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, 2023

□ **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. □

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). □

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, 2023), was approximately $14.4 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, 2023 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 4, 2023, the Registrant had outstanding 13,687,420 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 2024 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, 2023. 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;
- the substantial doubt relating to our ability to continue as a going concern;
- our need for 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) which would dilute the ownership held by stockholders;
- our business strategy and the timing of our expansion plans, including the development of new production facilities for our Therapeutic DNA Production Services;
- demand for Therapeutic DNA Production Services;
- demand for DNA Tagging Services;

- demand for MDx Testing Services, including in light of significantly decreasing demand for COVID 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;
- whether we are able to achieve the benefits expected from the acquisition of Spindle Biotech, Inc. ("Spindle");
- 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;
- including formulations and treatments that utilize our Therapeutic DNA Production Services;
- the inherent uncertainties associated with clinical trials of product candidates, including product candidates that utilize our Therapeutic DNA Production Services;
- the inherent uncertainties associated with the process of obtaining regulatory clearance or approval to market product candidates, including product candidates that utilize our Therapeutic DNA Production Services;
- the inherent uncertainties associated with commercialization of products that have received regulatory clearance or approval, including products that utilize our Therapeutic DNA Production Services;
- economic and industry conditions generally and in our specific markets;
- the volatility of, and decline in, our stock price; and
- our ability to obtain the necessary financing to fund our operations and effect our strategic development plan.

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

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®, LineaDNA™, Linea RNAP™, Linea™ COVID-19 Diagnostic Assay Kit, safeCircle™ COVID-19 testing and TR8™ pharmacogenetic testing. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. All trademarks, service marks and trade names included or incorporated by reference in this Annual Report on Form 10-K are the property of the respective owners.

ITEM 1. BUSINESS.

Overview

We are a biotechnology company developing and commercializing technologies to produce and detect deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA"). Using polymerase chain reaction ("PCR") to enable the production and detection of DNA and RNA, we currently operate in three primary business markets: (i) the enzymatic manufacture of synthetic DNA for use in the production of nucleic acid-based therapeutics (including biologics and drugs) and, through our recent acquisition of Spindle , the development and sale of a proprietary RNA polymerase ("RNAP") for use in the production of mRNA therapeutics ("Therapeutic DNA Production Services"); (ii) the detection of DNA and RNA in molecular diagnostics and genetic testing services ("MDx Testing Services"); and (iii) the manufacture and detection of synthetic DNA for industrial supply chain security services ("DNA Tagging and Security Products and Services").

Our current 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 the production of nucleic acid-based therapies, and to further expand and commercialize our MDx Testing Services through genetic testing.

We will continue to update our business strategy and monitor the use of our resources regarding our various business markets. In addition, we expect that based on available opportunities and our beliefs regarding future opportunities, we will continue to modify and refine our business strategy, which could include restructuring our business.

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 of DNA and the detection of DNA and RNA 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 services. 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 LineaRx, Inc. ("LRx") our 98% owned subsidiary we are developing and commercializing our Linea DNA and Linea IVT platforms.

Linea DNA Platform

Our Linea DNA platform is our core enabling technology, and enables the rapid, efficient, and large-scale cell-free manufacture of high-fidelity DNA sequences for use in the manufacturing of a broad range of nucleic acid-based therapeutics. The Linea DNA platform enzymatically produces a linear form of DNA we call "LineaDNA" that is an alternative to plasmid-based DNA manufacturing technologies that have supplied the DNA used in biotherapeutics for the past 40 years.

As of the third quarter of calendar year 2023, there were 3,866 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 2023 Quarterly Report). Due to what we believe are the Linea DNA platform's numerous advantages over legacy nucleic acid-based therapeutic manufacturing platforms, we believe this large number of therapies under development represents a substantial market opportunity for the Linea DNA platform to supplant legacy manufacturing methods in the manufacture of nucleic acid-based therapies.

We believe our Linea DNA platform holds several important 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 bacterial 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 Linea DNA platform does not require living cells and instead amplifies DNA via the enzymatic process of PCR. The Linea DNA platform is simple and can rapidly produce very large quantities of DNA without the need for complex purification steps.

We believe the key advantages of the Linea DNA platform include:

- Speed – Production of Linea DNA can be measured in terms of hours, not days and weeks as is the case with plasmid-based DNA manufacturing platforms.
- Scalability – Linea DNA 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 the plasmid backbone and antibiotic resistance genes, inherent to plasmid DNA, are not present in Linea DNA.
- Simplicity – The production of Linea DNA is streamlined relative to plasmid-based DNA production. Linea DNA 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 Linea DNA platform can be easily chemically modified to suit specific customer applications. In addition, the Linea DNA 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 long homopolymers such as polyadenylation sequences (poly (A) tail) important for gene therapy and messenger RNA ("mRNA") therapies, respectively.

Preclinical studies conducted by the Company have shown that Linea DNA is substitutable for plasmid DNA in numerous nucleic acid-based therapies, including:

- DNA vaccines;
- DNA templates to produce RNA, including mRNA therapeutics; and
- adoptive cell therapy (CAR-T) manufacturing.

Further, we believe that Linea DNA 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 gene therapy; and
- non-viral gene therapy.

Linea IVT Platform

The number of mRNA therapies under development is growing at a rapid rate, thanks in part to the success of the mRNA COVID-19 vaccines. mRNA therapeutics are produced via a process called *in vitro* transcription ("IVT") that requires DNA as a starting material. As of the 3rd quarter of calendar 2023, there were almost 400 mRNA therapies under development, with the large majority of these therapies (68%) in the preclinical stage (Source: ASGCT Gene, Cell & RNA Therapy Landscape: Q3 2023 Quarterly Report). The Company believes that the mRNA market is in a nascent stage that represents a large growth opportunity for the Company via the production of DNA IVT templates to produce mRNA therapies.

In August 2022, the Company launched DNA IVT templates manufactured via its Linea DNA platform and has since secured proof of concept contracts with numerous mRNA manufacturing customers. In response to this demand, the continued growth of the mRNA therapeutic market, and the unique abilities of the Linea DNA platform, the Company acquired Spindle in July 2023 to potentially increase its mRNA-related total addressable market ("TAM").

Through our acquisition of Spindle, we recently launched our Linea IVT platform, which combines Spindle's proprietary high-performance RNA polymerase ("RNAP"), now marketed by the Company as Linea RNAP, with our enzymatically produced Linea DNA IVT templates. We believe the Linea IVT platform enables our customers to make better mRNA, faster. Based on data generated by the Company, we believe the integrated Linea IVT platform offers the following advantages over conventional mRNA production to therapy developers and manufacturers:

- The prevention or reduction of double stranded RNA ("dsRNA") contamination resulting in higher target mRNA yields with the potential to reduce downstream processing steps. dsRNA is a problematic immunogenic byproduct produced during conventional mRNA manufacture;
- delivery of IVT templates in as little as 14 days for milligram scale and 30 days for gram scale; and
- reduced mRNA manufacturing complexities.

According to the Company's internal modeling, the ability to sell both Linea DNA IVT templates and Linea RNAP under the Linea IVT platform potentially increases the Company's mRNA-related TAM by approximately 3x as compared to selling Linea DNA IVT templates alone, while also providing a more competitive offering to the mRNA manufacturing market. Currently, Linea RNAP is produced for the Company by a third-party CDMO located in the United States.

Manufacturing Scale-up

The Company plans to offer several quality grades of Linea DNA, each of which will have different permitted uses.

Quality Grade	Permitted Use	Company Status
GLP	Research and pre-clinical discovery	Currently available
GMP for Starting Materials	DNA critical starting materials for the production of mRNA therapies	Planned availability first half of CY2024 (1)
GMP	DNA biologic, drug substance and/or drug product	Planned availability first half of CY 2025 (1)

(1) Dependent on the availability of future financing.

The Company currently manufactures Linea DNA pursuant to Good Laboratory Practices ("GLP") and, subject to the availability of future financing, is creating a fit for purpose manufacturing facility within our current Stony Brook, NY laboratory space capable of producing Linea DNA IVT templates under Good Manufacturing Practices ("GMP") suitable for use as a critical starting material for clinical and commercial mRNA therapeutics, with a planned completion date in the first half of calendar year 2024. The Company also plans to offer Linea DNA materials manufactured under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product, with availability expected during the first half of calendar year 2025, dependent upon future funding. GMP is a quality standard used globally and by the U.S. Food and Drug Administration ("FDA") to ensure pharmaceutical quality. Starting materials are raw materials, intermediates, or an active pharmaceutical ingredients used in the production of biologics, drug substances and/or drug products.

Segment Business Strategy

Our business strategy for our Therapeutic DNA Production Services is to capitalize upon the rapid growth of mRNA therapies in the near term via our planned near term future availability of Linea DNA IVT templates manufactured under GMP, while at the same time laying the basis for additional clinical and commercial applications of Linea DNA with our future planned availability of Linea DNA manufactured under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product. Our current plan is: (i) through our Linea IVT platform and planned near term future GMP manufacturing capabilities for IVT templates to secure commercial-scale supply contracts with clinical and commercial mRNA and/or self-amplifying mRNA ("sa-RNA") manufacturers for Linea DNA IVT templates and/or Linea RNAP as critical starting materials; (ii) to utilize our current GLP production capacity for non-IVT template applications to secure supply and/or development contracts with pre-clinical therapy developers that use DNA in their therapy manufacturing, and (iii) upon our development of our planned future Linea DNA production under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product, to convert existing and new Linea DNA customers into large-scale supply contracts to supply Linea DNA for clinical and commercial use as, or incorporation into, a biologic, drug substance and/or drug product in a wide range of nucleic acid therapies. Until we complete our GMP facility to produce DNA critical starting materials (DNA IVT templates) for mRNA manufacturing, we will not be able to realize significant revenues from this business. We estimate the cost of creating the critical starting materials fit-for-purpose manufacturing facility will be approximately $1.5 million. If we were to expand the facility to enable GMP production of Linea DNA for use as, or incorporation, into a biologic, drug substance and/or drug product, the cost may be up to approximately $7 million which would require additional funding. We anticipate that the fit-for-purpose manufacturing facility would be created within our existing laboratory space. We anticipate that a facility to enable GMP production of biologic, drug substances and/or drug products would require us to acquire additional space.

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 Linea DNA-based therapeutic or prophylactic vaccines for high-value veterinary health indications (collectively "Linea DNA Vaccines"). We currently seek to commercialize our Linea DNA Vaccines 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 Linea DNA encapsulated by LNPs. For the *in vivo* study, successful

expression of the LNP-encapsulated Linea DNA was administered and achieved via IM injection. We believe that our Linea DNA Vaccines under development provide a substantial advantage over plasmid DNA-based vaccines for the veterinary health market.

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 and genetic (collectively "MDx") testing services. ADCL is a NYSDOH CLEP-permitted, CLIA-certified laboratory which is currently permitted for virology. Permitting for genetics (molecular) is currently pending with the NYSDOH. In providing MDx testing services, ADCL employs its own or third-party molecular diagnostic tests.

We have successfully validated internally our pharmacogenomics testing services (the "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 33 genes and provide genotyping information relevant to certain cardiac, mental health, oncology, and pain management drug therapies. Our PGx Testing Services cannot commence until we receive approval from NYSDOH.

On March 22, 2023, we submitted our validation package to the NYSDOH for our PGx Testing Services. On September 21, 2023, we received a first set of comments from NYSDOH requesting additional data and clarifications. A response was submitted to NYSDOH on November 17, 2023. Currently, timing of any approval by NYSDOH for our PGx Testing Services is unclear. Recently published studies show that population-scale PGx enabled medication management can significantly reduce overall population healthcare costs, reduce adverse drug events, and increase overall population wellbeing. These benefits can result in significant cost savings to large entities and self-insured employers, the latter accounting for approximately 65% of all U.S. employers in 2022. If and when approved by NYSDOH, we plan to leverage our PGx Testing Services to provide PGx testing services to large entities and self-insured employers.

Historically, the majority of our revenue attributable to our MDx Testing Services has been derived from our safeCircle™ COVID-19 testing solutions, for which testing demand has significantly dropped. While we continue to support several safeCircle customers, we are currently observing a marked decrease in market demand for COVID-19 testing, resulting in significant reduced revenues. We expect future demand for COVID-19 testing to continue to be reduced, and we intend to pursue future COVID-19 testing opportunities on an opportunistic basis.

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 Linea DNA platform to mark objects in a unique manner and then identify these objects by detecting the absence or presence of the DNA tag. 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 Linea DNA platform, provide a methodology to authenticate goods within large and complex supply chains with a focus on cotton, nutraceuticals and other products.

- SigNify® portable DNA readers and SigNify consumable reagent test kits provide definitive real-time authentication of the Company's DNA tags in the field.

- fiberTyping® and other product genotyping services use PCR-based DNA detection to determine a cotton species or cultivar, via a product's naturally occurring DNA sequence for the purposes of product provenance authentication.

- Isotopic analysis testing services, provided in partnership with third-party labs, use cotton's carbon, hydrogen and oxygen elements to indicate origin of its fiber through finished goods.

To date, our largest commercial application for our DNA Tagging and Security Products and Services is in the tracking and provenance authentication of cotton.

We believe the Uyghur Forced Labor Prevention Act ("UFLPA") signed into law on December 23, 2021 has increased interest in our CertainT platform for DNA Tagging, fiberTyping and isotopic analysis services. The UFLPA establishes 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. On June 17, 2022, the UFLPA additionally listed DNA tagging and isotopic analysis as evidence that importers may use to potentially prove that a good did not originate in XUAR.

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

Sales and Marketing

We have five employees engaged in sales and marketing, of which three 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 LineaDNA platform, and our Linea IVT platform, as well as the development of lineaDNA-based vaccines for the veterinary health market. lineaDNA platform development and optimization is focused on increased DNA yields, purification workflows and sequence fidelity. Linea IVT platform development and optimization is focused on performance of the Linea RNAP enzyme, as well as increasing the manufacturing yields of the Linea RNAP. For our lineaDNA-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 lineaDNA to facilitate IM administration of LNP encapsulated lineaDNA 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 with the assistance of a healthcare provider. Our PGx testing services are designed to interrogate DNA targets on over approximately 33 genes and provide genotyping information potentially relevant to certain cardiac, mental health, oncology 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 $3.7 million and $3.9 million on research and development activities for the fiscal years ended September 30, 2023 and 2022, respectively.

Raw Materials and Suppliers

We utilize DNA polymerase ("DNAP") in all of our PCR reactions to amplify DNA. DNAP is available from multiple sources. Our sources of raw materials also include synthesized sources of DNA templates which we are able to amplify to use in our product/services offerings and that are available from multiple sources. For our Therapeutic DNA Production Services, our services may be optimized for inputs, including DNAP, from a specific source or sources. 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. In addition, while our Linea RNAP is manufacturable by multiple sources, it is currently manufactured by a single provider. Cessation of Linea RNAP production by this single provider could cause production delays and/or delays in customer deliveries as manufacturing of Linea RNAP is transferred to a new provider.

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 lineaDNA platform at our facility in Stony Brook. For our Therapeutic DNA Production Services, we currently manufacture GLP grade DNA, with plans to offer GMP non-drug substance grade, and GMP drug substance grade DNA in calendar year 2024 and calendar year 2025, respectively. Linea RNAP is produced for the Company by a third-party CDMO located in the United States. 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.

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.

Cornell University College of Veterinary Medicine. During June 2023 the Company and Cornell University College of Veterinary Medicine ("Cornell University") entered into an additional Sponsored Research Agreement under which the parties seek to develop and optimize LNP formulations and lineaDNA expression vectors for use in high-value veterinary disease indications with an initial focus on equine infectious diseases.

Customers

Our revenues earned from sale of products and services for the fiscal year ended September 30, 2023 includes 65% and 14% from two customers within our MDx Testing Services segment. 65% and 58% of the revenues earned for the fiscal years ended September 30, 2023 and 2022, respectively were derived from the COVID-19 testing contract with CUNY that terminated during June 2023. At September 30, 2023, three customers accounted for 60% of our accounts receivable. 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. 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 termination of the CUNY testing contract has resulted in a significant reduction of revenues. 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: MilliporeSigma, Precigen, Inc., Aldevron, LLC, Charles River Laboratories,, Integrated DNA Technologies, Inc., 4basebio PLC, MaxCyte, Inc., Touchlight Genetics Ltd., Quantoom Bioscience, Syngoi Technologies, S.L.U., 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 therapeutic and 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, Fulgent Genetics, 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;
- manufacturing scale and turnaround time;
- 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 4, 2023, our patent portfolio included the following issued and pending patent applications applicable to each of our three primary business markets:

- Therapeutic DNA Production Services
    - 6 issued patents and 13 pending patent applications in the United States
    - 11 issued foreign patents and 9 pending foreign patent applications
- MDx Testing Services
    - 5 issued patents and no pending patent applications in the United States
    - 4 issued foreign patents and no pending foreign patent applications
- DNA Tagging and Security Products and Services
    - 28 issued patents and 4 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 Laboratory Developed Tests ("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 Regulation of Drug and Biologic Products

The DNA manufactured via our lineaDNA 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 lineaDNA platform, except with respect to the veterinary health market, but the demand for our lineaDNA is in part dependent on our customer's ability to seek and obtain approval of a drug or biological product using our technology. Biologics include a wide range of products such as vaccines, gene therapy, and recombinant therapeutic proteins, including mRNA therapeutics.

Drug and biologic products are subject to extensive regulation by FDA and other regulatory agencies in the United States and by comparable authorities in foreign countries. 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.

Some of our products may be incorporated into drugs and biologics that are or will be subject to regulation. Some of our products may be drugs or biologics that are subjected themselves to regulation. 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.

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.

Laboratory Developed Tests

As an LDT, our MDx Testing Services are currently subject to enforcement discretion by the FDA. On September 29, 2023, however, the FDA published a proposed rule on LDTs, in which FDA proposes to end enforcement discretion for virtually all LDTs in five stages over a four-year period from the date FDA publishes a final rule. In Phase 1 (effective one year post-finalization), labs would be required to comply with medical device (adverse event) reporting and correction/removal reporting requirements. In Phase 2 (effective two years post-finalization), labs would be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for quality systems and premarket review. In Phase 3 (effective three years post-finalization), labs would be required to comply with quality systems requirements. In Phase 4 (effective three and a half years post-finalization, but not before October 1, 2027), labs would be required to comply with premarket review requirements for high-risk tests (*i.e.*, tests subject to premarket approval (PMA) requirement). Finally, in Phase 5 (effective four years post-finalization, but not before April 1, 2028), labs would be required to comply with premarket review requirements for moderate- and low-risk tests (*i.e.*, tests subject to *de novo* or 510(k) requirement). Unlike previous proposals, the proposed rule does not "grandfather" existing tests. The content and timing of any final rule on LDTs is uncertain at this time.

Congress is also working on legislative language that would clarify FDA's authority with respect to LDTs. In this regard, most recently, the "Verifying Accurate Leading-edge IVCT Development Act," or VALID Act, was introduced in March 2020, then in June 2021, Spring 2022, and March 2023. The bill proposes a risk-based approach that would subject many LDTs to FDA regulation by creating a new *in vitro* clinical test, or IVCT, category of regulated products. As proposed, the bill would grandfather 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 would be needed to be established. Under VALID, a precertification process would be 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 be subject to pre-market review. The new regulatory framework would include quality control and post-market reporting requirements. The FDA would have 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, 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

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. ADCL is a New York State Department of Health Clinical Laboratory Evaluation Program-permitted, Clinical Laboratory Improvement Amendments-certified laboratory which is currently permitted for virology. Permitting for genetics (molecular) is currently pending with the NYSDOH.

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, 2023, we had a total of 55 employees (52 fulltime and 3 part-time), consisting of 4 in executive management, 12 in research and development, 9 in quality and compliance, 3 in finance, accounting and human resources, 10 in operations/production, 5 in sales and marketing, 4 in administration and support services, 3 in information services, and 5 in clinical laboratory 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, 2023, 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.
- There is substantial doubt relating to our ability to continue as a going concern.
- 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.
- We may not successfully implement our business strategies, including achieving our growth objectives.
- 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.
- Our operating results have been and 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 current 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 GMP.
- 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, including in light of significantly decreasing demand for COVID-19 testing services.
- 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.

- We have received written notice from Nasdaq that we are not in compliance with Nasdaq's minimum bid requirements and if we are unable to regain compliance with the Nasdaq continued listing standards, which may require effecting a reverse stock split of our common stock, we could be delisted from The Nasdaq Stock Market, which would negatively impact our business, our ability to raise capital, and the market price and liquidity of our common stock.

- 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. While our revenues increased from $1.9 million in fiscal 2020 to $18.2 million in fiscal 2022, primarily as a result of our COVID-19 testing revenues, in fiscal 2023 our revenues declined to $13.4 million and are expected to decline further in fiscal 2024. 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.

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

We have recurring net losses, which have resulted in an accumulated deficit of $302,447,147 as of September 30, 2023. We have incurred a net loss of $10,022,916 for the twelve-month period ended September 30, 2023. At September 30, 2023, we had cash and cash equivalents of $7,151,800. We have concluded that these factors raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the financial statements. We will continue to seek to raise additional working capital through public equity, private equity or debt financings. If we fail to raise additional working capital, or do so on commercially unfavorable terms, it would materially and adversely affect our business, prospects, financial condition and results of operations, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

Our opportunities to work with customers to develop drug 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 drug or biologic products. If our customers fail to successfully identify, finance and develop drug and/or biologic candidates incorporating our lineaDNA platform, commercial opportunities in drugs and biologics may be limited.

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

Investment in drug 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 lineaDNA 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 drug 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 lineaDNA 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 not successfully implement our business strategies, including achieving our growth objectives.

We may not be able to fully implement our business strategies or realize, in whole or in part within the expected time frames, the anticipated benefits of our various growth or other initiatives. Our various business strategies and initiatives, including our growth, operational and management initiatives and the development in particular of our Therapeutic DNA Production Services, are subject to business, economic and competitive uncertainties and contingencies, many of which are beyond our control. The execution of our business strategy and our financial performance will continue to depend in significant part our ability to obtain sufficient financing and on our executive management team and other key management personnel, our ability to identify and complete suitable acquisitions and our executive management team's ability to execute new operational initiatives. In addition, we may incur certain costs as we pursue our growth, operational and management initiatives, and we may not meet anticipated implementation timetables or stay within budgeted costs. As these initiatives are undertaken, we may not fully achieve our expected efficiency improvements or growth rates, or these initiatives could adversely impact our customer retention, supplier relationships or operations. Also, our business strategies may change from time to time in light of our ability to implement our business initiatives, competitive pressures, economic uncertainties or developments, or other factors.

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. 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.

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

Our revenue earned from the sale of products and services for the fiscal year ended September 30, 2023 included an aggregate of 65% and 14% of our total revenue from two customers within our MDx Testing Services segment. 65% and 58% of the revenues earned for the fiscal years ended September 30, 2023 and 2022, respectively were derived from the COVID-19 testing contract with CUNY that terminated during June 2023. At September 30, 2023, three customers accounted for an aggregate of 60% of our total accounts receivable. Our revenue earned from the sale of products and services for the fiscal year ended September 30, 2022 included an aggregate of 58% of our total revenues 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. 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 has resulted in and 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 conflicts between Russia and Ukraine and Israel and Hamas 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 conflicts in Ukraine and the Middle East 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.

Further, on October 7, 2023, Hamas, a U.S. designated Foreign Terrorist Organization, launched terrorist attacks against Israel. Israel then declared war on Hamas and there is currently an armed conflict in Israel and the Gaza Strip. The extent and duration of the wars in Ukraine and Israel/Gaza and expanding geopolitical tensions and any resulting market disruptions could be significant and could potentially have a substantial impact on the global economy, market volatility and our business for an unknown period of time. Any of the above-mentioned factors could materially adversely affect our business, financial condition, and results of operations.

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 current 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 current 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 without raising additional capital.

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 Linea DNA 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 for use as critical starting materials and/or incorporation into a biologic, drug substance or drug product, 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 GMP 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.

Depending on the type and intended use of the synthetic DNA produced by the Company we may be required to register our facilities and list our products manufactured after beginning 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 applicable GMP regulations or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of synthetic DNA 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.

Some 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 GMP requirements. If we are a registered facility and 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 GMP 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 drug 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 GMP 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.

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

As laboratory-developed tests ("LDTs"), our MDx Testing Services are currently subject to enforcement discretion by the FDA. In addition, ADCL is currently subject to NYSDOH oversight as a CLEP-permitted and CLIA-certified laboratory. On September 29, 2023, however, the FDA published a proposed rule on LDTs, in which FDA proposes to end enforcement discretion for virtually all LDTs in five stages over a four-year period from the date FDA publishes a final rule. In Phase 1 (effective one year post-finalization), labs would be required to comply with medical device (adverse event) reporting and correction/removal reporting requirements. In Phase 2 (effective two years post-finalization), labs would be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for quality systems and premarket review. In Phase 3 (effective three years post-finalization), labs would be required to comply with quality systems requirements. In Phase 4 (effective three and a half years post-finalization, but not before October 1, 2027), labs would be required to comply with premarket review requirements for high-risk tests (*i.e.*, tests subject to premarket approval (PMA) requirement). Finally, in Phase 5 (effective four years post-finalization, but not before April 1, 2028), labs would be required to comply with premarket review requirements for moderate- and low-risk tests (*i.e.*, tests subject to *de novo* or 510(k) requirement). Unlike previous proposals, the proposed rule does not "grandfather" existing tests. The content and timing of any final rule on LDTs is uncertain at this time.

Congress is also working on legislative language that would clarify FDA's authority with respect to LDTs. In this regard, most recently, the "Verifying Accurate Leading-edge IVCT Development Act," or VALID Act, was introduced in March 2020, then in June 2021, Spring 2022, and March 2023. The bill proposes a risk-based approach that would subject many LDTs to FDA regulation by creating a new *in vitro* clinical test, or IVCT, category of regulated products. As proposed, the bill would grandfather 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 would be needed to be established. Under VALID, a precertification process would be 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 be subject to pre-market review. The new regulatory framework would include quality control and post-market reporting requirements. The FDA would have 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, 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.

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 and RNAP), nucleotides, or synthetic DNA templates, which are available from multiple suppliers, but some of which we currently primarily source from a 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 the synthetic DNA produced via our Therapeutic DNA Production Services are very competitive, and we may be unable to continue to compete effectively in these industries in the future.

The principal markets for 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 synthetic DNA, drug and biologic candidates utilizing synthetic DNA, 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 LineaDNA 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, synthetic DNA, drug and biologic candidates utilizing synthetic DNA, and other forms of therapeutic DNA developed by our competitors may render our LineaDNA uneconomical or obsolete, and we may not be successful in marketing any drug and biologic candidates and LineaDNA 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: Digimarc Corporation, Haelixa Ltd., ICA Bremen GmbH, IEH Corporation, Oritain Global Limited, SafeTraces, Inc., DeterTech (acquired SmartWater Technology, Inc.), Sun Chemical Corporation, TraceTag International Ltd., TruTag Technologies, Inc., and Tailorlux gmbH.

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. In June 2023, our COVID-19 testing contract with CUNY which accounted for a substantial portion of our revenues was terminated and we have seen a significant decline in our MDx Testing Services revenue. It is unclear whether we will be able to maintain our current 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 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 and drug 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 and drug 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, gives rise to cybersecurity risks, including security breaches, 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:

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

The DNA produced via our Therapeutic DNA Production Services may be incorporated into our customers' products in the drug and/or biologic markets 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 drug or biologic product that incorporates or utilizes our Therapeutic DNA Production Services, 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 Linea DNA technology is 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 Linea DNA is utilized or 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 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 that incorporate or utilize our Therapeutic DNA Production Services will ever obtain regulatory approval. Applications for 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.

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 applicable cGMP regulations, and we will be subject to potential continual review and inspections to assess compliance with applicable 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 their products that incorporate our utilize our Therapeutic DNA Production Services 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 Risk Evaluation and Mitigation Strategy ("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 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.

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 forecasted change in our strategic focus 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, 2023, 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 4, 2023, we had 13,687,420 shares of common stock issued and outstanding, outstanding options to purchase 2,191,535 shares of common stock, outstanding warrants to purchase 5,220,588 shares of common stock, 282,640 unvested restricted stock units, and 1,340,948 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.

We have received written notice from Nasdaq that we are not in compliance with Nasdaq's minimum bid price requirements and if we are unable to regain compliance with Nasdaq continued listing standards, which may require effecting a reverse stock split of our common stock, we could be delisted from The Nasdaq Stock Market, which would negatively impact our business, our ability to raise capital, and the market price and liquidity of our common stock.

The Nasdaq Stock Market LLC ("Nasdaq") Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement") requires that the Company's common stock maintain a closing bid price for 30 consecutive business days of $1.00 per share. On December 1, 2023, the Company received a letter (the "Notice") from Nasdaq notifying the Company that, because the closing bid price for its common stock has been below $1.00 per share for 30 consecutive business days, it no longer complies with the Minimum Bid Price Requirement for continued listing on The Nasdaq Capital Market. There is no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement. The Notice had no immediate effect on the listing of the Company's common stock on The Nasdaq Capital Market. The Company has been provided an initial compliance period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement. During the compliance period, the Company's shares of common stock will continue to be listed and traded on The Nasdaq Capital Market. To regain compliance, the closing bid price of the Company's common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during the 180-day compliance period. The Company intends to actively monitor the bid price for its common stock and will consider available options, including effecting a reverse stock split, to regain compliance with the Minimum Bid Price Requirement.

If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets but will lack the market efficiencies associated with Nasdaq. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees and customers, the loss of institutional investor interest and fewer business development opportunities.

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 1C CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees or customers; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. Our cybersecurity program is aligned with industry standards and best practices, such as the National Institute of Standards and Technology ("NIST") Cybersecurity Framework. We use various tools and methodologies to manage cybersecurity risk that are tested on a regular cadence. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans, penetration tests and threat intelligence feeds. We require third-party service providers with access to personal, confidential or proprietary information to implement and maintain comprehensive cybersecurity practices consistent with applicable legal standards and industry best practices.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, customer service, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, customer dissatisfaction, harm to our vendor relationships, or loss of market share.

The company is currently in the process of implementing a more formalized cybersecurity program.

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. We entered into an amended lease agreement on February 1, 2023. The initial term is for three years and expires on February 1, 2026. The lease for the corporate headquarters requires monthly payments of $48,861, which is adjusted annually based on the US Consumer Price Index ("CPI"). In lieu of a security deposit, the Company provided a standby letter of credit of $750,000. In addition, the Company also has 2,500 square feet of laboratory space, which it entered into an amended lease agreement for on February 1, 2023. The initial lease term for the laboratory space is one year from the commencement date. The lease requires monthly payments of $8,750. 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 2023, the Company renewed this lease with a new expiration date of July 31, 2024. The base rent is approximately $6,500 per annum. The laboratory lease, as well as the testing facility in Ahmedabad are both considered short-term lease obligations.

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 4, 2023, we had 133 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 Equiniti Trust Company, LLC, 48 Wall Street, Floor 23, New York, NY 10005.

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") and ribonucleic acid ("RNA"). Using polymerase chain reaction ("PCR") to enable the production and detection of DNA and RNA, we currently operate in three primary business markets: (i) the enzymatic manufacture of synthetic DNA for use in the production of nucleic acid-based therapeutics (including biologics and drugs) and, through our recent acquisition of Spindle Biotech, Inc. ("Spindle"), the development and sale of a proprietary RNA polymerase ("RNAP") for use in the production of mRNA therapeutics ("Therapeutic DNA Production Services"); (ii) the detection of DNA and RNA in molecular diagnostics and genetic 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 current 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 the production of nucleic acid-based therapies, and to further expand and commercialize our MDx Testing Services through genetic testing.

We will continue to update our business strategy and monitor the use of our resources regarding our various business markets. In addition, we expect that based on available opportunities and our beliefs regarding future opportunities, we will continue to modify and refine our business strategy, which could include restructuring our business.

Therapeutic DNA Production Services

Through LRx we are developing and commercializing our Linea DNA and Linea IVT platforms.

Linea DNA Platform

Our Linea DNA platform is our core enabling technology, and enables the rapid, efficient, and large-scale cell-free manufacture of high-fidelity DNA sequences for use in the manufacturing of a broad range of nucleic acid-based therapeutics. The Linea DNA platform enzymatically produces a linear form of DNA we call "LineaDNA" that is an alternative to plasmid-based DNA manufacturing technologies that have supplied the DNA used in biotherapeutics for the past 40 years.

As of the third quarter of calendar year 2023, there were 3,866 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 2023 Quarterly Report). Due to what we believe are the Linea DNA platform's numerous advantages over legacy nucleic acid-based therapeutic manufacturing platforms, we believe this large number of therapies under development represents a substantial market opportunity for the Linea DNA platform to supplant legacy manufacturing methods in the manufacture of nucleic acid-based therapies.

We believe our Linea DNA platform holds several important 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 bacterial 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 Linea DNA platform does not require living cells and instead amplifies DNA via the enzymatic process of PCR. The Linea DNA platform is simple and can rapidly produce very large quantities of DNA without the need for complex purification steps.

We believe the key advantages of the Linea DNA platform include:

- Speed – Production of Linea DNA can be measured in terms of hours, not days and weeks as is the case with plasmid-based DNA manufacturing platforms.
- Scalability – Linea DNA 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 the plasmid backbone and antibiotic resistance genes, inherent to plasmid DNA, are not present in Linea DNA.
- Simplicity – The production of Linea DNA is streamlined relative to plasmid-based DNA production. Linea DNA 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 Linea DNA platform can be easily chemically modified to suit specific customer applications. In addition, the Linea DNA 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

long homopolymers such as polyadenylation sequences (poly (A) tail) important for gene therapy and messenger RNA ("mRNA") therapies, respectively.

Preclinical studies conducted by the Company have shown that Linea DNA is substitutable for plasmid DNA in numerous nucleic acid-based therapies, including:

- DNA vaccines;
- DNA templates to produce RNA, including messenger RNA ("mRNA") therapeutics; and
- adoptive cell therapy (CAR-T) manufacturing.

Further, we believe that Linea DNA 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 gene therapy; and
- non-viral gene therapy.

Linea IVT Platform

The number of mRNA therapies under development is growing at a rapid rate, thanks in part to the success of the mRNA COVID-19 vaccines. mRNA therapeutics are produced via a process called *in vitro* transcription ("IVT") that requires DNA as a starting material. As of the 3rd quarter of calendar 2023, there were almost 400 mRNA therapies under development, with the large majority of these therapies (68%) in the preclinical stage (Source: ASGCT Gene, Cell & RNA Therapy Landscape: Q3 2023 Quarterly Report). The Company believes that the mRNA market is in a nascent stage that represents a large growth opportunity for the Company via the production of DNA IVT templates to produce mRNA therapies.

In August 2022, the Company launched DNA IVT templates manufactured via its Linea DNA platform and has since secured proof of concept contracts with numerous mRNA manufacturing customers. In response to this demand, the continued growth of the mRNA therapeutic market, and the unique abilities of the Linea DNA platform, the Company acquired Spindle in July 2023 to potentially increase its mRNA-related total addressable market ("TAM").

Through our acquisition of Spindle, we recently launched our Linea IVT platform, which combines Spindle's proprietary high-performance RNA polymerase ("RNAP"), now marketed by the Company as Linea RNAP, with our enzymatically produced Linea DNA IVT templates. We believe the Linea IVT platform enables our customers to make better mRNA, faster. Based on data generated by the Company, we believe the integrated Linea IVT platform offers the following advantages over conventional mRNA production to therapy developers and manufacturers:

- The prevention or reduction of double stranded RNA ("dsRNA") contamination resulting in higher target mRNA yields with the potential to reduce downstream processing steps. dsRNA is a problematic immunogenic byproduct produced during conventional mRNA manufacture;
- delivery of IVT templates in as little as 14 days for milligram scale and 30 days for gram scale; and
- reduced mRNA manufacturing complexities.

According to the Company's internal modeling, the ability to sell both Linea DNA IVT templates and Linea RNAP under the Linea IVT platform potentially increases the Company's mRNA-related TAM by approximately 3x as compared to selling Linea DNA IVT templates alone, while also providing a more competitive offering to the mRNA manufacturing market. Currently, Linea RNAP is produced for the Company by a third-party CDMO located in the United States.

Manufacturing Scale-up

The Company plans to offer several quality grades of Linea DNA, each of which will have different permitted uses.

Quality Grade	Permitted Use	Company Status
GLP	Research and pre-clinical discovery	Currently available
GMP for Starting Materials	DNA critical starting materials for the production of mRNA therapies	Planned availability first half of CY2024 (1)
GMP	DNA biologic, drug substance and/or drug product	Planned availability first half of CY 2025 (1)

(1) Dependent on the availability of future financing.

The Company currently manufactures Linea DNA pursuant to Good Laboratory Practices ("GLP") and, subject to the availability of future financing, is creating a fit for purpose manufacturing facility within our current Stony Brook, NY laboratory space capable of producing Linea DNA IVT templates under Good Manufacturing Practices ("GMP") suitable for use as a starting material for clinical and commercial mRNA therapeutics, with a planned completion date in the first half of calendar year 2024. The Company also plans to offer Linea DNA materials manufactured under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product, with availability expected during the first half of calendar year 2025, dependent upon future funding. GMP is a quality standard used globally and by the U.S. Food and Drug Administration ("FDA") to ensure pharmaceutical quality. Drug substances are the pharmaceutically active components of drug products.

Segment Business Strategy

Our business strategy for our Therapeutic DNA Production Services is to capitalize upon the rapid growth of mRNA therapies in the near term via our planned near term future availability of Linea DNA IVT templates manufactured under GMP, while at the same time laying the basis for additional clinical and commercial applications of Linea DNA with our future planned availability of Linea DNA manufactured under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product. Our current plan is: (i) through our Linea IVT platform and planned near term future GMP manufacturing capabilities for IVT templates to secure commercial-scale supply contracts with clinical and commercial mRNA and/or self-amplifying mRNA ("sa-RNA") manufacturers for Linea DNA IVT templates and/or Linea RNAP as critical starting materials; (ii) to utilize our current GLP production capacity for non-IVT template applications to secure supply and/or development contracts with pre-clinical therapy developers that use DNA in their therapy manufacturing, and (iii) upon our development of our planned future Linea DNA production under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product, to convert existing and new Linea DNA customers into large-scale supply contracts to supply Linea DNA for clinical and commercial use as, or incorporation into, a biologic, drug substance and/or drug product in a wide range of nucleic acid therapies. Until we complete our GMP facility to produce DNA critical starting materials (DNA IVT templates) for mRNA manufacturing, we will not be able to realize significant revenues from this business. We estimate the cost of creating the critical starting materials fit-for-purpose manufacturing facility will be approximately $1.5 million. If we were to expand the facility to enable GMP production of Linea DNA for use as, or incorporation into, a biologic, drug substance and/or drug product, the cost may be up to approximately $7 million which would require additional funding. We anticipate that the fit-for-purpose manufacturing facility would be created within our existing laboratory space. We anticipate that a facility to enable GMP production of biologic, drug substances and/or drug products would require us to acquire additional space.

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 Linea DNA-based therapeutic or prophylactic vaccines for high-value veterinary health indications (collectively "Linea DNA Vaccines"). We currently seek to commercialize our Linea DNA Vaccines 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 Linea DNA encapsulated by LNPs. For the *in vivo* study, successful expression of the LNP-encapsulated Linea DNA was administered and achieved via IM injection. We believe that our Linea DNA Vaccines under development provide a substantial advantage over plasmid DNA-based vaccines for the veterinary health market.

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 and genetic (collectively "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. Permitting for genetics (molecular) is currently pending with the NYSDOH. In providing MDx testing services, ADCL employs its own or third-party molecular diagnostic tests.

We have successfully validated internally our pharmacogenomics testing services (the "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 33 genes and provide genotyping information relevant to certain cardiac, mental health, oncology, and pain management drug therapies. Our PGx Testing Services cannot commence until we receive approval from NYSDOH.

On March 22, 2023, we submitted our validation package to the NYSDOH for our PGx Testing Services. On September 21, 2023, we received a first set of comments from NYSDOH requesting additional data and clarifications. A response was submitted to NYSDOH on November 17, 2023. Currently, timing of any approval by NYSDOH for our PGx Testing Services is unclear. Recently published studies show that population-scale PGx enabled medication management can significantly reduce overall population healthcare costs, reduce adverse drug events, and increase overall population wellbeing. These benefits can result in significant cost savings to large entities and self-insured employers, the latter accounting for approximately 65% of all U.S. employers in 2022. If and when approved by NYSDOH, we plan to leverage our PGx Testing Services to provide PGx testing services to large entities and self-insured employers.

Historically, the majority of our revenue attributable to our MDx Testing Services has been derived from our safeCircle™ COVID-19 testing solutions, for which testing demand has significantly dropped. While we continue to support several safeCircle customers, we are currently observing a marked decrease in market demand for COVID-19 testing, resulting in significant reduced revenues. We expect future demand for COVID-19 testing to continue to be reduced, and we intend to pursue future COVID-19 testing opportunities on an opportunistic basis.

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 Linea DNA platform to mark objects in a unique manner and then identify these objects by detecting the absence or presence of the DNA tag. 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 Linea DNA platform, provide a methodology to authenticate goods within large and complex supply chains with a focus on cotton, nutraceuticals and other products.

- SigNify® portable DNA readers and SigNify consumable reagent test kits provide definitive real-time authentication of the Company's DNA tags in the field.

- fiberTyping® and other product genotyping services use PCR-based DNA detection to determine a cotton species or cultivar, via a product's naturally occurring DNA sequence for the purposes of product provenance authentication.

- Isotopic analysis testing services, provided in partnership with third-party labs, use cotton's carbon, hydrogen and oxygen elements to indicate origin of its fiber through finished goods.

To date, our largest commercial application for our DNA Tagging and Security Products and Services is in the tracking and provenance authentication of cotton.

We believe the Uyghur Forced Labor Prevention Act ("UFLPA") signed into law on December 23, 2021 has increased interest in our CertainT platform for DNA Tagging, fiberTyping and isotopic analysis services. The UFLPA establishes 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. On June 17, 2022, the UFLPA additionally listed DNA tagging and isotopic analysis as evidence that importers may use to potentially prove that a good did not originate in XUAR.

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

General

Historically, a substantial portion of our revenues has been generated from our safeCircle COVID-19 testing solutions, for which testing demand has significantly dropped. While we continue to support several safeCircle customers, we are currently observing a marked decrease in market demand for COVID-19 testing, resulting in significantly reduced revenues. We expect future demand for COVID-19 testing to continue to be reduced. We expect future growth in revenues to be derived from our Therapeutic DNA Production Services and our MDx testing services, as the latter transitions to a focus on genetic testing. To a lesser extent, we expect to grow revenues our DNA Tagging and Security Products and Services offerings as we work with companies and governments to secure supply chains for various types of products and product labeling throughout the world with a focus on cotton provenance. We have continued to incur expenses in expanding our business to meet current and anticipated future demand. We have limited sources of liquidity. We will continue to update our business strategy and monitor the use of our resources regarding our various business markets. In addition, we expect that based on available opportunities and our beliefs regarding future opportunities, we will continue to modify and refine our business strategy.

Comparison of the Fiscal Year Ended September 30, 2023 to the Fiscal Year Ended September 30, 2022

Revenues

Product revenues

For the twelve-month periods ended September 30, 2023 and 2022, we generated $1,218,185 and $1,882,804 in revenues from product sales, respectively. Product revenue decreased by $664,619 or 35% for the twelve-month period ended September 30, 2023 as compared to the prior fiscal year. Revenues decreased by $628,000 in sales of our Linea™ COVID-19 Assay kits and supplies, as well as decreases of $341,000 in the textiles market due to a decline year over year in cotton DNA tagging revenue, nutraceuticals market of $95,000, consumer asset marking of $64,000, cash and valuables in transit of $37,000 and military of $50,000. These decreases were offset by an increase of approximately $560,000 within our biopharmaceutical market for large scale DNA production order that resumed after the COVID-19 pandemic.

Service revenues

For the twelve-month periods ended September 30, 2023 and 2022, we generated $996,866 and $759,138 in service revenues, respectively. Service revenue increased by $237,728 or 31% for the twelve-month period ended September 30, 2023 as compared to the prior fiscal year. The increase in service revenues is primarily related to an increase in our isotopic testing services in our textile market.

Clinical laboratory service revenues

For the twelve-month periods ended September 30, 2023 and 2022, we generated $11,152,392 and $15,526,735 in revenues from clinical laboratory testing services, respectively. Clinical laboratory service revenue decreased by $4,374,343 or 28% for the twelve-month period ended September 30, 2023 as compared to the prior fiscal year. The decrease in revenue is primarily due to a decrease in demand for COVID-19 testing services during the fiscal year ended September 30, 2023 compared to the same period during fiscal 2022, as well as lower testing volumes year over year under our testing contract with the City University of New York and as a result of this contract ending mid-June 2023.

Costs and Expenses

Gross Profit

Gross profit for the twelve-month period ended September 30, 2023 increased by $479,792 or 9% from $5,053,640 for the twelve-month period ended September 30, 2022 to $5,533,432 for the twelve-month period ended September 30,2023. The gross profit percentage was 41% and 28% for the twelve-month periods ended September 30, 2023 and 2022, respectively. The increase in gross profit percentage was the result of an improvement in gross profit percentage for our MDx testing services segment. This improvement was the result of cost management efforts for our COVID-19 testing services contracts where we also provided and staffed the test collection centers. Also, during fiscal 2022 the COVID-19 positivity rate was higher than during fiscal 2023, which resulted in our clinical laboratory having to reduce the test pooling size, which increased the cost of consumables per sample, therefore having a negative impact on gross profit for fiscal 2022.

Selling, General and Administrative

Selling, general and administrative expenses for the twelve-month period ended September 30, 2023 decreased by $2,345,716 or 16% to $12,751,644 from $15,097,360 in the twelve-month period ended September 30, 2022. The decrease is primarily attributable to an decrease in stock-based compensation expense of approximately $1,485,000 relating to officer stock option grants that vested immediately during fiscal 2022, compared to the officer grant during fiscal 2023 have a four year vesting term. The remainder of the decrease relates to a decrease in bad debt expense of approximately $508,000, to fully reserve a customer balance that was deemed to be uncollectible during the twelve-month period ended September 30, 2022 that was subsequently collected during fiscal 2023 as well as a decrease of approximately $329,000 in freight charges during the twelve-month period ended September 30, 2023 primarily related to the decrease in ourCOVID-19 testing contracts.

Research and Development

Research and development expenses for the twelve-month period ended September 30, 2023 decreased by $190,965 or 5% to $3,735,078 from $3,926,043 in the twelve-month period ended September 30, 2022. This decrease is primarily due to a decrease in laboratory supplies to support genetic sequencing and isotopic research analysis projects during the twelve-month period ended September 30, 2022. This decrease was offset by research and development costs related to our continued development projects within our Therapeutic DNA production segment during the twelve-month period ended September 30, 2023.

***Interest* income**

Interest income for the twelve-month period ended September 30, 2023, increased to $75,332 from $7,200 in the same period of 2022. This increase relates to higher average cash balances in our interest-bearing accounts, coupled with increased interest rates.

Other income (expense), net

Other income (expense), net for the twelve-month periods ended September 30, 2023 and 2022, was income of $642 and expense of $47,305, respectively. The change of $47,947 is due to a gain on the sale of a vehicle of $6,083 during the current fiscal year, offset by foreign exchange transaction expenses during the prior fiscal year.

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 warrants classified as a liability

Unrealized gain on change in fair value of warrants classified as a liability for the twelve-month periods ended September 30, 2023 and 2022 of $854,400and $17,999,521, respectively, relates to the change in fair value of the warrants that are classified as a liability. The primary driver of the change is the decrease in our stock price, as well as the Series B Warrants expiring during September 2023.

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 $1,752,857, or 21% to $10,022,916 for the fiscal year ended September 30, 2023 compared to $8,270,059 for the fiscal year ended September 30, 2022, 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, 2023, we had working capital of $5,281,149. For the fiscal year ended September 30, 2023, we used cash in operating activities of $6,217,677 consisting primarily of our net loss of $10,022,916 net with non-cash adjustments of $1,362,249 in depreciation and amortization charges, $1,033,889 in stock-based compensation expense, $854,400 in unrealized gain on change in fair value of warrants classified as a liability, $6,083 in gain on sale of property and equipment, and $239,043 of bad debt expense. Additionally, we had a net decrease in operating assets of $4,091,112 and a net decrease in operating liabilities of $1,644,485. Cash used in investing activities of $1,095,808 was primarily for cash paid of $1,062,360, for the Spindle asset purchase.

The Company has recurring net losses, which have resulted in an accumulated deficit of $302,447,147 as of September 30, 2023. The Company incurred a net loss of $10,022,916 and generated negative operating cash flow of $6,217,677 for the twelve-month period ended September 30, 2023.These factors raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the financial statements. The ability of the Company to continue as a going concern is dependent on the Company's ability to further implement its business plan, raise capital, and generate revenues. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

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

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 2024. Our primary investments are expected to be in our Therapeutic DNA Production segment's research and development activities. We estimate the cost of creating the critical starting materials fit-for-purpose manufacturing facility will be approximately $1.5 million. If we were to expand the facility to enable GMP production of Linea DNA for use as or, or incorporation into, a biologic, drug substance and/or drug product, the cost may be up to approximately $7 million which would require additional funding. We anticipate that the fit-for-purpose manufacturing facility would be created within our existing laboratory space. We anticipate that a facility to enable GMP production of biologic, drug substances and/or drug products would require us to acquire additional space.

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;
- 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 critical estimates include recoverability of long-lived assets, including the values assigned to intangible assets, fair value calculations for warrants, and contingencies. 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") Accounting Standards Codifications ("ASC"), Revenue Recognition ("ASC 606" or "Topic 606"). We measure revenue at the amounts that reflect the consideration to which we are expected to be entitled in exchange for transferring control of goods and services to customers. We recognize revenue either at the point in time or over the period of time that performance obligations to customers are satisfied. Our contracts with customers may include multiple performance obligations (e.g., taggants, maintenance, authentication services, research and development services, etc.). For such arrangements, we allocate revenues to each performance obligation based on their relative standalone selling price.

Due to the short-term nature of our contracts with customers, we have 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

Our PCR-produced linear DNA product revenues are accounted for/recognized in accordance with contracts with customers. We recognize revenue upon satisfying our promises to transfer goods or services to customers under the terms of our contracts. These performance obligations are satisfied at the point in time we transfer 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. We invoice customers upon shipment, and our collection terms range, on average, from 30 to 60 days.

Authentication Services

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

Clinical Laboratory Testing Services

We record revenue for our clinical laboratory testing service contracts, which includes our COVID-19 Testing Services, upon satisfying our promise to provide services to customers under the terms of our contracts. These performance obligations are satisfied at the point in time that our 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

We record revenue for our research and development contracts using the over-time revenue recognition model. Revenue is primarily measured using the cost-to-cost method, which we believe 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. We have elected not to disclose the value of unsatisfied performance obligations for contracts with an original expected duration of one year or less.

Warrant Liabilities

We 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.

Nasdaq Delisting Notice

On December 1, 2023, we received written notice from the Listing Qualifications Department of Nasdaq notifying us that we are not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. The Minimum Bid Price Requirement requires listed securities to maintain a minimum bid price of $1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of thirty (30) consecutive business days. Based on the closing bid price of our common stock for the thirty (30) consecutive business days from October 18, 2023 to November 30, 2023, we no longer meet the Minimum Bid Price Requirement.

The Notice does not impact our listing on The Nasdaq Capital Market at this time. The Notice states that we have 180 calendar days, or until May 29, 2024, to regain compliance with Nasdaq Listing Rule 5550(a)(2). To regain compliance, the bid price of our common stock must have a closing bid price of at least $1.00 per share for a minimum of ten (10) consecutive business days. If we do not regain compliance with Nasdaq Listing Rule 5550(a)(2) by May 29, 2024, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the staff of Nasdaq (the "Staff") that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that our securities would be subject to delisting. In the event of such a notification, we may appeal the Staff's determination to delist our securities, but there can be no assurance the Staff would grant our request for continued listing.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider implementing available options, including, but not limited to, implementing a reverse stock split of our outstanding securities, to regain compliance with the Minimum Bid Price Requirement.

If our common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws, and greater difficulty in obtaining financing. In addition, delisting of our common stock could deter broker-dealers from making a market in or otherwise seeking or generating interest in our common stock, could result in a loss of current or future coverage by certain sell-side analysts, and might deter certain institutions and persons from investing in our securities at all. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers, and employees, which could harm our business and future prospects. We will consider available options to resolve the deficiencies and regain compliance with all applicable Nasdaq listing rules.

Recent Debt and Equity Financing Transactions

On November 7, 2023, we entered into an Equity Distribution Agreement (the "Agreement") with Maxim Group LLC, as sales agent (the "Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, par value $0.001 per share, in an aggregate offering price of up to $6,397,939 (the "Shares") through the Agent.

The offer and sales of the shares made pursuant to the Agreement, if any, will be made under the Company's effective "shelf" registration statement on Form S-3. Under the terms of the Agreement, the Agent may sell the Shares at market prices by any method that is deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended. As of December 4, 2023, we have issued 28,900 shares of our common stock for net proceeds of $26,098 under this Agreement.

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 the Company's 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 the Company's 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 the Company's 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.

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.

Product Research and Development

We anticipate spending approximately $3,000,000 for product research and development activities during the next twelve months. We plan to focus these activities on the further development and commercialization of our Therapeutic DNA Production services, including without limitation, research and development activities relating to our Linea DNA and Linea IVT platforms.

Off-Balance Sheet Arrangements

As a requirement of our lease agreement for our corporate headquarters entered into during January, 2023, in lieu of a security deposit, we provided a standby letter of credit of $750,000. The letter of credit is effective through January 2026.

Inflation

The effect of inflation on our revenue and operating results was not significant during the fiscal years ended September 30, 2023 and 2022.

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, 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, 2023. 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, 2023, our disclosure controls and procedures were effective.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our internal control over financial reporting was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published consolidated financial statements. Internal control over financial reporting is promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting, no matter how well designed, has inherent limitations and may not prevent or detect misstatements. Therefore, even effective internal control over financial reporting can only provide reasonable assurance with respect to the financial statement preparation and presentation.

Our management has conducted, with the participation of our CEO and CFO, an assessment, including testing of the effectiveness, of our internal control over financial reporting as of September 30, 2023. Management's assessment of internal control over financial reporting was based on assessment criteria established in the 2013 Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on such evaluation, management concluded that our internal control over financial reporting was effective as of September 30, 2023 and that our previously reported material weakness for the prior fiscal year ended September 30, 2022 has been remediated. Management concluded that the expanded practices and/or procedures to 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 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 2024 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, 2023. 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 2024 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, 2023. 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 2024 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, 2023. The relevant portions of such definitive proxy statement are incorporated herein by reference.

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

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, 2023. 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 2024 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, 2023. 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, 2023 and 2022 and for the years ended September 30, 2023 and 2022, 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.

ITEM 16. FORM 10-K SUMMARY.

None.

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 7, 2023

/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 7, 2023
/s/ BETH M. JANTZEN Beth M. Jantzen	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	December 7, 2023
/s/ **ROBERT CATELL** Robert Catell	Director	December 7, 2023
/s/ **JOSEPH D. CECCOLI** Joseph D. Ceccoli	Director	December 7, 2023
/s/ **YACOV A. SHAMASH** Yacov A. Shamash	Director	December 7, 2023
/s/ **SANFORD R. SIMON** Sanford R. Simon	Director	December 7, 2023
/s/ **ELIZABETH M. SCHMALZ SHAHEEN** Elizabeth M. Schmalz Shaheen	Director	December 7, 2023

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	
2.1*†	Share Purchase Agreement, dated July 12, 2023, by and among Spindle Acquisition Corp., Spindle Biotech Inc., the persons listed on Schedule 1.1 therein, Lai Him Chung and Applied DNA Sciences, Inc.	8-K	2.1	001-36745	7/13/2023	
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	Registration Rights Agreement, dated November 29, 2018	8-K	10.2	001-36745	12/6/2018
10.15	Securities Purchase Agreement, dated November 29, 2018	8-K	10.3	001-36745	12/6/2018
10.16	Registration Rights Agreement, dated August 31, 2018	8-K/A	10.2	001-36745	12/10/2018
10.17	Securities Purchase Agreement, dated August 31, 2018	10-K	10.45	001-36745	12/18/2018
10.18+	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
10.19	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
10.20	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
10.21	Asset Purchase Agreement, dated July 29, 2019 by and between LineaRX, Inc. and Vitatex Inc.	8-K	10.1	001-36745	8/12/2019
10.22	Form of Subscription Agreement between investors and Applied DNA Sciences, Inc., dated August 22, 2019.	8-K	10.1	001-36745	8/26/2019

10.23	Underwriting Agreement entered into by and between Applied DNA Sciences, Inc. and Maxim Group LLC, as Representative of the Underwriters listed in Schedule I hereto, dated November 13, 2019.	8-K	1.1	001-36745	11/14/2019
10.24	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
10.25†	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
10.26	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
10.27	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
10.28	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
10.29	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
10.30	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
10.31	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
10.32	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
10.33	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
10.34+	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

10.35	Animal Clinical Trial Agreement, dated September 14, 2020, between Applied DNA Sciences, Inc., Evvivax S.R.L. and Veterinary Oncology Services, PLLC	10-K	10.47	001-36745	12/17/2020	
10.36	Letter Agreement dated March 2, 2021, by and between the Company and Dr. James Hayward	8-K	10.1	001-36745	3/4/2021	
10.37	Office Lease Renewal Letter Agreement, dated February 1, 2022, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc.	10-K	10.43	001 36745	12/14/2022	
10.38	Laboratory Lease Renewal Letter Agreement, dated February 1, 2022, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc.	10-K	10.44	001 36745	12/14/2022	
10.39+	Contract Number T212206, dated August 3, 2021, by and between The City University of New York and Applied DNA Clinical Labs, LLC.	10-K	10.45	001 36745	12/14/2022	
10.40+	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.	10-K	10.46	001 36745	12/14/2022	
10.41+	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.	10-K	10.47	001 36745	12/14/2022	
10.42	Equity Distribution Agreement, dated November 7, 2023, by and between Applied DNA Sciences, Inc. and Maxim Group LLC	8-K	10.1	001-36745	11/7/2023	
14.1	Code of Business Conduct and Ethics.	10-K	14.1	001-36745	12/14/2022	
21.1	Subsidiaries of Applied DNA Sciences, Inc.					Filed
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 Stockholders and Board of Directors of
Applied DNA Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Applied DNA Sciences, Inc. (the "Company") and Subsidiaries as of September 30, 2023 and 2022, the related consolidated statements of operations, equity and cash flows for each of the two years in the period ended September 30, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

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

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved 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 7, 2023

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

SEPTEMBER 30, 2023 AND 2022

	September 30, 2023	September 30, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,151,800	$ 15,215,285
Accounts receivable, net of allowance of $75,000 and $330,853 at September 30, 2023 and 2022, respectively	255,502	3,067,544
Inventories	330,027	602,244
Prepaid expenses and other current assets	389,241	1,058,056
Total current assets	8,126,570	19,943,129
Property and equipment, net	838,270	2,222,988
Other assets:		
Restricted cash	750,000	—
Intangible assets	2,698,975	—
Operating right of use asset	1,237,762	—
Deposits	—	98,997
Total assets	$ 13,651,577	$ 22,265,114
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,270,388	$ 3,621,751
Operating lease liability, current	498,598	—
Deferred revenue	76,435	563,557
Total current liabilities	2,845,421	4,185,308
Long term accrued liabilities	31,467	31,467
Deferred revenue, long term	194,000	—
Operating lease liability, long term	739,162	—
Deferred tax liability, net	684,115	—
Warrants classified as a liability	4,285,000	5,139,400
Total liabilities	8,779,165	9,356,175
Commitments and contingencies (Note J)		
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 2023 and 2022, respectively	—	—
Series A Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of June 30, 2023 and September 30, 2022, respectively	—	—
Series B Preferred stock, par value $0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2023 and 2022, respectively	—	—
Common stock, par value $0.001 per share; 200,000,000 shares authorized as of September 30, 2023 and 2022, 13,658,520 and 12,908,520 shares issued and outstanding as of September 30, 2023 and 2022, respectively	13,659	12,909
Additional paid in capital	307,384,647	305,399,008
Accumulated deficit	(302,447,147)	(292,500,088)
Applied DNA Sciences, Inc. stockholders' equity	4,951,159	12,911,829
Noncontrolling interest	(78,747)	(2,890)
Total equity	4,872,412	12,908,939
Total liabilities and equity	$ 13,651,577	$ 22,265,114

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, 2023 AND 2022

	Twelve Months Ended September 30,	
	2023	2022
Revenues		
Product revenues	$ 1,218,185	$ 1,882,804
Service revenues	996,866	759,138
Clinical laboratory service revenues	11,152,392	15,526,735
Total revenues	13,367,443	18,168,677
Cost of product revenues	1,308,620	2,116,717
Cost of clinical laboratory service revenues	6,525,391	10,998,320
Total cost of revenues	7,834,011	13,115,037
Gross profit	5,533,432	5,053,640
Operating expenses:		
Selling, general and administrative	12,751,644	15,097,360
Research and development	3,735,078	3,926,043
Total operating expenses	16,486,722	19,023,403
LOSS FROM OPERATIONS	(10,953,290)	(13,969,763)
Interest income	75,332	7,200
Transaction cost allocated to warrant liabilities	—	(1,668,112)
Unrealized gain on change in fair value of warrants classified as a liability	854,400	17,999,521
Loss on issuance of warrants	—	(10,591,600)
Other income (expense), net	642	(47,305)
Loss before provision for income taxes	(10,022,916)	(8,270,059)
Provision for income taxes	—	—
NET LOSS	$ (10,022,916)	$ (8,270,059)
Less: Net loss attributable to noncontrolling interest	75,857	2,168
NET LOSS attributable to Applied DNA Sciences, Inc.	$ (9,947,059)	$ (8,267,891)
Deemed dividend related to warrant modifications	—	110,105
NET LOSS attributable to common stockholders	$ (9,947,059)	$ (8,377,996)
Net loss per share attributable to common stockholders-basic and diluted	$ (0.76)	$ (0.93)
Weighted average shares outstanding-basic and diluted	13,075,416	8,967,704

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, 2023 AND 2022

	Common Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Total
Balance, October 1, 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
Stock based compensation expense	—	—	1,033,889	—	—	1,033,889
Common stock issued for Spindle asset purchase	750,000	750	951,750	—	—	952,500
Net loss	—	—	—	(9,947,059)	(75,857)	(10,022,916)
Balance, September 30, 2023	13,658,520	$ 13,659	$ 307,384,647	$ (302,447,147)	$ (78,747)	$ 4,872,412

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, 2023 AND 2022

	Twelve Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (10,022,916)	$ (8,270,059)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,362,249	1,290,480
Gain on sale of property and equipment	(6,083)	—
Unrealized gain on change in fair value of warrants classified as a liability	(854,400)	(17,999,521)
Transaction costs allocated to warrant liabilities	—	1,668,112
Loss on issuance of warrants	—	10,591,600
Stock-based compensation	1,033,889	2,518,665
Change in provision for bad debts	(239,043)	269,451
Write-off of property and equipment	62,000	—
Change in operating assets and liabilities:		
Accounts receivable	3,051,083	(532,957)
Inventories	272,217	767,689
Prepaid expenses and other current assets and deposits	767,812	(493,220)
Accounts payable and accrued liabilities	(1,351,363)	930,497
Deferred revenue	(293,122)	282,557
Net cash used in operating activities	(6,217,677)	(8,976,706)
Cash flows from investing activities:		
Cash paid for Spindle asset purchase	(1,062,360)	—
Proceeds from sale of property and equipment	45,000	—
Purchase of property and equipment	(78,448)	(489,553)
Net cash used in investing activities	(1,095,808)	(489,553)
Cash flows from financing activities:		
Net proceeds from exercise of warrants	—	3,700,075
Net proceeds from issuance of common stock and warrants	—	14,426,521
Net cash provided by financing activities	—	18,126,596
Net (decrease) increase in cash, cash equivalents and restricted cash	(7,313,485)	8,660,337
Cash, cash equivalents and restricted cash at beginning of period	15,215,285	6,554,948
Cash, cash equivalents and restricted cash at end of period	$ 7,901,800	$ 15,215,285
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:		
Deemed dividend warrant modifications	$ —	$ 110,105
Leased assets obtained in exchange for new operating lease liabilities	$ 1,545,916	$ —
Fair value of warrants issued	$ —	$ 25,939,000
Fair value of warrants exercised	$ —	$ 2,802,879
Common stock issued for Spindle asset purchase	$ 952,500	$ —
Deferred tax liability for Spindle Acquisition	$ 684,115	$ —
Issuance of stock options for payment of accrued bonus	$ —	$ 300,000

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 and commercializing technologies to produce and detect deoxyribonucleic acid ("DNA") and ribonucleic acid ("RNA"). Using polymerase chain reaction ("PCR") to enable the production and detection of DNA and RNA. The Company currently operates in three primary business markets: (i) the enzymatic manufacture of synthetic DNA for use in the production of nucleic acid-based therapeutics and, through the Company's recent acquisition of Spindle Biotech, Inc. ("Spindle"), the development and sale of a proprietary RNA polymerase ("RNAP") for use in the production of mRNA therapeutics ("Therapeutic DNA Production Services"); (ii) the detection of DNA and RNA in molecular diagnostics and genetic 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").

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 continued to incur expenses in expanding its business to meet current and anticipated future demand and it has limited sources of liquidity.

NOTE B – GOING CONCERN AND MANAGEMENT'S PLAN

The Company has recurring net losses, which have resulted in an accumulated deficit of $302,447,147 as of September 30, 2023. The Company incurred a net loss of $10,022,916 and generated negative operating cash flow of $6,217,677 for the twelve-month period ended September 30, 2023.These factors raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the financial statements. The ability of the Company to continue as a going concern is dependent on the Company's ability to further implement its business plan, raise capital, and generate revenues. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

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

NOTE C – BASIS OF PRESENTATION AND SUMMARY OF ACCOUNTING POLICIES

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, Applied DNA Clinical Labs, LLC ("ADCL"), Spindle Acquisition Corp. and its 98% majority–owned subsidiary, LineaRx, Inc. ("LRx"). Spindle Acquisition Corp. was incorporated in Ontario, Canada on June 12, 2023 for the purpose of purchasing the assets of Spindle Biotech Inc. (see Note E). Once the asset purchase was completed, Spindle Acquisition Corp. was amalgamated into Spindle Biotech Inc. 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 intangible assets and 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.

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

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

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.

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

Disaggregation of Revenue

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

	Fiscal Years Ended: September 30,	
	2023	2022
Research and development services (over-time)	$ 421,585	$ 592,001
Clinical laboratory testing services (point-in-time)	7,612,975	10,398,782
Clinical laboratory services (over-time)	3,540,456	5,127,953
Product and authentication services (point-in-time):		
Supply chain	827,603	887,061
Large Scale DNA Production	653,015	—
Asset marking	311,809	534,594
MDx test kits and supplies	—	628,286
Total	$ 13,367,443	$ 18,168,677

Contract balances

As of September 30, 2023, the Company has entered into contracts with customers for which revenue has not yet been recognized. Consideration received from a customer prior to revenue recognition is recorded to a contract liability and is recognized as revenue when the Company satisfies the related performance obligations under the terms of the contract. The Company's contract liabilities, which are reported as deferred revenue on the consolidated balance sheet, consist almost entirely of research and development contracts where consideration has been received and the development services have not yet been fully performed.

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

	Balance sheet classification	October 1, 2022	September 30, 2023	$ change
Contract liabilities	Deferred revenue	$ 563,557	$ 270,435	$ 293,122

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

For the fiscal year ended September 30, 2023, the Company recognized $345,480 of revenue that was included in contract liabilities as of October 1, 2022.

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.

Cash, Cash Equivalents, and Restricted Cash

For the purpose of the accompanying consolidated financial statements, all highly liquid investments with a maturity of three months or less from when purchased are considered to be cash equivalents. The following table provides a reconciliation of cash, cash equivalents and restricted cash to amounts shown in the statement of cash flows.

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

Cash, Cash Equivalents, and Restricted Cash continued

	September 30, 2023	September 30, 2022
Cash and cash equivalents	$ 7,151,800	$ 15,215,285
Restricted cash	750,000	—
Total cash, cash equivalents and restricted cash	$ 7,901,800	$ 15,215,285

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, 2023 and 2022, the Company has an allowance for doubtful accounts of $75,000 and $330,853, respectively. The Company writes-off receivables that are deemed uncollectible.

Inventories

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

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, Income Taxes ("ASC 740") 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, 2023 and 2022, the Company incurred losses from operations. Based upon these results and the trends in the Company's performance projected for fiscal year 2024, 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, 2023 and 2022. Tax years 2019 through 2022 remain subject to future examination by the applicable taxing authorities.

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

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,	
	2023	2022
Lab equipment	$ 4,069,175	$ 4,059,754
Vehicles	56,471	108,361
Leasehold improvements	124,825	124,825
Total	4,250,471	4,292,940
Accumulated depreciation	3,412,201	2,069,952
Property and equipment, net	$ 838,270	$ 2,222,988

As of September 30, 2023 and 2022, there was $0 and $127,935 of construction in progress, respectively that was included in lab equipment. Depreciation expense for the fiscal years ended September 30, 2023 and 2022 were $1,362,249 and $1,290,480, respectively.

Impairment of Long-Lived Assets

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

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, restricted stock units and warrants.

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, 2023 and 2022 are as follows:

	2023	2022
Warrants	5,220,588	7,313,963
Restricted Stock Units	282,640	—
Options	2,204,237	1,063,055
	7,707,465	8,377,018

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

Stock-Based Compensation

The Company accounts for stock-based compensation for employees, directors, and nonemployees in accordance with ASC 718, Compensation ("ASC 718"). ASC 718 requires all share-based payments, including grants of employee stock options, to be recognized in the statement of operations based on their fair values. Under the provisions of ASC 718, stock-based compensation costs are measured at the grant date, based on the fair value of the award, and are recognized as expense over the requisite service period (generally the vesting period of the equity grant). The fair value of the Company's common stock options is estimated using the Black Scholes option-pricing model with the following assumptions: expected volatility, dividend rate, risk free interest rate and the expected life. The Company expenses stock-based compensation by using the straight-line method. In accordance with ASC 740, excess tax benefits realized from the exercise of stock-based awards are classified as cash flows from operating activities. All excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) are recognized as income tax expense or benefit in the consolidated statements of operations.

Concentrations

Financial instruments and related items, which potentially subject the Company to concentrations of credit risk, consist primarily of cash, cash equivalents, restricted cash 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, 2023, the Company had cash and cash equivalents of approximately $6.9 million in excess of the FDIC insurance limit.

The Company's revenues earned from sale of products and services for the fiscal year ended September 30, 2023 included an aggregate of 65% and 14%, respectively from two customers within the MDx Testing Services segment. 65% and 58% of the revenues earned for the fiscal years ended September 30, 2023 and 2022, respectively was derived from the COVID-19 testing contract with CUNY that terminated during June 2023.

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. Three customers accounted for 60% of the Company's accounts receivable at September 30, 2023 and two customers accounted for 89% of the Company's accounts receivable at September 30, 2022.

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, 2023 and 2022, the Company incurred research and development expenses of 3,735,078 and $3,926,043, respectively.

Advertising

The Company follows the policy of charging the costs of advertising to expense as incurred. The Company charged to operations $185,115 and $293,395, as advertising costs for the fiscal years ended September 30, 2023 and 2022, respectively.

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

Intangible Assets

The acquired technology from the Spindle Asset Purchase (see Note E) has been classified as In Process Research and Development ("IPR&D"). Intangible assets related to IPR&D are considered to be indefinite-lived until the abandonment or completion of the associated research and development efforts. Indefinite-lived intangible assets are not amortized and, instead are tested for impairment annually or more frequently if events or changes in circumstances indicate that it is more likely than not that the assets are impaired. 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, 2023, the Company performed its qualitative assessment and indicated that there was no impairment.

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 G), 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 Chief Executive Officer ("CEO"), Chief Operating Officer ("COO"), Chief Financial Officer ("CFO") and Chief Legal Officer ("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 enzymatic manufacture of synthetic DNA for use in the production of nucleic acid-based therapeutics and, through our recent acquisition of Spindle, the development and sale of a proprietary RNAP for use in the production of mRNA therapeutics.

MDx Testing Services - Segment operations consist of performing and developing clinical molecular diagnostic and genetic tests and clinical laboratory testing services. Under the Company's MDx testing services, ADCL provides COVID-19 testing solutions under its safeCircle™ trademark, as well as its pharmacogenomics testing services that are currently waiting for approval from NYSDOH. In the prior fiscal year, it also included the sales of the Company's 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.

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

Segment Reporting continued

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 expenses 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.

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, 2023, there were no transfers between Levels 1, 2 and 3 of the fair value hierarchy.

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

Recent Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, "Measurement of Credit Losses on Financial Instruments" ("ASU-2016-13"), which changes the methodology for measuring credit losses on financial instruments and certain other instruments, including trade receivables and contract assets. The new standard replaces the current incurred loss model for measurement of credit losses on financial assets with a forward-looking expected loss model based on historical experience, current conditions, and reasonable and supportable forecasts. The new standard is effective for fiscal years beginning after December 15, 2022. The adoption of ASU 2016-13 is not expected to have a significant impact on the Company's consolidated financial statements.

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, 2023 and 2022:

	2023	2022
Raw materials	$ 212,079	$ 471,947
Work in progress	19,859	55,817
Finished goods	98,089	74,480
Total	$ 330,027	$ 602,244

NOTE E – ASSET PURCHASE AGREEMENT

On July 12, 2023, the Company acquired all outstanding shares of Spindle, an early-stage, private biotech company developing next-generation RNA manufacturing technologies based in Toronto. Under the terms of the stock purchase agreement ("SPA") entered into among Applied DNA, Spindle, and the former shareholders of Spindle, in exchange for Spindle shares, the Company paid consideration of $625,000 cash, as adjusted for debt and transaction expenses, and 750,000 restricted shares of the Company's common stock, in addition to future contingent consideration of up to 1.0 million shares of the Company's common stock upon the satisfaction of certain commercialization and revenue milestones. The SPA also provides for a 10-year revenue share based on the net sales generated by the Linear IVT platform. The total consideration paid was for the acquisition of the Spindle RNAP enzyme platform technology, with no assumption of any Spindle liabilities. As a result, the transaction was accounted for as an asset acquisition in accordance with ASC 805. The total consideration paid for this intellectual property ("IP") was $2,014,860, the estimated fair value of the IP acquired, recognized on the consolidated balance sheet as of the acquisition date as an intangible asset. The intangible asset is determined to be indefinite as the Platform does not have a finite useful life in terms of economic benefits that will be derived from it.

The consideration paid is broken down as follows:

Cash	$ 625,000
750,000 Company shares at $1.27/share (share price on July 12, 2023)	952,500
Direct transaction costs	437,360
Total consideration paid for acquiring Spindle RNAP enzyme platform	$ 2,014,860

NOTE F – ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities at September 30, 2023 and 2022 are as follows:

	2023	2022
Accounts payable	$ 1,072,161	$ 1,744,105
Accrued salaries payable	1,138,235	1,458,661
Other accrued expenses	59,992	418,985
Total	$ 2,270,388	$ 3,621,751

NOTE G – CAPITAL STOCK

Common Stock Transactions during the Fiscal Year Ended September 30, 2022:

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 the Company's 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 the Company's 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 the Company's 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.

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.

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 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 the Company's 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%.

NOTE G – CAPITAL STOCK, continued

The exercise price and number of the shares of the Company's 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 H). 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.

NOTE H – WARRANTS, STOCK OPTIONS AND RESTRICTED STOCK UNITS

Warrants

The following table summarizes the changes in warrants outstanding. These warrants were granted as part of financing transactions, as well as in lieu of cash compensation for Transactions involving warrants (see Note G) are summarized as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Balance at October 1, 2022	7,313,963	$ 3.68
Granted	—	—
Exercised	—	—
Cancelled or expired	(2,093,375)	(4.12)
Balance, September 30, 2023	5,220,588	$ 3.50

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, 2023, a total of 289,534 shares have been issued and options to purchase 1,656,677 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 H – WARRANTS, STOCK OPTIONS AND RESTRICTED STOCK UNITS, 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, 2022	1,063,055	$ 20.49		
Granted	1,224,421	1.29		
Exercised	—	—		
Forfeited, cancelled or expired	(83,239)	25.78		
Outstanding at September 30, 2023	2,204,237	9.95		
Vested at September 30, 2023	1,060,931	19.26	—	7.29
Non-vested at September 30, 2023	1,143,306	1.31	—	9.37

For the twelve-month period ended September 30, 2023, the Company granted 308,333 options to officers of the Company. These options have a ten-year term and vest evenly over four years starting on the first anniversary of the date of grant. Also, during the twelve-month period ended September 30, 2023, the Company granted 694,670 options to non-employee board of director members. The options granted to the non-employee board of directors have a ten-year term and vest on the one-year anniversary of the date of grant. The remaining options granted during the fiscal year ended September 30, 2023 were to employees.

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.

The fair value of options granted during the fiscal years ended September 30, 2023 and 2022 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:

	2023	2022
Stock price	$ 1.27	$ 5.55
Exercise price	$ 1.27	$ 594
Expected term	5.75	5.16
Dividend yield	—	—
Volatility	157 %	143 %
Risk free rate	3.64 %	1.18 %

The Company recorded $1,033,889 and $2,518,665 as stock compensation expense within selling, general and administrative for fiscal years ended September 30, 2023 and 2022, respectively. As of September 30, 2023, unrecorded compensation cost related to non-vested awards was $716,898 which is expected to be recognized over a weighted average period of approximately 2.16 years. The weighted average grant date fair value per share for options granted during the fiscal years ended September 30, 2023 and 2022 was $1.20 and $0.84, respectively.

Restricted Stock Units

Restricted stock unit awards are valued at the market price of the Company’s common stock on the grant date.

NOTE H – WARRANTS, STOCK OPTIONS AND RESTRICTED STOCK UNITS, continued

Stock Options, continued

Activity in our non-vested restricted stock unit awards for the fiscal year ended September 30, 2023 is as follows:

	Number of Shares
Outstanding at October 1, 2022	—
Granted	282,640
Exercised	—
Forfeited	—
Cancelled or expired	—
Outstanding at September 30, 2023	282,640
Vested at September 30, 2023	—
Non-vested at September 30, 2023	282,640

During the fiscal year ended September 30, 2023, the Company granted 282,640 restricted stock units ("RSUs") to certain officers of the Company. These RSUs vest on the first anniversary of the grant date. The fair value of the RSUs granted was the closing stock price on the date of grant.

NOTE I – INCOME TAXES

The income tax provision (benefit) for the fiscal years ended September 30, 2023 and 2022 consists of the following:

	2023	2022
Federal:		
Current	$ —	$ —
Deferred	(3,249,000)	(2,781,000)
	(3,249,000)	(2,781,000)
State and local:		
Current	—	—
Deferred	(1,161,000)	(852,000)
	(1,161,000)	(852,000)
Foreign:		
Current	—	—
Deferred	(121,000)	11,000
	—	—
Change in valuation allowance	4,531,000	3,622,000
Income tax provision (benefit)	$ —	$ —

NOTE I – INCOME TAXES, continued

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, 2023 and 2022 as follows:

	2022	2022
Statutory federal income tax rate	21.00 %	21.00 %
Statutory state and local income tax rate (1%, as of September 30, 2022 and 2021), net of federal benefit	9.56 %	6.20 %
Stock based compensation	(1.76)%	(5.01)%
Permanent differences related to warrants	1.80 %	14.60 %
Other permanent differences	1.97 %	1.70 %
Canada NOL	1.28 %	0.00 %
Federal R&D Credit	9.93 %	3.83 %
Change in deferred tax rate	1.67 %	1.56 %
Change in valuation allowance	(45.45)%	(43.88)%
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,	
	2023	2022
Deferred tax assets (liabilities):		
Stock based compensation	$ 993,000	$ 847,000
Depreciation and amortization	440,000	113,000
Net operating loss carry forward	25,250,000	22,872,000
Impairment of intangibles	227,000	205,000
Capitalized research and development	726,000	—
Lease liability	342,000	—
Tax credits	3,060,000	2,055,000
Other	324,000	397,000
Deferred tax assets	31,362,000	26,489,000
Intellectual property	(684,000)	—
ROU asset	(342,000)	—
	(1,026,000)	—
Less: valuation allowance	(31,020,000)	(26,489,000)
Net deferred tax liability	$ (684,000)	$ —

As of September 30, 2023, the Company has approximately $101,526,000 of Federal and $56,892,000 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 $4,531,000.

The Company has Federal research and development credits of approximately $2,539,000 that will begin to expire after 2034. The Company also has state investment tax credits of $475,000 that will begin to expire after 2029.

NOTE I – INCOME TAXES, continued

On August 16, 2022, President Biden signed the Inflation Reduction Act,, which is effective for tax years beginning on or after January 1, 2023 For tax years beginning after December 31, 2021 the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures as incurred and instead required taxpayers to capitalize and amortize them over five or fifteen years beginning in 2022. The Company included the impact of the research and development expenditures in its tax expense for the fiscal year ended September 30, 2023. The Company will continue to monitor the possible future impact of changes in tax legislation.

NOTE J – 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 Company entered into an amended lease agreement on February 1, 2023. The initial term is for three years and expires on February 1, 2026. The lease for the corporate headquarters requires monthly payments of $48,861, which is adjusted annually based on the US Consumer Price Index ("CPI"). In lieu of a security deposit, the Company provided a standby letter of credit of $750,000. In addition, the Company also has 2,500 square feet of laboratory space, which it entered into an amended lease agreement for on February 1, 2023. The initial lease term for the laboratory space is one year from the commencement date. The lease requires monthly payments of $8,750. 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 2023, the Company renewed this lease with a new expiration date of July 31, 2024. The base rent is approximately $6,500 per annum. The laboratory lease, as well as the testing facility in Ahmedabad are both considered short-term lease obligations. The total rent expense for the fiscal years ended September 30, 2023 and 2022 were $663,513 and $587,346, respectively.

The components of lease expense are as follows:

	Fiscal year ended September 30,	
Lease Cost	**2023**	**2022**
Operating lease cost	$ 657,241	$ 587,346
Short-term lease cost	6,272	—
Total lease cost	$ 663,513	$ 587,346

Other Information	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 390,889
Right-of-use assets obtained in exchange for new operating lease liabilities	1,545,916
Weighted-average remaining lease term — operating leases	2.3 years
Weighted-average discount rate — operating leases	9.1 %

Maturities of operating lease liabilities were as follows:

Maturity of Lease Liabilities	Fiscal year ended September 30, **Operating Leases**
2024	586,334
2025	586,334
2026	195,445
Total lease payments	1,368,113
Less: interest	(130,351)
Present value of lease liabilities	$ 1,237,762

NOTE J – COMMITMENTS AND CONTINGENCIES, continued

Employment Agreement

The employment agreement with Dr. James Hayward, the Company's President and 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, 2023. Under the employment agreement, the CEO is eligible for an annual special aggregate cash incentive bonus of up to $800,000 each fiscal year, $300,000 of which is payable if and when annual revenue reaches $8 million for such fiscal year, plus an additional $100,000 payable for each additional $2 million of annual revenue in excess of $8 million for such fiscal year. Pursuant to the contract, the CEO's annual salary is $400,000. The Board of Directors, acting in its discretion, may grant annual bonuses to the CEO. The CEO will be entitled to certain benefits and perquisites and will be eligible to participate in retirement, welfare and incentive plans available to the Company's other employees.

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

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

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.

In accordance with the terms of his employment agreement, for the fiscal year ended September 30, 2023, the CEO earned a $500,000 bonus as the Company's fiscal year revenue was greater than $12 million. The bonus has not yet been paid 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 K – 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, 2023 is as follows:

	Therapeutic DNA Production	MDx Testing Services	DNA Tagging and Security Products	Consolidated
Revenues:				
Product revenues	$ 560,000	$ —	$ 658,185	$ 1,218,185
Service revenues	506,285	—	490,581	996,866
Clinical laboratory service revenues	—	11,253,312	—	11,253,312
Less intersegment revenues	—	(100,920)	—	(100,920)
Total revenues	$ 1,066,285	$ 11,152,392	$ 1,148,766	$ 13,367,443
Gross profit	$ 748,940	$ 4,409,186	$ 375,306	$ 5,533,432
(Loss) income from segment operations (a)	$ (3,792,871)	$ 1,206,652	$ (3,550,794)	$ (6,137,013)

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)

Reconciliation of segment loss from operations to corporate loss:

	September 30, 2023	September 30, 2022
Loss from operations of reportable segments	$ (6,137,013)	$ (9,615,379)
General corporate expenses (b)	(4,816,277)	(4,354,384)
Interest income	75,332	7,200
Unrealized gain on change in fair value of warrants classified as a liability	854,400	17,999,521
Transaction costs allocated to warrant liabilities	—	(1,668,112)
Loss on issuance of warrants	—	(10,591,600)
Other income (expense), net	642	(47,305)
Consolidated loss before provision for income taxes	$ (10,022,916)	$ (8,270,059)

(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 K – 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,	
	2023	2022
Americas	$ 12,222,650	$ 17,544,444
Europe	258,355	448,847
Asia and other	886,438	175,386
Total	$ 13,367,443	$ 18,168,677

NOTE L – 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, 2023 and summarizes the significant unobservable inputs in fair value measurement of Level 3 financial assets and liabilities as of September 30, 2023. The Company did not have any assets or liabilities categorized as Level 1 or 2 as of September 30, 2023.

	Fair value at September 30, 2023	Valuation Technique	Unobservable Input	Weighted Average
Liabilities:				
Common Warrants	$ 1,468,000	Monte Carlo simulation	Annualized volatility	160 %
Series A Warrants	$ 2,817,000	Monte Carlo simulation	Annualized volatility	160 %

The change in fair value of the Common Warrants for the twelve-month period ended September 30, 2023 is summarized as follows:

	Common Warrants
Fair value at October 1, 2022	$ 1,477,000
Change in fair value	(9,000)
Fair Value at September 30, 2023	$ 1,468,000

The change in fair value of the Series A and Series B Warrants for the twelve-month period ended September 30, 2023 is summarized as follows:

	Series A Warrants	Series B Warrants
Fair value at October 1, 2022	$ 2,883,000	$ 779,400
Change in fair value	(66,000)	(779,400)
Fair Value at September 30, 2023	$ 2,817,000	—

NOTE M — SUBSEQUENT EVENTS

On November 7, 2023, the Company entered into an Equity Distribution Agreement (the "Agreement") with Maxim Group LLC, as sales agent (the "Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, par value $0.001 per share, in an aggregate offering price of up to $6,397,939 (the "Shares") through the Agent.

The offer and sales of the Shares made pursuant to the Agreement, if any, will be made under the Company's effective "shelf" registration statement on Form S-3. Under the terms of the Agreement, the Agent may sell the Shares at market prices by any method that is deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act of 1933, as amended. As of December 4, 2023, the Company has issued 28,900 shares of its common stock for net proceeds of approximately $26,098 under this Agreement.

Exhibit 21.1

SUBSIDIARIES OF APPLIED DNA SCIENCES, INC.

Subsidiary	State or Country of Incorporation
APDN (B.V.I.) Inc.	British Virgin Islands
Applied DNA Sciences Europe Limited	United Kingdom
Applied DNA Sciences India Private Limited	India
LineaRX, Inc.	Delaware
Applied DNA Clinical Labs LLC	Delaware
Spindle Biotech, Inc.	Canada

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, 333-266217 and 333-272267) and Form S-8 (File Nos. 333-182350, 333-205123, 333-231944 and 333-249365) of our report dated December 7, 2023, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Applied DNA Sciences, Inc. and Subsidiaries as of September 30, 2023 and 2022 and for each of the two years in the period ended September 30, 2023, which report is included in this Annual Report on Form 10-K of Applied DNA Sciences, Inc. for the year ended September 30, 2023.

/s/ Marcum LLP

Marcum LLP
Melville, NY
December 7, 2023

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 7, 2023

/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 7, 2023

/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, 2023, 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 7, 2023

* 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, 2023, 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 7, 2023

* 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.