknowledgement for your records.

ACKNOWLEDGEMENT

I have read, understand, and agree to comply with the foregoing policies, rules, and conditions governing Applied DNA Sciences, Inc. Code of Business Conduct and Ethics. Furthermore, I understand that this policy can be amended at any time.

***Employee Signature*_____*Date:*_____**

***Print Name*_____**

Please sign and return this acknowledgement to Human Resources.

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, 333-234664, 333-266223 and 333-266512), Form S-3 (File Nos. 333-252280, 333-202432, 333-220481, 333-218158, 333-214920, 333-238557 and 333-266217) and S-8 (File Nos. 333-182350, 333-205123, 333-231944 and 333-249365) of our report dated December 14, 2022, with respect to our audits of the consolidated financial statements of Applied DNA Sciences, Inc. as of September 30, 2022 and 2021 and for each of the two years in the period ended September 30, 2022, which report is included in this Annual Report on Form 10-K of Applied DNA Sciences, Inc. for the year ended September 30, 2022.

/s/ Marcum LLP

Marcum LLP
Melville, NY
December 14, 2022

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 14, 2022

/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 14, 2022

/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, 2022, 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 14, 2022

* 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, 2022, 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 14, 2022

* 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.