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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended September 30, 2024

☐ **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 ☒ No

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

☐ Yes ☒ No

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

☒ Yes ☐ No

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

☒ Yes ☐ No

Indicate by check mark 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 ☒ Smaller reporting company ☒

Emerging growth company ☐

If an emerging growth company, indicate by a check mark if the registrant has elected to not use the extended transition period of complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant 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 ☒ 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, 2024), was approximately $5.7 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 10% or more of the Registrant's outstanding common stock as of March 31, 2024 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 13, 2024, the Registrant had outstanding 52,294,359 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 2025 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, 2024. 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, and 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 (as defined below);
- demand for Therapeutic DNA Production Services;
- demand for DNA Tagging Services (as defined below);
- demand for MDx Testing Services (as defined below);

- 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, upon which our business strategy is substantially dependent;
- 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;
- our expectations concerning potential restructuring of our business model;
- our current non-compliance with Nasdaq's Minimum Bid Price Requirement (as defined below), which in the absence of a reverse split, may lead to delisting, potentially negatively impacting our business, our ability to raise capital, and the market price and liquidity of our Common Stock;
- our expectations of when or if we will become profitable;
- the risk that our Laboratory Developed Tests ("LDTs") may become subject to additional regulatory requirements due to U.S. Food and Drug Administration ("FDA") rulemaking activity, and that compliance with such requirements may be expensive and time-consuming, resulting in significant or unanticipated delay; and
- unknown future market demand for the Linea Mpox Virus 1.0 Assay and associated mpox testing services.

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;
- 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;
- the inherent uncertainties associated with commercialization of our PGx Testing Services (as defined below);
- 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™ 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), as well as the development and sale of a proprietary RNA polymerase ("RNAP") for use in the production of messenger RNA ("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 chains and 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 and associated enzymes for use in the production of nucleic acid-based therapies.

We will continue to update our business strategy and monitor the use of our resources regarding our various business segments. The Company's management is currently engaged in a strategic review of the Company's business segments that may result in the closure or divestiture of the Company's DNA Tagging and Security Products and Services and/or MDx Testing Services, as well as workforce reductions and potential management changes. To this end, on December 17, 2024, the Company announced it is exploring the potential divestiture of its DNA Tagging and Security Products and Services business segment. No assurance can be given that a divestiture will be completed. Further, the definitive terms and structure of any possible closure or divestiture have not been determined or approved by the Company's Board of Directors. Although the purpose of any closure or divestiture would be to reduce the Company's expenses and effectuate cost savings, it is possible that there may be related restructuring costs. We expect that based on available opportunities and our beliefs regarding future opportunities, we will continue to modify and refine our business strategy.

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 LineaDNA and Linea IVT platforms for the manufacture of synthetic DNA and associated enzymes for use in the production of nucleic acid-based therapeutics.

LineaDNA Platform

Our LineaDNA 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 LineaDNA 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 2024, there were 4,099 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 2024 Quarterly Report). Due to what we believe are the LineaDNA 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 LineaDNA platform to supplant legacy manufacturing methods in the manufacture of nucleic acid-based therapies although no assurance can be given that we will be successful in exploiting this market opportunity.

We believe our LineaDNA 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, costs and regulatory burdens. Unlike plasmid-based DNA manufacturing, the LineaDNA platform does not require living cells and instead amplifies DNA via the enzymatic process of PCR. The LineaDNA platform is simple and can rapidly produce very large quantities of DNA utilizing a cell-free process without the need for complex purification steps.

We believe the key advantages of the LineaDNA platform include:

- Speed – Production of LineaDNA can be measured in terms of hours or days, opposed to in terms of weeks as is the case with plasmid-based DNA manufacturing platforms.

- Scalability – LineaDNA production takes place on efficient bench-top instruments, allowing for rapid scalability in a minimal physical footprint.

- Purity – DNA produced via PCR is pure, resulting in only large quantities of only the target DNA sequence. Unwanted DNA sequences and contaminates such as the plasmid backbone, antibiotic resistance genes and host bacterial DNA, as well as endotoxin, which all inherent to plasmid DNA, are not present in LineaDNA.

- Simplicity – The production of LineaDNA is streamlined relative to plasmid-based DNA production. LineaDNA 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 LineaDNA platform can be easily chemically modified to suit specific customer applications. In addition, the LineaDNA 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 mRNA therapies, respectively.

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

- DNA vaccines;

- DNA templates to produce various types of RNA, including non-replicating, and self-amplifying mRNA therapeutics;

- adoptive cell therapy (CAR-T) manufacturing, and

- homology-directed repair (HDR) mediated gene editing.

Further, we believe that LineaDNA 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 third quarter of calendar 2024, there were over 450 mRNA therapies under development, with the majority of these therapies (67%) in the preclinical stage (Source: ASGCT Gene, Cell & RNA Therapy Landscape: Q3 2024 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 and supply of DNA critical starting materials and RNAP to produce mRNA therapies.

In August 2022, the Company launched DNA IVT templates manufactured via its LineaDNA platform that have resulted in evaluations of the Company's IVT templates by numerous therapeutic developers and CDMOs in the United States, Europe and the Asia-Pacific. In addition, the Company’s IVT templates are currently under late-stage evaluations by two therapeutic developers and one CDMO for use as DNA templates to produce mRNA intended for clinical use in calendar year 2025. However, there can be no assurance that related contracts will be entered into. In response to this demand, the continued growth of the mRNA therapeutic market, and the unique abilities of the LineaDNA platform, the Company acquired Spindle in July 2023 to potentially increase its mRNA-related total addressable market (“TAM”) to include the manufacture and sale of RNAP for use in conjunction with our LineaDNA IVT templates.

Through our acquisition of Spindle, we launched our Linea IVT platform in July 2023, which combines Spindle's proprietary high-performance RNAP, now marketed by the Company as Linea RNAP, with our enzymatically produced LineaDNA IVT templates. We believe the Linea IVT platform enables our customers to make better mRNA, faster. Based on data generated by the Company and its collaborators, 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;
- reduced mRNA manufacturing complexities; and
- potentially enabling mRNA manufactures to produce mRNA drug substance in less than 45 days.

According to the Company's internal modeling, the ability to sell both LineaDNA IVT templates and Linea RNAP under the Linea IVT platform potentially increases the Company's mRNA-related TAM by approximately 3-5x as compared to selling LineaDNA IVT templates alone, while also providing a more competitive offering to the mRNA manufacturing market. Currently, Linea RNAP is produced for the Company under an ISO 13485 quality system by Alphazyme, LLC ("Alphazyme") a third-party CDMO located in the United States, which the Company believes is sufficient for early-stage clinical use of the enzyme. In conjunction with Alphazyme, the Company recently completed manufacturing process development work on its Linea RNAP to increase the production scale of the enzyme and reduce unit costs.

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 in January 2025 (GMP Site 1)
GMP	DNA biologic, drug substance and/or drug product	Planned availability first half of CY 2026 (1) (GMP Site 2)

(1) Dependent on the availability of future financing.

We are currently manufacturing LineaDNA pursuant to Good Laboratory Practices ("GLP") and, are in the final stages of creating a fit for purpose manufacturing facility within our current Stony Brook, NY laboratory space capable of producing LineaDNA IVT templates under Good Manufacturing Practices ("GMP") suitable for use as a critical starting material for clinical and commercial mRNA therapeutics, with an anticipated completion date in January 2025 ("GMP Site 1"). We also plan to offer additional capacity for LineaDNA IVT templates as well as capacity for LineaDNA 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 2026, dependent upon the availability of future funding ("GMP Site 2") and customer demand. GMP is a quality standard used globally and by the 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 LineaDNA IVT templates manufactured under GMP at our GMP Site 1, while at the same time laying the basis for additional clinical and commercial applications of LineaDNA with our future planned availability of LineaDNA manufactured under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product at planned GMP Site 2. Planned GMP Site 2 may also be used for additional LineaDNA IVT template manufacturing if customer demand exceeds the capacity of GMP Site 1. In addition, we believe GMP Site 1 is capable of manufacturing LineaDNA for use as, or incorporation, into a biologic, drug substance, and/or drug product manufacturing via facility upgrades to its existing footprint.

Our current plan is: (i) through our Linea IVT platform and planned near term future GMP manufacturing capabilities for IVT templates at GMP Site 1 to secure commercial-scale supply contracts with clinical and commercial mRNA and/or self-amplifying mRNA ("sa-RNA") manufacturers for LineaDNA 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 LineaDNA production under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product at our planned GMP Site 2, and/or our upgrade to GMP Site 1, to convert existing and new LineaDNA customers into large-scale supply contracts to supply LineaDNA 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. In addition, the Company plans to utilize its planned DNA manufacturing capabilities in GMP Site 1 and/or GMP Site 2 to convert new and existing LineaDNA IVT template customers to LineaIVT platform customers to increase the Company's mRNA-related TAM.

Until we complete our GMP Site 1 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 remaining capital expenditure ("CAPEX") costs to creating GMP Site 1 will be less than $0.30 million. If we were to expand our facilities to enable GMP production of LineaDNA for use as, or incorporation, into a biologic, drug substance and/or drug product as planned for GMP Site 2, the additional CAPEX may be up to approximately $10 million which would require additional funding. We anticipate upgrades to GMP Site 1 to enable the manufacture of LineaDNA for use as, or incorporation, into a biologic, drug substance and/or drug product manufacture to be less than $1 million. We are currently building GMP Site 1 within our existing laboratory space. We anticipate that a GMP Site 2 would require us to acquire additional space.

MDx Testing Services

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

We have successfully internally validated our pharmacogenomics testing services (the "PGx Testing Services"). Our PGx Testing Services utilizes a 120-target PGx panel test to evaluate the unique genotype of a specific patient to help guide the patient's healthcare provider in making 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.

On June 12, 2024 we received full approval from NYSDOH for our PGx Testing Services. 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.We plan to leverage our PGx Testing Services to provide PGx testing services to large entities, self-insured employers and healthcare providers, as well as concierge healthcare providers.

On September 11, 2024, we announced that ADCL has launched an expansion of its clinical testing services for the detection of Mpox (formerly monkeypox) to include testing for both Mpox Clade I and Clade II. The launch of the expanded Mpox testing service comes after ADCL's interaction with relevant regulatory bodies, including the NYSDOH and the FDA. The Company believes that ADCL will be able to support New York and other states' response to the threat of Mpox. ADCL's Linea Mpox Virus 1.0 Assay was previously approved as a laboratory-developed test for the detection of Mpox Clade II by NYSDOH in September 2022. In August 2024, ADCL conducted additional validation testing showing the Assay can also detect the genetic sequence of Mpox Clade I, which is the subject of

the World Health Organization's ("WHO") August 14, 2024 declaration of a public health emergency of international concern. ADCL will provide the testing service from its CLEP/CLIA molecular diagnostics laboratory in Stony Brook, N.Y. Currently, Mpox instances in the United States are very low and the future path of Mpox is currently unknown. Accordingly, there can be no assurance that we will be able to generate revenue and profits from our approved Mpox testing.

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 declined commencing in our fiscal third quarter of 2023, resulting in substantially reduced revenues. We expect future demand for COVID-19 testing to continue to be reduced and we may terminate COVID-19 testing services in the future.

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 LineaDNA 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 LineaDNA platform, provide a methodology to authenticate goods within large and complex supply chains with a focus on cotton 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.

The Uyghur Forced Labor Prevention Act ("UFLPA") signed into law on December 23, 2021 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. Recently, in July of 2024, the Company announced a multi-year commercialization agreement for its CertainT platform with Indus Group, a multinational apparel/textile manufacturing and sourcing company.

Our current business plan is to leverage consumer and governmental awareness for product traceability to expand our existing partnerships and seek new partnerships for our DNA Tagging and Security Products and Services with a focus on cotton, though this business plan could change based on the outcome of the Company's strategic review of its business segments.

On December 17, 2024, the Company announced it is exploring the potential divestiture of its DNA Tagging and Security Products and Services business segment. No assurance can be given that a divestiture will be completed.

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 and Linea IVT platforms. LineaDNA platform development and optimization is focused on increased DNA yields, purification workflows, reducing costs of goods and DNA sequence fidelity. Further 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.

Currently, Company activities relating to our MDx Testing Services and DNA Tagging and Security Products and Services business segments are focused on commercializing existing products and services, and therefore, research and development activities are currently minimal.

We incurred approximately $3.6 million and $3.7 million on research and development activities for the fiscal years ended September 30, 2024 and 2023, 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 can 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 in January 2025, and GMP drug substance grade DNA in the first half calendar year 2026. 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.

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

Cornell University College of Veterinary Medicine. During June 2023 the Company and Cornell University College of Veterinary Medicine entered into an additional Sponsored Research Agreement (“SRA”) 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. The period of performance under the SRA is until June 30, 2025, and can be terminated by either party upon at least sixty (60) days written notice

Customers

Our revenues earned from the sale of products and services for the fiscal year ended September 30, 2024 includes 26% and 17% from two customers within our MDx Testing Services and Therapeutic DNA Production segments, respectively. 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% of the revenues earned for the fiscal year ended September 30, 2023 was derived from the COVID-19 testing contract with CUNY that terminated during June 2023. At September 30, 2024, four customers accounted for 59% of our accounts receivable. At September 30, 2023, three customers accounted for 60% of our accounts receivable. Generally, our customers do not have an obligation to make purchases from us and may stop ordering our products and services or may terminate existing orders or contracts at any time with little or no financial penalty. The loss of any of our significant customers, any substantial decline in sales to these customers, or any significant change in the timing or volume of purchases by our customers, could result in lower revenues and could harm our business, financial condition or results of operations.

Competition

Some of our competitors that operate in the nucleic-acid based therapeutic, biologics and DNA manufacturing markets include: 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, Elegen, Inc., ANSA Biotechnologies, Merck & Co., Inc. and others.

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, MyOme, Inc., 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, quality and turnaround time;
- regulatory approval;
- price;
- timing of product introductions;
- ability to develop, maintain and protect proprietary products and technologies;
- sales and distribution capabilities;
- technical support and service;
- brand loyalty; and
- applications support.

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

Intellectual Property

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

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

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

As of December 9, 2024, our patent portfolio included the following issued and pending patent applications applicable to each of our three primary business markets:

- Therapeutic DNA Production Services
    - 8 issued patents and 11 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
    - 26 issued patents and 2 pending patent applications in the United States
    - 47 issued foreign patents and 10 pending foreign patent applications

In addition to patent protection, we also rely on trademarks, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. In our Therapeutic DNA Production Services, we currently rely heavily on trade secret protection. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees

also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see "*Risk Factors — Risks Related to Our Intellectual Property* ."

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

Government Approvals of Commercial Non-Biologic Products

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

Government Regulations for COVID-19 Testing

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

In addition, clinical diagnostic testing and the review and approval of LDTs in New York State currently falls under the jurisdiction of NYSDOH and the FDA. 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, 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 the 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, the Public Health Service 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 the FDA's 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.

Laboratory Developed Tests

Our MDx Testing Services utilize LDTs developed and validated by the Company. Historically, the FDA has exercised enforcement discretion over most LDTs. On April 29, 2024, however, the FDA published a final rule on LDTs, in which the FDA outlines its plans to end enforcement discretion for many LDTs in five stages over a four-year period. In Phase 1 (effective May 6, 2025), clinical laboratories running LDTs will be required to comply with medical device (adverse event) reporting and correction/removal reporting requirements, as well as requirements for maintenance of complaint files under the FDA's quality systems regulation (QSR). In Phase 2 (effective May 6, 2026), clinical laboratories will be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for the remaining QSR requirements and premarket review. In Phase 3 (effective May 6, 2027), clinical laboratories will be required to comply with all remaining applicable QSR requirements. In Phase 4 (effective November 6, 2027), clinical laboratories will be required to comply with premarket review requirements for high-risk tests (i.e., tests subject to the premarket approval (PMA) requirement). Finally, in Phase 5 (effective May 6, 2028), clinical laboratories will be required to comply with premarket review requirements for moderate- and low-risk tests (i.e., tests subject to the de novo or 510(k) requirement).

Under the final rule, several types of tests will be eligible for some degree of continued enforcement discretion. For example, LDTs approved by the New York State Department of Health will be exempt from premarket review requirements but will remain subject to the requirements of Phases 1 through 3. Similarly, LDTs first marketed prior to May 6, 2024 that are not subsequently modified, or are modified only in certain limited ways, will be exempt from the premarket review and most quality systems requirements, but will remain subject to the requirements of Phases 1 and 2. The FDA notes, however, that it retains discretion to pursue enforcement action for violations of the Federal Food, Drug and Cosmetic Act at any time and intends to do so when appropriate. The FDA further explains that it may update any of the enforcement discretion policies set forth in the final rule as circumstances warrant or if the circumstances that inform those policies change, consistent with the FDA's good guidance practices.

Multiple lawsuits have been filed challenging the LDT final rule, in which the plaintiffs argue FDA lacks authority to regulate LDTs as medical devices. We cannot predict the likelihood of success of these lawsuits at this time.

Congress is also working on legislative language that, if enacted, would clarify the FDA's authority with respect to LDTs. In this regard, most recently, the "Verifying Accurate Leading-edge IVCT Development Act," or VALID Act, was first introduced in March 2020, and most recently reintroduced in 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 allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre-certified, certain low-risk IVCTs developed by the laboratory and falling within the scope of a certification order from the FDA 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 NYSDOH CLEP-permitted and CLIA-certified laboratory which is currently permitted for virology and genetic (molecular).

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, 2024, we had a total of 48 employees (46 fulltime and 2 part-time), consisting of 4 in executive management, 8 in research and development, 8 in quality and compliance, 3 in finance, accounting and human resources, 8 in operations/production, 5 in sales and marketing, 4 in administration and support services, 4 in information services, and 4 in clinical laboratory operations. 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, 2024, 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.
- We may not successfully implement our business strategies, including achieving our growth objectives, including the development of new production facilities for our Therapeutic DNA Production Services.
- We may require additional financing which may in turn require the issuance of additional shares of Common Stock, preferred stock or other debt or equity securities (including convertible securities) and which would dilute the ownership held by or stockholders.
- We may modify and refine our business strategy, including a possible divesture or closing of our DNA Tagging and Security Products and Services and/or MDx Testing Services segments.
- 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 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.
- We will need to develop and maintain facilities that meet GMP.
- 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.
- Pharmaceutical and biologic-related revenue will be dependent on our collaborators' and customers' demand for our manufacturing 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 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 within our MDx Testing Services segment.
- 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.
- 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.
- Stockholders may suffer substantial dilution if certain provisions in the May 2024 Series Warrants (as defined below) are utilized.
- Stockholders may suffer substantial dilution if certain provisions in the October 2024 Series D Warrants (as defined below) are utilized.
- The exercisability of the October 2024 Private Placement Warrants (as defined below) is contingent upon us obtaining Warrant Stockholder Approval (as defined below). If we do not obtain such Warrant Stockholder Approval, the October 2024 Private Placement Warrants may never become exercisable.
- 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.
- 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 further declined to $3.4 million 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 $309,672,755 as of September 30, 2024. We have incurred a net loss of $7,088,306 for the fiscal year ended September 30, 2024. At September 30, 2024, we had cash and cash equivalents of $6,431,095. 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. As discussed in Note M to our consolidated financial statements, on October 31, 2024, we closed on a registered direct offering and received net proceeds, after deducting placement agent fees and other estimated offering expenses payable by us, of approximately $5.8 million. As a result of this offering, our consolidated cash balance as of November 30, 2024 was approximately $10.1 million.

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, our executive management team's ability to execute new operational initiatives, and certain matters outside of our control. 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 modify and refine our business strategy, including a possible divesture or closing of our DNA Tagging and Security Products and Services and/or MDx Testing Services segments.

Our management is currently engaged in a strategic review of the Company's business segments that may result in the divestiture or closure of the Company's DNA Tagging and Security Products and Services segment and/or MDx Testing Services, as well as workforce reductions and potential management changes. To this end, on December 17, 2024, the Company announced it is exploring the potential divestiture of its DNA Tagging and Security Products and Services business segment. No assurance can be given that a divestiture will be completed. Further, the definitive terms and structure of any possible closure or divestiture have not been determined or approved by the Company's Board of Directors. Although the purpose of any closure or divestiture would be to reduce the Company's expenses and effectuate cost savings, it is possible that there may be related restructuring costs. We expect that based on available opportunities and our beliefs regarding future opportunities, we will continue to modify and refine our business strategy. The initial cash received from any divestiture, if any, may be limited, although the terms of a divesture may include future royalties, earn-outs or similar terms, any of which could fail to be earned or received.

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 existing 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 our common stock. Our public offerings completed in November 2014, April 2015, December 2018, November 2019, August 2022 and May 2024, our registered direct offerings completed in December 2017, January 2021 and February 2022, our registered direct public offering and concurrent private placement completed in November 2015, January 2024 and October 2024, and our private placements completed in November 2016, June 2017, and August 2019 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, 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.

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, Israel and Hamas and Israel and Hezbollah have 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. At the same time, and because of the war declaration against Hamas, the clash between Israel and Hezbollah in Lebanon has escalated to an armed conflict and there is a high possibility that it will turn into a greater regional conflict in the future. The extent and duration of the wars in Ukraine, Israel/Gaza and Lebanon, as well as 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 conflicts in Ukraine and the Middle East. 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 human therapeutics, diagnostics and 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. In addition, as discussed in our risk factor disclosure above on page 19, our management is currently engaged in a strategic review of the Company's business segments that may result in the divestiture or closure of the Company's MDx Testing Services and/or DNA Tagging and Security Products and Services, as well as workforce reductions and potential management changes.

If we are unable to manage this growth and/or potential restructuring 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.

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 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 LineaDNA platform and GMP Site 1 and GMP Site 2, we need to build additional manufacturing capacity that will require additional capital expenditures and additional financing. 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 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 applicable 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 other 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 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.

Our MDx Testing Services utilize LDTs developed and validated by the Company. ADCL is currently subject to NYSDOH oversight as a CLEP-permitted and CLIA-certified laboratory. Historically, the FDA has exercised enforcement discretion over most LDTs. On April 29, 2024, however, the FDA published a final rule on LDTs, in which the FDA outlines its plans to end enforcement discretion for many LDTs in five stages over a four-year period. In Phase 1 (effective May 6, 2025), clinical laboratories running LDTs will be required to comply with medical device (adverse event) reporting and correction/removal reporting requirements, as well as requirements for maintenance of complaint files under the FDA's quality systems regulation (QSR). In Phase 2 (effective May 6, 2026), clinical laboratories will be required to comply with all other device requirements (e.g., registration/listing, labeling, investigational use), except for the remaining QSR requirements and premarket review. In Phase 3 (effective May 6, 2027), clinical laboratories will be required to comply with all remaining applicable QSR requirements. In Phase 4 (effective November 6, 2027), clinical laboratories will be required to comply with premarket review requirements for high-risk tests (i.e., tests subject to the premarket approval (PMA) requirement). Finally, in Phase 5 (effective May 6, 2028), clinical laboratories will be required to comply with premarket review requirements for moderate- and low-risk tests (i.e., tests subject to the de novo or 510(k) requirement).

Under the final rule, several types of tests will be eligible for some degree of continued enforcement discretion. For example, LDTs approved by the New York State Department of Health will be exempt from premarket review requirements but will remain subject to the requirements of Phases 1 through 3. Similarly, LDTs first marketed prior to May 6, 2024 that are not subsequently modified, or are modified only in certain limited ways, will be exempt from the premarket review and most quality systems requirements, but will remain subject to the requirements of Phases 1 and 2. The FDA notes, however, that it retains discretion to pursue enforcement action for violations of the Federal Food, Drug and Cosmetic Act at any time and intends to do so when appropriate. The FDA further explains that it may update any of the enforcement discretion policies set forth in the final rule as circumstances warrant or if the circumstances that inform those policies change, consistent with the FDA's good guidance practices.

Multiple lawsuits have been filed challenging the LDT final rule, in which the plaintiffs argue FDA lacks authority to regulate LDTs as medical devices. We cannot predict the likelihood of success of these lawsuits at this time.

Congress is also working on legislative language that, if enacted, would clarify the FDA's authority with respect to LDTs. In this regard, most recently, the "Verifying Accurate Leading-edge IVCT Development Act," or VALID Act, was first introduced in March 2020, and most recently reintroduced in 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 allow a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre-certified, certain low-risk IVCTs developed by the laboratory and falling within the scope of a certification order from FDA 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 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, without limitation: 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., Elegen, Inc., ANSA Biotechnologies, 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 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 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, MyOme, Inc., 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. In addition, revenues associated with our clinical testing services for the detection of Mpox are closely tied to the prevalence of Mpox within the United States, which is currently very low. Accordingly, there can be no assurance that we will be able to generate revenue and profits from Mpox testing. 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.

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 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 synthetic DNA performance characteristics will meet or exceed DNA produced by our competitors.

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.

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 LineaDNA 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 LineaDNA is utilized or incorporated do not gain market acceptance, our revenues and profitability may be adversely affected.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If our customers are ultimately unable to obtain regulatory approval for products incorporating our Therapeutic DNA Production Services, we will be unable to generate meaningful revenue and our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application submitted by one of our customers. 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, 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 or 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 and state agencies, 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.

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.

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, 2024, 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 13, 2024, we had 52,294,359 shares of Common Stock issued and outstanding, outstanding options to purchase 108,176 shares of Common Stock, outstanding warrants to purchase 136,325,980 shares of Common Stock, and 269,069 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.

Stockholders may suffer substantial dilution if certain provisions in the May 2024 Series Warrants are utilized.

On May 29, 2024 we closed on such date a public offering (the "May 2024 Offering") of Common Stock and warrants, including 9,230,769 series A common stock purchase warrants ("May 2024 Series A Warrants") and 9,230,769 series B common stock purchase warrants ("May 2024 Series B Warrants", and, with the May 2024 Series A Warrants, the "May 2024 Series Warrants"), with Craig-Hallum Capital Group LLC ("Craig-Hallum") and Laidlaw & Company (UK) Ltd. ("Laidlaw") as placement agents. As part of the May

2024 Offering, the Company entered into a Placement Agency Agreement, dated May 28, 2024, with Craig-Hallum and Laidlaw (the "May 2024 Placement Agency Agreement").

If the May 2024 Series B Warrants are exercised by way of an alternative cashless exercise, such exercising holder will receive three times the number of shares of Common Stock they would receive in a cash exercise for each May 2024 Series B Warrant they exercise, without any cash payment to us. In addition, the May 2024 Series A Warrants and May 2024 Series B Warrants each include a provision that resets their exercise price in the event of a reverse split of our Common Stock, to a price equal to the lesser of (i) the then exercise price and (ii) lowest volume weighted average price (VWAP) during the period commencing five trading days immediately preceding and the five trading days commencing on the date we effect a reverse stock split in the future with a proportionate adjustment to the number of shares underlying the applicable warrant.

In addition, subject to certain exemptions, the May 2024 Series A Warrants provide for an adjustment to the exercise price and number of shares underlying the May 2024 Series A Warrants if we sell, enter into an agreement to sell, or grant any option to purchase, or sell, enter into an agreement to sell, or grant any right to reprice (excluding Exempt Issuances, as defined in the May 2024 Placement Agency Agreement), or otherwise dispose of or issue (or announce any offer, sale, grant or any option to purchase or other disposition) any shares of Common Stock, at an effective price per share less than the exercise price of the May 2024 Series A Warrants then in effect (the "Price Reset Mechanism").

On October 30, 2024, the Company and certain holders of the May 2024 Series A Warrants entered into an amendment to such holders' May 2024 Series A Warrants (the "Warrant Amendment"), pursuant to which the Price Reset Mechanism became subject to a floor equal to $0.20.

The Price Reset Mechanism of the May 2024 Series A Warrants, when triggered, would reduce the exercise price of the May 2024 Series A Warrants to the lower of the price per share of the Common Stock issued or (i) $0.20 with respect to the May 2024 Series A Warrants as amended by the Warrant Amendment or (ii) the lowest volume weighted average price (VWAP) during the five consecutive trading days immediately following such dilutive issuance or announcement thereof with respect to the remaining May 2024 Series A Warrants not amended by the Warrant Amendment. The number of shares issuable upon exercise after the Price Reset Mechanism has been triggered will be proportionately adjusted such that the aggregate exercise price will remain unchanged.

In connection with the October 2024 Offering (as described below), the Price Reset Mechanism in the May 2024 Series A Warrants was triggered, which resulted in the number of shares of Common Stock issuable upon exercise of the May 2024 Series A Warrants increasing from 9,230,769 to 91,890,698. The exercise price of the May 2024 Series A Warrants was adjusted from $1.99 per share to $0.20 per share with respect to the May 2024 Series A Warrants amended by the Warrant Amendment, and to $0.19 with respect to the May 2024 Series A Warrants not amended by the Warrant Amendment.

If any of the above provisions in the May 2024 Series Warrants are further utilized, our stockholders may suffer substantial dilution.

Stockholders may suffer substantial dilution if certain provisions in the October 2024 Series D Warrants are utilized.

On October 30, 2024, we entered into a securities purchase agreement (the "October 2024 Purchase Agreement") with certain institutional investors (each, an "October 2024 Purchaser" and, collectively, the "October 2024 Purchasers"), pursuant to which the Company agreed to issue and sell, (i) in a registered direct public offering (the "October 2024 Registered Direct Offering") of 19,247,498 shares of the Company's Common Stock and pre-funded warrants ("October 2024 Pre-Funded Warrants") to purchase up to 1,065,002 shares of Common Stock, and (ii) in a concurrent private placement (the "October 2024 Private Placement", and together with the October 2024 Registered Direct Offering the "October 2024 Offering"), unregistered Series C Common Stock Purchase Warrants ("October 2024 Series C Warrants") to purchase up to 20,312,500 shares of Common Stock and unregistered Series D Common Stock Purchase Warrants ("October 2024 Series D Warrants", and together with the October 2024 Series C Warrants, the "October 2024 Series Warrants") to purchase up to 20,312,500 shares of Common Stock. Craig-Hallum acted as placement agent in connection with the October 2024 Offering. The Company also agreed to issue to Craig-Hallum, or its respective designees, Placement Agent Warrants ("October 2024 Placement Agent Warrants", and, with the October 2024 Series Warrants, the "October 2024 Private Placement Warrants") to purchase up to 1,015,625 shares of Common Stock.

If the October 2024 Series D Warrants are exercised by way of an alternative cashless exercise, assuming receipt of Warrant Stockholder Approval (as defined below), such exercising holder will receive one share of Common Stock for each share of Common Stock they would receive in a cash exercise for each October 2024 Series D Warrant they exercise, without any cash payment to us.

In addition, the October 2024 Series D Warrants include a provision that resets their exercise price in the event of a reverse split of our Common Stock, to a price equal to the lesser of (i) the then exercise price and (ii) lowest volume weighted average price (VWAP) during the period commencing five trading days immediately preceding and the five trading days commencing on the date we effect a reverse stock split in the future with a proportionate adjustment to the number of shares underlying the October 2024 Series D Warrants, subject to a floor of $0.0634.

If any of the above provisions in the October 2024 Series D Warrants are utilized, our stockholders may suffer substantial dilution.

The exercisability of the October 2024 Private Placement Warrants is contingent upon us obtaining Warrant Stockholder Approval. If we do not obtain such Warrant Stockholder Approval, the October 2024 Private Placement Warrants may never become exercisable.

The exercisability of the October 2024 Private Placement Warrants will be available only upon receipt of such stockholder approval (the "Warrant Stockholder Approval") as may be required by the applicable rules and regulations of The Nasdaq Stock Market LLC. Each October 2024 Series C Warrant has an exercise price of $0.32 per share of Common Stock, will become exercisable upon the first trading day (the "Stockholder Approval Date") following the Company's notice to warrantholders of Warrant Stockholder Approval, and will expire on the five-year anniversary of the Stockholder Approval Date. Each October 2024 Series D Warrant has an exercise price of $0.32 per share of Common Stock, will become exercisable upon the Stockholder Approval Date, and will expire on the 18-month anniversary of the Stockholder Approval Date. Each October 2024 Placement Agent warrant has an exercise price of $0.32, will become exercisable upon the Stockholder Approval date and will expire on October 30, 2029.

While we intend to promptly seek Warrant Stockholder Approval for these mechanisms, there is no guarantee that it will ever be obtained. In the event that we cannot obtain Warrant Stockholder Approval, the October 2024 Private Placement Warrants may never become exercisable and may have no value.

We have agreed to hold a special meeting of shareholders (which may also be at the annual meeting of shareholders) at the earliest practicable date after the date hereof, but in no event later than ninety days after the closing of the offering, in order to obtain Warrant Stockholder Approval. There is no guarantee we will be able to hold a special meeting within this timeframe, or at all. If we do not obtain Warrant Stockholder Approval at the first meeting, we are obligated to call a meeting every ninety days thereafter to seek Warrant Stockholder Approval until the earlier of the date on which Stockholder Approval is obtained or the October 2024 Series Warrants are no longer outstanding.

We may be required to repurchase certain of our warrants.

Under certain of 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 November 12, 2024, 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, with a longer period potentially required by the staff of Nasdaq (the "Staff"). 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.

Pursuant to the October 2024 Purchase Agreement, the Company is required to effect a reverse stock split of its outstanding shares of Common Stock if, at any time after the Stockholder Approval Date, it is not in compliance with Nasdaq's Bid Price Rule and has received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC (the "Reverse Stock Split"). The Company must effect the Reverse Stock Split within 30 days of the Stockholder Approval Date; provided that if within such 30 day period the Company regains compliance with the Minimum Bid Price Requirement, the Company shall have no obligation to effect the Reverse Stock Split. The Company intends to implement a reverse stock split of its outstanding securities to regain compliance with the Bid Price Rule and to comply with the provisions of the October 2024 Purchase Agreement.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C CYBERSECURITY

Applied DNA Sciences operates 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 conduct periodic risk assessments using various tools and methodologies to identify and manage the potential impact and likelihood of various cyber scenarios, including those involving third-party service providers, and to determine the appropriate mitigation strategies and controls. 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.

Our Chief Information Officer ("CIO") conducts the regular assessment and management of material risks from cybersecurity threats, including review with our IT team and third party providers. All employees and consultants are directed to report to senior management

with any irregular or suspicious activity that could indicate a cybersecurity threat or incident. The Audit Committee of our Board of Directors evaluates our cybersecurity assessment and management policies, including quarterly interviews with our senior officers and independent registered accounting firm.

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 on February 1, 2023. The initial lease term for the laboratory space is one year from the commencement date and has been extended through January 31, 2025. The lease requires monthly payments of $10,417. The Company also had a satellite testing facility in Ahmedabad, India, which occupied 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. As of June 30, 2024 the Company has ceased operations of its testing facility in India. The Company vacated the lease on August 31, 2024. The base rent was approximately $6,500 per annum. The laboratory lease, as well as the testing facility in Ahmedabad were 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 13, 2024, we had 375 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, 90 Park Avenue, New York, NY 10016.

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 DNA and RNA. Using 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), as well as the development and sale of a proprietary RNA polymerase RNAP for use in the our Therapeutic DNA Production Services; (ii) the detection of DNA and RNA in our MDx Testing Services; and (iii) the manufacture and detection of DNA for our 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 CDMO for the manufacture of synthetic DNA and associated enzymes for use in the production of nucleic acid-based therapies.

We will continue to update our business strategy and monitor the use of our resources regarding our various business segments. The Company's management is currently engaged in a strategic review of the Company's business segments that may result in the closure or divestiture of the Company's DNA Tagging and Security Products and Services and/or MDx Testing Services, as well as workforce reductions and potential management changes. To this end, on December 17, 2024, the Company announced it is exploring the potential divestiture of its DNA Tagging and Security Products and Services business segment. No assurance can be given that a divestiture will be completed. Further, the definitive terms and structure of any possible closure or divestiture have not been determined or approved by the Company's Board of Directors. Although the purpose of any closure or divestiture would be to reduce the Company's expenses and effectuate cost savings, it is possible that there may be related restructuring costs. We expect that based on available opportunities and our beliefs regarding future opportunities, we will continue to modify and refine our business strategy.

Industry Background and Markets

Therapeutic DNA Production Services

Through LRx, our 98% owned subsidiary we are developing and commercializing our LineaDNA and Linea IVT platforms for the manufacture of synthetic DNA and associated enzymes for use in the production of nucleic acid-based therapeutics.

LineaDNA Platform

Our LineaDNA 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 LineaDNA 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 2024, there were 4,099 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 2024 Quarterly Report). Due to what we believe are the LineaDNA 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 LineaDNA platform to supplant legacy manufacturing methods in the manufacture of nucleic acid-based therapies although no assurance can be given that we will be successful in exploiting this market opportunity.

We believe our LineaDNA 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, costs and regulatory burdens. Unlike plasmid-based DNA manufacturing, the LineaDNA platform does not require living cells and instead amplifies DNA via the enzymatic process of PCR. The LineaDNA platform is simple and can rapidly produce very large quantities of DNA utilizing a cell-free process without the need for complex purification steps.

We believe the key advantages of the LineaDNA platform include:

- Speed – Production of LineaDNA can be measured in terms of hours, or days, as opposed to in terms of weeks as is the case with plasmid-based DNA manufacturing platforms.

- Scalability – LineaDNA production takes place on efficient bench-top instruments, allowing for rapid scalability in a minimal physical footprint.

- Purity – DNA produced via PCR is pure, resulting in only large quantities of only the target DNA sequence. Unwanted DNA sequences and contaminates such as the plasmid backbone, antibiotic resistance genes and host bacterial DNA, as well as endotoxin, which all inherent to plasmid DNA, are not present in LineaDNA. Simplicity – The production of LineaDNA is streamlined relative to plasmid-based DNA production. LineaDNA 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 LineaDNA platform can be easily chemically modified to suit specific customer applications. In addition, the LineaDNA 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 ITRs and long homopolymers such as polyadenylation sequences (poly (A) tail) important for gene therapy and mRNA therapies, respectively.

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

- DNA vaccines;

- DNA templates to produce various types of RNA, including non-replicating and self-amplifying mRNA therapeutics;

- CAR-T manufacturing, and

- HDR mediated gene editing.

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

- viral vector manufacturing for *in vivo* and *ex vivo* gene editing;

- 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 IVT that requires DNA as a starting material. As of the third quarter of calendar 2024, there were over 450 mRNA therapies under development, with the majority of these therapies (67%) in the preclinical stage (Source: ASGCT Gene, Cell & RNA Therapy Landscape: Q3 2024 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 and supply of DNA critical starting materials and RNAP to produce mRNA therapies.

In August 2022, the Company launched DNA IVT templates manufactured via its LineaDNA platform that have resulted in evaluations of the Company's IVT templates by numerous therapeutic developers and CDMOs in the United States, Europe and the Asia-Pacific. In addition, the Company's IVT templates are currently under late-stage evaluations by two therapeutic developers and one CDMO for use as DNA templates to produce mRNA intended for clinical use in calendar year 2025. However there can be no assurance that related contracts will be entered into. In response to this demand, the continued growth of the mRNA therapeutic market, and the unique abilities of the LineaDNA platform, the Company acquired Spindle in July 2023 to potentially increase its mRNA-related TAM to include the manufacture and sale of RNAP for use in conjunction with our LineaDNA IVT templates.

Through our acquisition of Spindle, we launched our Linea IVT platform in July 2023, which combines Spindle's proprietary high-performance RNAP, now marketed by the Company as Linea RNAP, with our enzymatically produced LineaDNA IVT templates. We believe the Linea IVT platform enables our customers to make better mRNA, faster. Based on data generated by the Company and its collaborators, 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 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;
- reduced mRNA manufacturing complexities; and
- potentially enabling mRNA manufactures to produce mRNA drug substance in less than 45 days.

According to the Company's internal modeling, the ability to sell both LineaDNA IVT templates and Linea RNAP under the Linea IVT platform potentially increases the Company's mRNA-related TAM by approximately 3-5x as compared to selling LineaDNA IVT templates alone, while also providing a more competitive offering to the mRNA manufacturing market. Currently, Linea RNAP is produced for the Company under an ISO 13485 quality system by Alphazyme, LLC a third-party CDMO located in the United States, which the Company believes is sufficient for early-stage clinical use of the enzyme. In conjunction with Alphazyme, the Company recently completed manufacturing process development work on its Linea RNAP to increase the production scale of the enzyme and reduce unit costs.

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 in January 2025 (GMP Site 1)
GMP	DNA biologic, drug substance and/or drug product	Planned availability first half of CY 2026 (1) (GMP Site 2)

(1) Dependent on the availability of future financing.

We are currently manufacturing LineaDNA pursuant to GLP and, are in the final stages of creating GMP Site 1, a fit for purpose manufacturing facility within our current Stony Brook, NY laboratory space capable of producing LineaDNA IVT templates under GMP suitable for use as a critical starting material for clinical and commercial mRNA therapeutics, with an anticipated completion date in January 2025. We also plan to offer additional capacity for LineaDNA IVT templates as well as capacity for LineaDNA materials

manufactured under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product at GMP Site 2, with availability expected during the first half of calendar year 2026, dependent upon the availability of future funding and customer demand. GMP is a quality standard used globally and by the 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 LineaDNA IVT templates manufactured under GMP at our GMP Site 1, while at the same time laying the basis for additional clinical and commercial applications of LineaDNA with our future planned availability of LineaDNA manufactured under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product at planned GMP Site 2. Planned GMP Site 2 may also be used for additional LineaDNA IVT template manufacturing if customer demand exceeds the capacity of GMP Site 1. In addition, we believe GMP Site 1 is capable of manufacturing LineaDNA for use as, or incorporation, into a biologic, drug substance, and/or drug product manufacturing via facility upgrades to its existing footprint.

Our current plan is: (i) through our Linea IVT platform and planned near term future GMP manufacturing capabilities for IVT templates at GMP Site 1 to secure commercial-scale supply contracts with clinical and commercial mRNA and/or sa- RNA manufacturers for LineaDNA 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 LineaDNA production under GMP suitable for use as, or incorporation into, a biologic, drug substance and/or drug product at our planned GMP Site 2, and/or our upgrade to GMP Site 1, to convert existing and new LineaDNA customers into large-scale supply contracts to supply LineaDNA 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. In addition, the Company plans to utilize its planned DNA manufacturing capabilities in GMP Site 1 and/or GMP Site 2 to convert new and existing LineaDNA IVT template customers to LineaIVT platform customers to increase the Company's mRNA-related TAM.

Until we complete our GMP Site 1 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 remaining CAPEX costs to creating GMP Site 1 will be less than $0.30 million. If we were to expand our facilities to enable GMP production of LineaDNA for use as, or incorporation, into a biologic, drug substance and/or drug product as planned for GMP Site 2, the additional CAPEX may be up to approximately $10 million which would require additional funding. We anticipate upgrades to GMP Site 1 to enable the manufacture of LineaDNA for use as, or incorporation, into a biologic, drug substance and/or drug product manufacture to be less than $1 million. We are currently building GMP Site 1 within our existing laboratory space. We anticipate that a GMP Site 2 would require us to acquire additional space.

MDx Testing Services

Through ADCL, our clinical laboratory subsidiary, we leverage our expertise in DNA and RNA detection via PCR to provide and develop MDx Testing Services. ADCL is a NYSDOH CLIA-certified laboratory which is currently permitted for virology and genetics (molecular). In providing MDx Testing Services, ADCL employs its own or third-party molecular diagnostic tests.

We have successfully internally validated our PGx Testing Services. Our PGx Testing Services utilizes a 120-target PGx panel test to evaluate the unique genotype of a specific patient to help guide the patient's healthcare provider in making 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.

On June 12, 2024 we received full approval from NYSDOH for our PGx Testing Services. 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.We plan to leverage our PGx Testing Services to provide PGx testing services to large entities, self-insured employers and healthcare providers, as well as concierge healthcare providers.

On September 11, 2024, we announced that ADCL launched an expansion of its clinical testing services for the detection of Mpox (formerly monkeypox) to include testing for both Mpox Clade I and Clade II. The launch of the expanded Mpox testing service comes after ADCL's interaction with relevant regulatory bodies, including the NYSDOH and the FDA. The Company believes that ADCL will

be able to support New York and other states' response to the threat of Mpox. ADCL's Linea Mpox Virus 1.0 Assay was previously approved as a laboratory-developed test for the detection of Mpox Clade II by NYSDOH in September 2022. In August 2024, ADCL conducted additional validation testing showing the Assay can also detect the genetic sequence of Mpox Clade I, which is the subject of the WHO;s August 14, 2024 declaration of a public health emergency of international concern. ADCL will provide the testing service from its CLEP/CLIA molecular diagnostics laboratory in Stony Brook, N.Y. Currently, Mpox instances in the United States are very low and the future path of Mpox is currently unknown. Accordingly, there can be no assurance that we will be able to generate revenue and profits from Mpox testing.

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 LineaDNA 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 LineaDNA platform, provide a methodology to authenticate goods within large and complex supply chains with a focus on cotton, 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.

The UFLPA signed into law on December 23, 2021 establishes that any goods mined, produced, or manufactured wholly or in part in the 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. In July of 2024, the Company announced a multi-year commercialization agreement for its CertainT platform with Indus Group, a multinational apparel/textile manufacturing and sourcing company.

Our current business plan is to leverage consumer and governmental awareness for product traceability to expand our existing partnerships and seek new partnerships for our DNA Tagging and Security Products and Services with a focus on cotto, though this business plan could change based on the outcome of the Company's strategic review of its business segments.

On December 17, 2024, the Company announced it is exploring the potential divestiture of its DNA Tagging and Security Products and Services business segment. No assurance can be given that a divestiture will be completed.

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. 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, which

may result in the divestiture or closure of the Company's MDx Testing Services and/or DNA Tagging and Security Products and Services segments, as well as workforce reductions and potential management changes.

Comparison of the Fiscal Year Ended September 30, 2024 to the Fiscal Year Ended September 30, 2023

Revenues

Product revenues

For the fiscal year ended September 30, 2024 and 2023, we generated $1,074,813 and $1,218,185 in revenues from product sales, respectively. Product revenue decreased by $143,372 or 12% for the fiscal year ended September 30, 2024 as compared to the prior fiscal year. The decrease in product revenues was primarily due to a decrease within our DNA Tagging and Security Products and Services segment due to a decline in revenue from our consumer asset marking and textile customers of approximately $113,000 and $75,000, respectively. These decreases were offset by an increase in shipments of approximately $49,000 to a nutraceutical customer.

Service revenues

For the fiscal year ended September 30, 2024 and 2023, we generated $1,038,677 and $996,866 in service revenues, respectively. Service revenue increased by $41,811 or 4% for the fiscal year ended September 30, 2024 as compared to the prior fiscal year. The increase in service revenues is primarily related to a $213,000 increase within our DNA Tagging and Security Products and Services segment due to an increase in our textile isotopic testing services. This increase was offset by a $171,000 decrease within our Therapeutic DNA Production Services segment due to decreased research and development projects.

Clinical laboratory service revenues

For the fiscal year ended September 30, 2024 and 2023, we generated $1,317,930 and $11,152,392 in revenues from clinical laboratory testing services, respectively. Clinical laboratory service revenue decreased by $9,834,462 or 88% for the fiscal year ended September 30, 2024 as compared to the prior fiscal year. The decrease in revenue is primarily due to a decrease from COVID-19 testing services. The fiscal year ended September 30, 2023 included testing revenues under our contract with CUNY, which terminated during June 2023.

Costs and Expenses

Gross Profit

Gross profit for fiscal year ended September 30, 2024 decreased by $4,516,553 or 82% from $5,533,432 for the fiscal year ended September 30, 2023 to $1,016,879 for the fiscal year ended September 30,2024. The gross profit percentage was 30% and 41% for the fiscal years ended September 30, 2024 and 2023, respectively. The decrease in gross profit percentage was primarily the result of a decline in gross profit percentage for our MDx Testing Services segment specifically related to significantly decreased testing volumes year over year.

Selling, General and Administrative

Selling, general and administrative expenses for the fiscal year ended September 30, 2024 decreased by $1,303,750 or 10% to $11,447,894 from $12,751,644 in the fiscal year ended September 30, 2023. The decrease is attributable to a decrease in payroll of approximately $1,527,000 primarily related to officer bonuses paid and accrued during fiscal 2023 as compared to no bonuses paid during fiscal 2024 and the bonus accrual was reversed. The remainder of the decrease is attributable to a decrease in stock-based compensation expense of approximately $462,000 relating to the timing of the annual grants of options to non-employee members of the board of directors and restricted stock units issued to officers. These decreases were offset by an increase in professional fees pertaining to an increase in legal and accounting expenses of $700,000 relating to the Spindle acquisition and legal and accounting fees pertaining to regulatory compliance.

Research and Development

Research and development expenses for the fiscal year ended September 30, 2024 decreased by $141,328 or 4% to $3,593,750 from $3,735,078 in the fiscal year ended September 30, 2023. This decrease is primarily due to a decrease in depreciation expense of $524,000 for laboratory equipment becoming fully depreciated year over year, offset by an increase of $217,000 for consultants being utilized to further develop the technology acquired from the Spindle acquisition and $156,000 of research and development costs related to our continued development projects within our Therapeutic DNA production segment during the fiscal year ended September 30, 2024.

***Interest* income**

Interest income for the fiscal year ended September 30, 2024, increased to $176,301 from $75,332 in the same period of 2023. This increase relates to higher average cash balances in our interest-bearing accounts, coupled with increased interest rates.

Other (expense) income, net

Other (expense) income, net for the fiscal year ended September 30, 2024 and 2023, was expense of $8,877 and income of $642, respectively.

Transaction cost allocated to warrant liabilities

Transaction cost allocated to warrant liabilities for the fiscal year ended September 30, 2024 was $633,198. These transaction costs represent the closing costs from the February 2024 financing transaction. These costs were expensed as it would have resulted in negative additional paid in capital.

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 fiscal year ended September 30, 2024 and 2023 of $9,430,000 and $854,400, 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 certain warrants expiring during September 2023.

Unrealized loss on change in fair value of warrants classified as a liability-warrant modifications

Unrealized loss on change in fair value of warrants classified as a liability-warrant modifications of $394,000 for the fiscal year ended September 30, 2024 represents the change in fair value for the modifications made to certain warrants as a result of the February 2024 financing.

Loss on issuance of warrants

The loss on issuance of warrants of $1,633,767 for the fiscal year ended September 30, 2024 relates to the February 2024 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 $2,934,610, or 29% to $7,088,306 for the fiscal year ended September 30, 2024 compared to $10,022,916 for the fiscal year ended September 30, 2023, 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, 2024, we had working capital of $5,649,546. For the fiscal year ended September 30, 2024, we used cash in operating activities of

$13,711,397 consisting primarily of our net loss of $7,088,306 net with non-cash adjustments of $696,425 in depreciation and amortization charges, $572,293 in stock-based compensation expense, $9,430,000 in unrealized gain on change in fair value of warrants classified as a liability, $1,633,767 in loss on issuance of warrants, $394,000 in unrealized loss on change in fair value of warrants classified as liability-warrant modification, $633,198 in transaction costs allocated to warrant liabilities, and $17,125 for shares issued related to Spindle earnout. Additionally, we had a net increase in operating assets of $641,805 and a net decrease in operating liabilities of $498,094. Cash used in investing activities of $407,904 was primarily for cash paid for property, plant and equipment.

The Company has recurring net losses, which have resulted in an accumulated deficit of $309,672,755 as of September 30, 2024. The Company incurred a net loss of $7,088,306 for the fiscal year ended September 30, 2024.These factors raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of the financial statements. The ability of the Company to continue as a going concern is dependent on the Company's ability to further implement its business plan, raise capital, and generate revenues. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

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

As discussed in Note M to our consolidated financial statements, on October 31, 2024, we closed on a registered direct offering and received net proceeds, after deducting placement agent fees and other estimated offering expenses payable by us, of approximately $5.8 million. As a result of this offering, our consolidated cash balance as of November 30, 2024 was approximately $10.1 million.

We expect CAPEX to be less than $1,500,000 in fiscal 2025. 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 LineaDNA for use as or, or incorporation into, a biologic, drug substance and/or drug product, the cost may be up to approximately $10 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 FASB issued accounting standard updates which clarify the principles for recognizing revenue arising from contracts with customers ("ASC 606" or "Topic 606").

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

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

Product Revenues

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

Authentication Services

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

Clinical Laboratory Testing Services

The Company records revenue for its clinical laboratory testing service contracts, which includes its COVID-19 testing services, upon satisfying its promise to provide services to customers under the terms of its contracts. These performance obligations are satisfied at the point in time that Company services are complete, which in nearly all cases is when the testing results are released to the customer. For those customers with a fixed monthly fee, the revenue is recognized over-time as the services are provided.

Research and Development Services

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

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

Warrant Liabilities

The Company evaluates its warrants issued 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 certain of its warrant agreements, the instruments do not qualify for equity treatment. As such, the Common Warrants, Series A Warrants and Private Common 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 condensed consolidated statement of operations in the period of change.

Nasdaq Delisting Notice

On November 12, 2024, we received Notice from Nasdaq notifying us that we are not in compliance with the Minimum Bid Price Requirement. Based on the closing bid price of the Company's Common Stock for the thirty-one (31) consecutive business days from September 27, 2024 to November 11, 2024, 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 the Company has 180 calendar days, or until May 12, 2025, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the bid price of the Company's Common Stock must have a closing bid price of at least $1.00 per share for a minimum of ten (10) consecutive business days, with a longer period potentially required by the Staff. If the Company does not regain compliance with the Minimum Bid Price Requirement by May 12, 2025, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company 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 Minimum Bid Price Requirement, and would need to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary, no later than ten (10) business days prior to May 12, 2025.

However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq would notify the Company that its securities would be subject to delisting. In the event of such a notification, the Company may appeal the Staff's determination to delist its securities, but there can be no assurance the Staff would grant the Company's request for continued listing.

As previously reported on its current report on Form 8-K on October 31, 2024, the Company closed on such date the October 2024 Offering. Pursuant to the October 2024 Purchase Agreement entered into in connection with the October 2024, the Company is required to effect the Reverse Stock Split if, at any time after the Stockholder Approval Date, it is not in compliance with the Minimum Bid Price Requirement and has received a deficiency letter from Nasdaq. The Company must effect the Reverse Stock Split within 30 days of the Stockholder Approval Date; provided that if within such 30 day period the Company regains compliance with the Bid Price Rule, the Company shall have no obligation to effect the Reverse Stock Split. The Company intends to implement a reverse stock split of its outstanding securities to regain compliance with the Bid Price Rule and to comply with the provisions of the October Purchase Agreement, unless the Company otherwise regains compliance with the Bid Price Rule within 30 days of the Stockholder Approval Date.

Recent Debt and Equity Financing Transactions

Registered Direct Offering and Concurrent Private Placement

On October 31, 2024, we closed the October 2024 Offering in which, pursuant to the October 2024 Securities Purchase Agreement dated October 31, 2024, by and between the Company and the October 2024 Purchasers, the Company issued and sold 19,247,498 shares of the Company's Common Stock, and October 2024 Pre-Funded Warrants ("October 2024 Pre-Funded Warrants") to purchase up to 1,065,002 shares of Common Stock, and

(ii) in the October 2024 Private Placement, October 2024 Series C Warrants to purchase up to 20,312,500 shares of Common Stock and October 2024 Series D Warrants to purchase up to 20,312,500 shares of Common Stock. The purchase price for each share of Common Stock and accompanying October 2024 Series C Warrant and October 2024 Series D Warrant was $0.32 and the purchase price for each October 2024 Pre-Funded Warrant and accompanying October 2024 Series C Warrant and October 2024 Series D Warrant was $0.3199. Craig-Hallum acted as placement agent in connection with the October 2024 Offering.

The Company received gross proceeds from the October 2024 Offering, before deducting placement agent fees and other estimated offering expenses payable by the Company, of approximately $6.5 million.

Pursuant to that certain engagement letter, dated August 23, 2024, by and between the Company and Craig-Hallum, the Company agreed to pay the Placement Agent a cash placement fee equal to 6.0% of the aggregate gross proceeds raised in the October 2024 Offering from sales arranged for by Craig-Hallum. Subject to certain conditions, the Company also agreed to reimburse certain expenses of Craig-Hallum in connection with the October 2024 Offering, including but not limited to legal fees, up to a maximum of $100,000. The Company also agreed to issue to Craig-Hallum, or its respective designees, October 2024 Placement Agent Warrants to purchase up to 1,015,625 shares of Common Stock (which equals 5.0% of the number of shares of Common Stock and October 2024 Pre-Funded Warrants offered) with an exercise price per share of $0.32. The October 2024 Placement Agent Warrants are exercisable upon the Stockholder Approval Date and will expire on October 30, 2029.

The October 2024 Pre-Funded Warrants have an exercise price of $0.0001 per share and are immediately exercisable and can be exercised at any time after their original issuance until such October 2024 Pre-Funded Warrants are exercised in full. Each share of Common Stock is being sold at an offering price of $0.32 and each Pre-Funded Warrant is being sold at an offering price of $0.3199 (equal to the purchase price per share of Common Stock minus the exercise price of the Pre-Funded Warrant).

The exercisability of the October 2024 Private Placement Warrants will be available only upon receipt of Warrant Stockholder Approval. Each October 2024 Series C Warrant has an exercise price of $0.32 per share of Common Stock, will become exercisable upon the Stockholder Approval Date, and will expire on the five-year anniversary of the Stockholder Approval Date. Each October 2024 Series D Warrant has an exercise price of $0.32 per share of Common Stock, will become exercisable upon the Stockholder Approval Date, and will expire on the 18-month anniversary of the Stockholder Approval Date. Each October 2024 Placement Agent Warrant has an exercise price of $0.32 per share of Common Stock, will become exercisable upon the Stockholder Approval Date and will expire on October 30, 2029.

The Company has agreed to hold a special meeting of stockholders to obtain the Warrant Stockholder Approval no later than 90 days after the closing of the Offering (the “Special Meeting”). If the Company does not obtain Warrant Stockholder Approval at the first meeting, the Company is obligated to call a meeting every ninety days thereafter to seek Warrant Stockholder Approval until the earlier of the date on which Warrant Stockholder Approval is obtained or the October 2024 Series Warrants are no longer outstanding. The Company agreed to file a preliminary proxy statement with respect to obtaining Warrant Stockholder Approval at the Special Meeting within 20 days following the closing date of the October Purchase Agreement, and such preliminary proxy statement was filed on November 14, 2024.

Under the alternate cashless exercise option of the October 2024 Series D Warrants, the holder of an October 2024 Series D Warrant, has the right to receive an aggregate number of shares equal to the product of (x) the aggregate number of shares of Common Stock that would be issuable upon a cash exercise of the October 2024 Series D Warrant and (y) 1.0. In addition, the October 2024 Series D Warrants will include a provision that resets their exercise price in the event of a reverse split of our Common Stock, to a price equal to the lesser of (i) the then exercise price and (ii) lowest volume weighted average price (VWAP) during the period commencing five trading days immediately preceding and the five trading days commencing on the date we effect a reverse stock split in the future with a proportionate adjustment to the number of shares underlying the October 2024 Series D Warrants, subject to a floor of $0.0634.

The October 2024 Private Placement Warrants and the shares of Common Stock issuable upon the exercise of the October 2024 Private Placement Warrants are not registered under the Securities Act. The October 2024 Private Placement Warrants were issued, and the shares of Common Stock issuable upon exercise thereof will be issued, in reliance on the exemptions from registration provided by Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder, for transactions not involving a public offering.

Pursuant to the October 2024 Purchase Agreement, within 20 calendar days from the date of the October 2024 Purchase Agreement, the Company agreed to file a registration statement on Form S-1 providing for the resale by the October 2024 Purchasers of the shares of Common Stock issuable upon exercise of the October 2024 Private Placement Warrants. The Company agreed to use commercially reasonable efforts to cause such registration statement to become effective within 50 calendar days following the closing date of the October 2024 Purchase Agreement (or 90 calendar days following the closing date of the October 2024 Purchase Agreement in the event that the SEC requires the Company to include its audited year-end financial statements for the fiscal year ended September 30, 2024 in such registration statement) and to keep such registration statement effective at all times until no Purchaser owns any Series Warrants or shares of Common Stock issuable upon exercise thereof. The Company filed the registration statement with the SEC on November 19, 2024.

In the event of any fundamental transaction, as described in the October 2024 Private Placement Warrants and generally including any merger with or into another entity, sale of all or substantially all of the Company's assets, tender offer or exchange offer, reclassification of the shares of Common Stock, or the acquisition of greater than 50% of the Company's then outstanding shares of Common Stock by a person or persons, subject to certain exceptions, then upon any subsequent exercise of an October 2024 Private Placement Warrant, the holder will have the right to receive as alternative consideration, for each share of Common Stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation of the Company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of Common Stock for which the October 2024 Private Placement Warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the October 2024 Private Placement Warrants have the right to require the Company or a successor entity to purchase the October 2024 Private Placement Warrants for cash in the amount of the Black Scholes Value (as defined in the October 2024 Series Warrants) of the unexercised portion of the October 2024 Private Placement Warrants concurrently with or within 30 days following the consummation of a fundamental transaction. However, in the event of a fundamental transaction which is not in the Company's control or in which the consideration payable consists of equity securities of a successor entity that is quoted or listed on a nationally recognized securities exchange, the holders of the October 2024 Private Placement Warrants will only be entitled to receive from the Company or its successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the October 2024 Private Placement Warrants that is being offered and paid to the holders of Common Stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of Common Stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction.

Amendment to Series A Warrants

As previously disclosed on our current report on Form 8-K filed on May 29, 2024 we closed on such date the May 2024 Offering of Common Stock and warrants, including 9,230,769 May 2024 Series A Warrants and 9,230,769 May 2024 Series B Warrants, with Craig-Hallum and Laidlaw acting as placement agents. As part of the May 2024 Offering, the Company entered into the May 2024 Placement Agency Agreement, dated May 28, 2024, with Craig-Hallum and Laidlaw.

Subject to certain exceptions, the Price Reset Mechanism in the May 2024 Series A Warrants provide for an adjustment to the exercise price and number of shares underlying the May 2024 Series A Warrants upon the Company's issuance of Common Stock or Common Stock equivalents at a price per share that is less than the exercise price of the May 2024 Series A Warrants.

On October 30, 2024, the Company and certain holders of the May 2024 Series A Warrants entered into the Warrant Amendment, pursuant to which the Price Reset Mechanism became subject to a floor equal to $0.20.

In connection with the October 2024 Offering, the Price Reset Mechanism in the May 2024 Series A Warrants was triggered, which resulted in the number of shares of Common Stock issuable upon exercise of the May 2024 Series A Warrants increasing from 9,230,769 to 91,890,698. The exercise price of the May 2024 Series A Warrants was adjusted from $1.99 per share to $0.20 per share with respect to the May 2024 Series A Warrants amended by the Warrant Amendment, and to $0.19 with respect to the May 2024 Series A Warrants not amended by the Warrant Amendment.

Waiver of Standstill in Placement Agency Agreement

As disclosed above, the Company closed the May 2024 Offering of Common Stock and warrants, including the May 2024 Series Warrants, with Craig-Hallum and Laidlaw as placement agents. As part of the May 2024 Offering, the Company entered into the May 2024 Placement Agency Agreement. The May 2024 Placement Agency Agreement contains a negative covenant which restricts the Company's ability to enter into certain equity sales of its securities for a period of time after the closing of the May 2024 Offering without the prior consent of Craig-Hallum (the "Negative Covenant").

On October 29, 2024, in connection with entering into the October 2024 Offering, the Company and Craig-Hallum entered into a waiver of the Negative Covenant, which permitted the Company to proceed with the October 2024 Offering.

Fiscal 2024

Registered Direct Offering

On February 2, 2024, the Company closed on a registered direct public offering (the "RDO") of 161,403 shares of the Company's Common Stock and pre-funded warrants ("RDO Pre-Funded Warrants") to purchase up to 120,800 shares of Common Stock, and in a concurrent private placement, unregistered common warrants ("Private Common Warrants") to purchase up to 564,407 shares of Common Stock. In connection with the RDO, the Company entered into securities purchase agreements (the "RDO Purchase Agreements") with certain institutional investors (each, an "RDO Purchaser" and, collectively, the "RDO Purchasers"). The Company received net proceeds from the RDO, after deducting placement agent fees and other estimated offering expenses payable by the Company, of approximately $2.8 million.

The RDO Pre-Funded Warrants had an exercise price of $0.0001 per share and are immediately exercisable and can be exercised at any time after their original issuance until such RDO Pre-Funded Warrants are exercised in full. Each share was sold at an offering price of $12.18 and each RDO Pre-Funded Warrant was sold at an offering price of $12.18 (equal to the purchase price per share of Common Stock minus the exercise price of the RDO Pre-Funded Warrant). Pursuant to the RDO Purchase Agreements, the Company also agreed to issue to the RDO Purchasers, in a concurrent private placement, the Private Common Warrants. Each Private Common Warrant has an exercise price of $12.18 per share, and became exercisable following shareholder approval obtained on April 15, 2024 and will expire on April 15, 2029. During the three-month period ended June 30, 2024, all of the 120,800 RDO Pre-Funded Warrants were exercised.

The Private Common Warrants and the shares of Common Stock issuable upon the exercise of the Private Common Warrants are not registered under the Securities Act. The Private Common Warrants and the shares of Common Stock issuable upon exercise thereof were issued or will be issued, respectively, in reliance on the exemptions from registration provided by Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder, for transactions not involving a public offering. Pursuant to the RDO Purchase Agreements, within 45 calendar days from the date of the RDO Purchase Agreements, the Company agreed to file a registration statement on Form S-3 (or other appropriate form if the Company is not then S-3 eligible) providing for the resale by the RDO Purchasers of the shares issuable upon exercise of the Private Common Warrants. The Company agreed to use commercially reasonable efforts to cause such registration statement to become effective within 90 days following the closing date of the RDO Purchase Agreements and to keep such registration statement effective at all times until no RDO Purchaser owns any Private Common Warrants or shares of Common Stock issuable upon exercise thereof. The Company filed the registration statement on March 12, 2024, and the registration statement was declared effective on March 20, 2024.

In connection with the RDO and the RDO Purchase Agreements, the Company agreed to reduce the exercise price of warrants previously issued to the RDO Purchasers with exercise prices ranging from $25.80 to $80.00 per warrant to $12.18 per warrant. The Company also agreed to extend the expiration dates for such warrants to August 2028. In addition, 2,904 outstanding common stock warrants held by other investors who did not participate in the RDO had their exercise price reduced to $12.18 per warrant share and had their warrant expiration dates extended to August 2028. The foregoing reductions of the exercise price and extension of expiration dates of such warrants were approved by shareholders on April 15, 2024. The incremental change in fair value as a result of the modification for the warrants that are recorded as a liability was $1,633,767 and is recorded as a unrealized loss on the change in fair value of warrants classified as a liability in the condensed consolidated statement of operations for the nine-month period ended June 30, 2024. The incremental change in fair value as a result of the modification for the warrants that are recorded to equity was $155,330 and is recorded as a deemed dividend in the condensed consolidated statement of operations for the nine-month period ended June 30, 2024.

April 2024 Special Meeting & Reverse Stock Split

On April 15, 2024, the Company held a special meeting of stockholders (the "April 2024 Special Meeting") pursuant to which its stockholders approved the following: (i) in accordance with Nasdaq Listing Rule 5635(d), the issuance to certain holders of common stock purchase warrants in connection with a private placement; (ii) in accordance with Nasdaq Listing Rule 5635(d), the repricing of certain of our common stock purchase warrants; (iii) a grant of discretionary authority to the Board of Directors giving them the authority to amend the Company's certificate of incorporation, as amended, to effect a reverse stock split of Common Stock, at a ratio in the range from one-for-five to one-for-fifty, with such specific ratio to be determined by the Company's Board of Directors following the Special Meeting (the "Reverse Split Proposal") in order to regain compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq, as set forth in the Nasdaq Listing Rule 5550(a)(2) ; and (iv) an amendment to the Company's 2020 Equity Incentive Plan to increase the number of authorized shares of Common Stock reserved for issuance by 200,000 shares.

The reverse stock split was effected at 12:01 a.m. Eastern Time on Thursday, April 25, 2024 and combined each twenty shares of our outstanding Common Stock into one share of Common Stock, without any change in the par value per share. Moreover, the reverse stock split correspondingly adjusted, (i) the per share exercise price and the number of shares issuable upon the exercise of all outstanding options, and (ii) the number of shares underlying any of our outstanding warrants by adjusting the conversion ratio for each instrument and increasing the applicable exercise price or conversion price in accordance with the terms of each instrument and based on the reverse stock split ratio. No fractional shares were issued in connection with the reverse stock split. Any fractional shares resulting from the reverse stock split were rounded up to the nearest whole share.

Public Offering

On May 28, 2024, the Company entered into the May 2024 Placement Agency Agreement with Craig-Hallum and Laidlaw pursuant to which they agreed to serve as the co-placement agents, on a “reasonable best efforts” basis, in connection with the issuance and sale of 9,230,769 units (the “Units”), with each Unit consisting of either (A) one share of the Company’s Common Stock, and one May 2024 Series A Warrant to purchase one share of Common Stock and one May 2024 Series B Warrant to purchase on share of Common Stock, or (B) one pre-funded warrant (each, a “May 2024 Pre-Funded Warrant”) to purchase one share of Common Stock and one May 2024 Series A Warrant and one May 2024 Series B Warrant. In connection with the May 2024 Offering, the Company also issued placement agent warrants (“May 2024 Placement Agent Warrants”) to purchase up to 461,538 shares of Common Stock. The May 2024 Offering closed on May 29, 2024. The purchase price of each Unit was $1.30, except for Units which include May 2024 Pre-Funded Warrants, which had a purchase price of $1.2999. The Units had no stand-alone rights and will not be certificated or issued as stand-alone securities.

The Company received net proceeds from the May 2024 Offering, after deducting placement agent fees and other offering expenses payable by the Company, of approximately $10.5 million.

The exercisability of the May 2024 Series Warrants was available only upon receipt of such stockholder approval as may be required by the applicable rules and regulations of the Nasdaq Capital Market (the “May 2024 Warrant Stockholder Approval”). Each May 2024 Series A Warrant would become exercisable beginning on the date of the May 2024 Warrant Stockholder Approval at an exercise price of $1.99 per share of Common Stock, and will expire five years from the date of the May 2024 Warrant Stockholder Approval. Each May 2024 Series B Warrant would become exercisable beginning on the date of the May 2024 Warrant Stockholder Approval at an exercise price of $1.99 per share of Common Stock, and will expire one year from the date of the May 2024 Warrant Stockholder Approval. The Company obtained May 2024 Warrant Stockholder Approval at its annual shareholder’s meeting which was held on September 30, 2024.

Under the alternate cashless exercise option of the May 2024 Series B Warrants, the holder of the May 2024 Series B Warrant has the right to receive an aggregate number of shares equal to the product of (x) the aggregate number of shares of Common Stock that would be issuable upon a cash exercise of the May 2024 Series B Warrant and (y) 3.0. In addition, the May 2024 Series A Warrants and May 2024 Series B Warrants include a provision that resets their respective exercise price in the event of a reverse split of the Company’s Common Stock, to a price equal to the lesser of (i) the then exercise price and (ii) lowest volume weighted average price (VWAP) during the period commencing five trading days immediately preceding and the five trading days commencing on the date the Company effects a reverse stock split in the future with a proportionate adjustment to the number of shares underlying the May 2024 Series A Warrants and May 2024 Series B Warrants.

Subject to certain exceptions, the Price Reset Mechanism in the May 2024 Series A Warrants provide for an adjustment to the exercise price and number of shares underlying the May 2024 Series A Warrants upon the Company’s issuance of Common Stock or Common Stock equivalents at a price per share that is less than the exercise price of the May 2024 Series A Warrants. In connection with the October 2024 Offering detailed above, the Price Reset Mechanism in the May 2024 Series A Warrants was triggered, which resulted in the number of shares of Common Stock issuable upon exercise of the May 2024 Series A Warrants increasing from 9,230,769 to 91,890,698. The exercise price of the May 2024 Series A Warrants was adjusted from $1.99 per share to $0.20 per share with respect to the May 2024 Series A Warrants amended by the Warrant Amendment, and to $0.19 with respect to the May 2024 Series A Warrants not amended by the Warrant Amendment.

The Common Stock and May 2024 Pre-Funded Warrants were only sold with the accompanying May 2024 Series A Warrants and May 2024 Series B Warrants that are part of a Unit, but the components of the Units were immediately separable and were issued separately in this Offering. During the three-month period ended June 30, 2024, all of the May 2024 Pre-Funded Warrants were exercised.

Product Research and Development

We anticipate spending approximately $2,000,000 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 LineaDNA 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, 2024 and 2023.

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-32 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, 2024. 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, 2024, 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, 2024. 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, 2024.

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

Board of Directors, Executive Officers and Key Employees

The Board of Directors (the "Board of Directors") currently consists of six members. The term of each Director expires at our next annual meeting or until his or her successor is appointed. Our executive officers are elected by, and serve at the discretion of, the Board of Directors. There are no family relationships between any directors or executive officers.

The ages of the directors and executive officers are shown as of December 13, 2024.

Name	Ages	Position
James A. Hayward	71	Chief Executive Officer and Chairman of the Board of Directors
Robert B. Catell	87	Director
Joseph D. Ceccoli	61	Director
Sanford R. Simon	82	Director
Yacov A. Shamash	74	Director
Elizabeth M. Schmalz Shaheen	73	Director
Beth Jantzen	48	Chief Financial Officer
Judith Murrah	66	President, Chief Operating Officer, Chief Information Officer and Secretary
Clay Shorrock	41	Chief Legal Officer, Executive Director of Business Development and President of LRx

Set forth below is biographical information with respect to the aforementioned individuals.

James A. Hayward, Ph.D., Sc.D.

Dr. James A. Hayward has been our Chief Executive Officer since March 17, 2006, a director on the Board of Directors since September 28, 2005 and the Chairman of the Board of Directors since June 12, 2007. He was previously our acting Chief Executive Officer from October 5, 2005 until March 17, 2006 and our President from June 12, 2007 until December 13, 2024. He also served as Acting Chief Financial Officer from August 20, 2013 through October 13, 2013. Dr. Hayward received his Ph.D. in Molecular Biology from the State University of New York at Stony Brook ("Stony Brook") in 1983 and an honorary Doctor of Science from the same institution in 2000. His experience with public companies began with the co-founding of one of England's first biotechnology companies — Biocompatibles, Ltd. Following this, Dr. Hayward was at the Estee Lauder companies for five years, eventually becoming Head of Product Development. In 1990, he founded The Collaborative Group, a provider of products and services to the biotechnology, pharmaceutical and consumer-product industries based in Stony Brook, where he served as Chairman, President and Chief Executive Officer for 14 years. During this period, The Collaborative Group created several businesses, including The Collaborative BioAlliance, a contract developer and manufacturer of human protein products that was sold to Dow Chemical in 2002, and Collaborative Labs, a service provider and manufacturer of ingredients for skincare and dermatology that was sold to Engelhard (now BASF) in 2004. He is the winner of the first Helix Award from BIO and has been twice elected Entrepreneur of the Year by Inc. Magazine and the Long Island Technology Hall of Fame. He has served on the Boards of The Stony Brook Foundation, the NYS Research Foundation, and the NYS Regents Advisory Board. Dr. Hayward also serves on the advisory board of the Manufacturing and Technology Resource Consortium of Stony Brook University, and on the boards of Softheon Corporation, NeoMatrix Formulations, Inc. and the TNPO2 Foundation.

Dr. Hayward's experience and senior leadership positions in companies in the biotechnology, pharmaceutical and consumer-product industries, and specifically his qualifications and skills in the areas of general operations, financial operations and administration, as

well as his role as the Company's Chief Executive Officer, led the Board of Directors to conclude that Dr. Hayward should serve as a director of the Company.

Yacov A. Shamash

Dr. Yacov A. Shamash has been a member of the Board of Directors since March 17, 2006. Dr. Shamash is a Professor of Electrical and Computer Engineering at Stony Brook, a position he has held since 1992. From 1992 to 2015, he was the Dean of Engineering and Applied Sciences, and from 1995 to 2004, Dr. Shamash was also the Dean of the Harriman School for Management and Policy at Stony Brook. He served as Vice President for Economic Development at Stony Brook from 2001 to 2019. He was founder of the New York State Center for Excellence in Wireless and Information Technology, and the New York State Center for Excellence in Advanced Energy Research, at Stony Brook. Dr. Shamash developed and directed the NSF Industry/University Cooperative Research Center for the Design of Analog/Digital Integrated Circuits from 1989 to 1992 and also served as Chairman of the Electrical and Computer Engineering Department at Washington State University from 1985 until 1992. Dr. Shamash serves on the board of directors of public companies Comtech Telecommunications Corp. and Keytronic Corp. He is on the boards of several not for profit organizations: the Long Island First Robotics and Listnet. Dr. Shamash holds a Ph.D. degree in Electrical Engineering from the Imperial College of Science and Technology in London, England.

Dr. Shamash encounters leaders of businesses large and small, regional and global in their reach, on a daily basis and, as a member of our Board of Directors, Dr. Shamash has played an integral role in our business development by providing the highest-level introductions to customers, channels to market and to the media. Dr. Shamash also brings to our Board of Directors his valuable experience gained from serving as a director at other private and public companies. The Board of Directors believes that Dr. Shamash's technical experience and other abilities make him a valuable member of the Board of Directors.

Sanford R. Simon

Dr. Sanford R. Simon has been a member of the Board of Directors since March 17, 2006. Dr. Simon was a Professor of Biochemistry, Cell Biology and Pathology at Stony Brook from 1969 to January 2022. He joined the faculty at Stony Brook as an Assistant Professor in 1969 and was promoted to Associate Professor with tenure in 1975. Dr. Simon was a member of the board of directors of The Collaborative Group from 1995 to 2004. From 1967 to 1969, Dr. Simon was a Guest Investigator at Rockefeller University. Dr. Simon received a B.A. in Zoology and Chemistry from Columbia University in 1963 and, a Ph.D. in Biochemistry from Rockefeller University in 1967, and he studied as a postdoctoral fellow with Nobel Prize winner Max Perutz in Cambridge, England. He has maintained an active research laboratory studying aspects of cell invasion in cancer and inflammation, the uses of small molecules in modulating diverse cell functions, and novel strategies of drug delivery; he also teaches undergraduate, graduate, medical and dental students.

Dr. Simon has worked in the use of large biomolecules in commercial media, and we have made use of his expertise in formulating DNA into commercial carriers for specific customers. As a member of our Board of Directors, Dr. Simon has advised us on patents, provided technical advice, and introduced us to corporate partners and customers. The Board of Directors believes that Dr. Simon's advice makes him a valuable member of the Board of Directors.

Joseph D. Ceccoli

Joseph D. Ceccoli has been a member of the Board of Directors since December 3, 2014. Since 2010, Mr. Ceccoli has been the Founder, President and CEO of Biocogent, LLC ("*Biocogent*"), a bioscience company located at the Stony Brook Long Island High Technology Incubator. Biocogent is focused on the invention, development and commercialization of skin-active molecules and treatment products used in regulated (over-the-counter / med-care), personal care and consumer products. Prior to starting Biocogent, Mr. Ceccoli was Global Director of Operations for BASF Corporation, a global Fortune 100 company and the world's largest global chemical company, where he was responsible for the integration, operations and growth of domestic and overseas business units from 2007 to 2008. Prior to BASF, Mr. Ceccoli was a General Manager for Engelhard Corporation, a U.S.-based Fortune 500 company and chief operating officer of Long Island-based The Collaborative Group from 2004 to 2007. Mr. Ceccoli holds a Bachelor of Science ("*B.S.*") degree in Biotechnology from Rochester Institute of Technology and advanced professional training in various pharmaceutical sciences, emulsion chemistry, engineering and management disciplines. He is a member of numerous professional organizations such as the American Chemical Society and the Society of Cosmetic Chemists. Mr. Ceccoli has authored and co-authored 16 technical papers that have appeared in peer reviewed and industry specific journals and magazines and is inventor on 16 patents.

The Board of Directors believes that Mr. Ceccoli's experience across the bioscience and chemical markets, including in global and U.S.-based operations and management, enriches our Board of Directors. Mr. Ceccoli's experience as an executive officer and director of several bioscience and chemical companies and organizations led the Board of Directors to conclude that he should serve as a director of the Company.

Robert B. Catell

Robert B. Catell has been a member of the Board of Directors since October 7, 2016. Mr. Catell serves as Chairman of the Advanced Energy Research and Technology Center (AERTC) at Stony Brook and the National Offshore Wind Research and Development Consortium (NOWRDC). He also serves on the board of several business and not-for-profit organizations, including Long Island Association (LIA), A+ Technology & Security Solutions, Inc., ThermoLift Inc., and Utility Technology Solutions (UTS). Mr. Catell was formerly Chairman and CEO of KeySpan Corporation and KeySpan Delivery (formerly Brooklyn Union Gas), Chairman of National Grid, U.S. and Deputy Chairman of National Grid plc, upon National Grid's acquisition of KeySpan, and has served on numerous boards including New York State Energy Research & Development Authority (NYSERDA.) Mr. Catell chaired the New York State Business Council from 2002 to 2003 and the Brooklyn Chamber of Commerce from 1994 to 1995.

Mr. Catell holds both a Master's and a Bachelor's degree in Mechanical Engineering from City College of New York and is a registered Professional Engineer. He has attended Columbia University's Executive Development Program, and the Advanced Management Program at the Harvard Business School.

The Board of Directors believe that Mr. Catell's extensive executive-level management experience, including as a director at other private and public companies and within regulated and technical industries, qualifies him to serve as one of our directors.

Elizabeth M. Schmalz Shaheen

Ms. Elizabeth M. Schmalz Shaheen has been a member of the Board of Directors since June 1, 2017. She has served as President of American Flavors & Fragrances LLC, a fragrance company, since 2003. Ms. Schmalz Shaheen also serves as President of her own consulting firm, Betsy Schmalz & Associates. She served as Senior Vice President of Corporate Product Development at Estée Lauder. Ms. Schmalz Shaheen's responsibilities included overseeing product development for some of the company's most prominent brands. Subsequently, she was Executive Vice President of Product Development at Bath and Body Works and Victoria's Secret for The Limited. Ms. Schmalz Shaheen started her senior management career at Revlon with responsibility for new product development for brands including Borghese, Ultima II and Prestige fragrances. She is an active member of Cosmetic Executive Women. She earned a bachelor's degree in psychology from Georgian Court University and serves on their Board of Trustees.

Ms. Schmalz Shaheen's track record of accomplishments as a strategist and products leader within the cosmetics and personal care industries led the Board of Directors to conclude she should serve as a director of the Company.

Beth Jantzen

Beth Jantzen has been our Chief Financial Officer since February 15, 2015. Previously, Ms. Jantzen held the position of Controller from May 2013 to her appointment as Chief Financial Officer. Prior to joining the Company, Ms. Jantzen was a senior manager at Marcum LLP, our independent registered accounting firm, from January 2000 until May 2013, where she managed multiple engagements and specialized in SEC policies, practices and procedures, including Sarbanes-Oxley compliance. Ms. Jantzen holds a B.S. in Accounting from the State University of New York at Binghamton and is also a Certified Public Accountant (CPA).

Judith Murrah

Ms. Judith Murrah has been our President since December 13, 2024, our Chief Operating Officer since January 19, 2021, our Chief Information Officer since June 1, 2013, and our Secretary since December 22, 2017. Ms. Murrah is responsible for our operations functions including production, quality, information technology and security, marketing, development of key customer and partner relationships, and field operations. Ms. Murrah was previously the Senior Director of Information Technology at Motorola Solutions, which had acquired her former firm, Symbol Technologies. Her role at Motorola Solutions included overseeing the global IT program management office, financial and supplier operations and quality assurance. At Symbol Technologies, Ms. Murrah held leadership positions in product line management, global account sales, corporate and marketing communications and IT. Ms. Murrah holds an MBA from Harvard Business School, and a B.S. in Industrial Engineering from the University of Rhode Island. She is an inventor on

14 U.S. patents. Ms. Murrah is active in Long Island's business and academic community. She has co-founded and volunteers with non-profits engaging students in science, technology, engineering, and math disciplines. She serves on the boards of the Middle Country (N.Y.) Library Foundation, the Tesla Science Center at Wardenclyffe, and Stony Brook University's Center for Corporate Education. Ms. Murrah was named to the Top 50 Women of Long Island Hall of Fame in 2023 and received the inaugural 2001 Diamond Award for Long Island Women Leaders in Technology.

Clay Shorrock

Mr. Shorrock has been our Chief Legal Officer and Executive Director of Business Development since April 2021, and has served as the President of LRx since December 13, 2024. Mr. Shorrock leads Applied DNA's legal, regulatory, risk mitigation, intellectual property, and business development functions. Mr. Shorrock previously served as general and intellectual property counsel to Applied DNA from November 2016 through April 2019. Prior to rejoining the Company in April 2021, Mr. Shorrock was a member of the intellectual property groups of Florida-based Lowndes, Drosdick, Doster, Kantor & Reed, P.A. and Allen, Dyer, Doppelt & Gilchrist, P.A. Earlier in his career Mr. Shorrock was an associate at several New Jersey-based law firms where he focused on intellectual property and complex commercial transactions. Mr. Shorrock holds a B.A. in Biology from Franklin and Marshall College and a J.D. with a concentration in intellectual property from Seton Hall University Law School.

No Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), requires our officers and directors and persons who beneficially own more than 10% of any class of our equity securities registered pursuant to Section 12 of the Exchange Act to file reports of securities ownership and changes in such ownership with the SEC. Officers, directors and greater than 10% beneficial owners ("10% stockholders") also are required by SEC rules to furnish us with copies of all Section 16(a) forms they file. Based solely upon a review of the copies of such forms furnished to us during or with respect to the fiscal year ended September 30, 2024, as the case may be, and upon written representations from these reporting persons, we believe that all reports required by Section 16(a) applicable to our officers, directors and 10% stockholders were filed on a timely basis, as disclosed in the forms described above, during the fiscal year ended September 30, 2024.

Governance of the Company

Code of Ethics

Our Board of Directors has adopted a "code of ethics" as defined by regulations promulgated under the Securities Act of 1933, as amended, and the Exchange Act (our "Code of Business Conduct and Ethics") that applies to all of our employees, officers and directors, including our Chief Executive Officer, our Chief Financial Officer and those officers and employees responsible for financial reporting. The Code of Business Conduct and Ethics is designed to codify the ethical standards that we believe are reasonably designed to deter wrong-doing and promote honest and ethical conduct.

We have established procedures to ensure that suspected violations of the Code of Business Conduct and Ethics may be reported anonymously. A current copy of our Code of Business Conduct and Ethics is available on our website at *https://investors.adnas.com/corporate-governance/governance-documents*. A copy may also be obtained, free of charge, from us upon a request directed to Applied DNA Sciences, Inc., 50 Health Sciences Drive, Stony Brook, New York 11790, c/o Investor Relations. We intend to disclose any amendments to or waivers of a provision of the Code of Business Conduct and Ethics granted to directors and officers by posting such information on our website available at *www.adnas.com* and/or in our public filings with the SEC.

Board Committees

The Board of Directors maintains three committees: the audit committee, compensation committee and the nominating committee.

Audit Committee

Messrs. Catell, Ceccoli, and Shamash (Chairperson) served on the audit committee during the fiscal year ended September 30, 2024 and continue to serve on the audit committee. The Board of Directors has determined that each member of the audit committee is independent within the meaning of the director independence standards of the Company and Nasdaq as well as the heightened director independence standards of the SEC for audit committee members, including Rule 10A-3(b)(1) under the Exchange Act. The Board of Directors has

also determined that each of the members of the audit committee is financially sophisticated and is able to read and understand consolidated financial statements and that Dr. Shamash is an "audit committee financial expert" as defined in the Exchange Act. During fiscal 2024, the audit committee held four formal meetings.

The composition and responsibilities of the audit committee and the attributes of its members, as reflected in the charter, are intended to be in accordance with applicable requirements for corporate audit committees. The audit committee charter will be reviewed, and amended if necessary, on an annual basis.

The audit committee assists the Board of Directors in fulfilling its oversight responsibility relating to our financial statements and the disclosure and financial reporting process, our system of internal controls, our internal audit function, the qualifications, independence and performance of our independent registered public accounting firm, compliance with our code of ethics and legal and regulatory requirements. The audit committee has the sole authority to appoint, retain, terminate, compensate and oversee the work of the independent registered public accounting firm, as well as to pre-approve all audit and non-audit services to be provided by the independent registered public accounting firm.

Compensation Committee

Messrs. Ceccoli and Shamash (Chairperson) and Ms. Schmalz Shaheen served on the compensation committee during the fiscal year ended September 30, 2024 and continue to serve on the compensation committee. The Board of Directors has determined that each member of the compensation committee is independent within the meaning of the director independence standards of the Company and Nasdaq as well as the director independence standards of the SEC for compensation committee members, including Rule 10C-1 under the Exchange Act. The compensation committee reviews and approves salaries and bonuses for all officers, reviews and approves non-employee directors' compensation, administers options outstanding under our stock incentive plan, provides advice and carries out the responsibilities required by SEC rules. The compensation committee believes that its processes and oversight should be directed toward attracting, retaining and motivating employees and non-employee directors to promote and advance our interests and strategic goals. As requested by the compensation committee, the Chief Executive Officer will provide information and may participate in discussions regarding compensation for other executive officers. The compensation committee also considers other general industry information and trends if available. During fiscal 2024, the compensation committee held two formal meetings.

Nominating Committee

Messrs. Shamash (Chairperson) and Simon and Ms. Schmalz Shaheen served on the nominating committee during the fiscal year ended September 30, 2024 and continue to serve on the nominating committee. The Board of Directors has determined that each member of the nominating committee is independent within the meaning of the director independence standards of the Company, Nasdaq and the SEC.

The nominating committee is responsible for, among other things: reviewing the Board of Directors' composition, procedures and committees, and making recommendations on these matters to the Board of Directors; and reviewing, soliciting and making recommendations to the Board of Directors and stockholders with respect to candidates for election to the Board of Directors. During fiscal 2024, the nominating committee held one formal meeting.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Overview

The Compensation Committee has overall responsibility for approving and evaluating the compensation arrangements for our named executive officers. Our named executive officers for fiscal 2024 are our Chairman, Chief Executive Officer and President, Dr. James Hayward, our Chief Financial Officer, Beth Jantzen, our Chief Operating Officer and Chief Information Officer, Judith Murrah, and our Chief Legal Officer and Executive Director of Business Development, Clay Shorrock. Our Chairman, Chief Executive Officer and President, Dr. Hayward, provides recommendations to the Compensation Committee with respect to the compensation of the named executive officers other than for Dr. Hayward himself. However, the Compensation Committee is free to make decisions that are contrary to the Chief Executive Officer and President's recommendations.

On December 13, 2024, Dr. Hayward stepped down as President of the Company and Judith Murrah was appointed President of the Company. Also on December 13, 2024, Clay Shorrock was named President of LRx.

Our Executive Compensation Philosophy and Objectives

General

The fundamental purpose of our executive compensation program is to assist us in achieving our financial and operating performance objectives. Specifically, we attempt to tailor an executive's compensation to (1) retain and motivate the executive, (2) reward him or her upon the achievement of Company-wide and individual performance, and (3) align the executive's interest with the creation of long-term stockholder value, without encouraging excessive risk taking. To that end, and within the context of the stage of our company, we have historically compensated our named executive officers through a mix of base salary, equity-based incentives and cash bonuses.

Our business model is based on our ability to establish long-term relationships with clients and to maintain our strong mission, client focus, entrepreneurial spirit and team orientation. We have sought to create an executive compensation package that balances short-term versus long-term components, in ways we believe are most appropriate to motivate senior management and reward them for achieving key business goals.

Base Salary

Except, as noted below, we did not change the annual base salary for any of our named executive officers in fiscal 2024, and their respective annual base salaries remained as follows: Dr. Hayward, $450,000, Ms. Jantzen, $300,000, Ms. Murrah, $325,000 and Mr. Shorrock, $300,000. Effective as of January 1, 2024, Dr. Hayward and Ms. Murrah voluntarily reduced their annual base salaries to $250,000 and $243,750, respectively, in response to the cash position of the Company. This voluntary reduction was effective until May 25, 2024. Effective November 25, 2024, the base salaries for Ms. Murrah and Mr. Shorrock were increased to $400,000 and $385,000 respectively. Also, Ms. Murrah was named the President of Applied DNA Sciences, Inc. and Mr. Shorrock was named the President of LineaRx, Inc, effective on December 13, 2024. Concurrently on December 13, 2024 Dr. Hayward stepped down as the President of APDN. Dr. Hayward remains as the CEO and Chairman of the Board. Effective December 7, 2024 Ms. Jantzen's base salary was increased to $385,000.

Bonuses

As of the date of this report, the Compensation Committee and the Board of Directors have determined that no cash incentive bonuses will be granted to Dr. Hayward, Ms. Jantzen, Mr. Shorrock or Ms. Murrah in respect of fiscal 2024 performance.

Long-Term Stock-Based Compensation

Our long-term compensation program has historically consisted solely of stock options. Stock option grants made to executive officers are designed to provide them with an incentive to execute their responsibilities in such a way as to generate long-term benefit to us and our stockholders.

We believe that, by only rewarding the creation of stockholder value, stock options provide our executive officers with an effective risk and reward profile.

There was no stock-based compensation granted to Dr. Hayward, Ms. Jantzen, Ms. Murrah, or Mr. Shorrock during the fiscal year ended September 30, 2024.

Benefits

We provide the following benefits to our named executive officers on the same basis as the benefits provided to all employees:

- health and dental insurance;
- life insurance;
- short-and long-term disability; and

- 401(k) plan (currently there is no employer match).

We believe these benefits are generally consistent with those offered by other companies and specifically with those companies with which we compete for employees.

Compensation Committee Interlocks and Insider Participation

None of the members of our Compensation Committee is or has been an officer or employee of our Company. None of our executive officers currently serves, or in the past year has served, as a member of the Compensation Committee or director (or other board committee performing equivalent functions or, in the absence of any such committee, the entire Board of Directors) of any entity that has one or more executive officers who currently serves, or will serve, on our Compensation Committee or our Board of Directors.

Summary Compensation Table

The following table sets forth the compensation of our named executive officers for the fiscal years ended September 30, 2024 and 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Nonequity Incentive Plan Compensation ($)	All Other Compensation ($)(1)	Total ($)
James A. Hayward	2024	369,623	—	—	—	—	18,000	387,623
Chairman, President and CEO[(2)]	2023	450,000	—	—	—	—	18,000	468,000
Beth M. Jantzen	2024	300,000	—	—	—	—	—	300,000
CFO	2023	300,000	—	99,000	102,000	—	—	501,000
Judith Murrah	2024	292,055	—	—	—	—	—	292,055
CIO, COO[(2)]	2023	325,000	—	107,250	110,500	—	—	542,750
Clay Shorrock	2024	300,000	—	—	—	—	—	300,000
CLO, Executive Director of Business Development[(2)]	2023	300,000	—	99,000	102,000	—	—	501,000

(1) Represents reimbursement payments to Dr. Hayward for costs associated with an automobile used by Dr. Hayward.

(2) On December 13, 2024, Dr. Hayward stepped down as President of the Company and Judith Murrah was appointed President of the Company. Also on December 13, 2024, Clay Shorrock was named President of LRx.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information concerning outstanding equity awards held by our named executive officers as of September 30, 2024, the last day of fiscal 2024.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable[1]	Number of Securities Underlying Unexercised Options (#) Unexercisable[2]	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Yet Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)
Dr. James A. Hayward	959	—	4,656.00	10/17/2027	—	—
	219	—	2,288.00	12/21/2024	—	—
	64	—	2,392.00	12/21/2025	—	—
	188	—	1,640.00	12/20/2026	—	—
	799	—	2,808.00	7/10/2028	—	—
	313	—	952.00	08/29/2028	—	—
	349	—	167.20	06/02/2030	—	—
	652	—	150.80	10/18/2030	—	—
	4,000	—	108.8	1/5/2031	—	—
	10,960	—	111.60	10/31/2031	—	—
Beth M. Jantzen						
	51	—	2,288.00	12/21/2024	—	—
	38	—	2,760.00	2/14/2025	—	—
	63	—	2,392.00	12/21/2025	—	—
	76	—	1,640.00	12/20/2026	—	—
	125	—	952.00	08/29/2028	—	—
	349	—	167.20	06/02/2030	—	—
	652	—	150.80	10/18/2030	—	—
	2,258	—	111.60	10/31/2031	—	—
	1,249	3,752	21.60	3/23/2033	—	—
Judith Murrah						
	95	—	2,288.00	12/21/2024	—	—
	63	—	2,392.00	12/21/2025	—	—
	76	—	1,640.00	12/20/2026	—	—
	188	—	952.00	08/29/2028	—	—
	349	—	167.20	06/02/2030	—	—
	652	—	150.80	10/18/2030	—	—
	2,608	—	111.60	10/31/2031	—	—
	1,353	4,064	21.60	3/23/2033	—	—
Clay Shorrock						
	2,258	—	111.60	10/31/2031	—	—
	1,248	3,752	21.60	3/23/2033	—	—

(1) All Option grants reflected in this column are fully vested and exercisable.

(2) Each of the Option grants made in fiscal 2023 vests in equal 25% installments on each of the first four anniversaries of the date of grant (i.e., March 23rd of each of 2024, 2025, 2026 and 2027), subject to the relevant named executive officer's continued employment with the Company through each applicable vesting date.

Employment Agreement with Dr. James A. Hayward

The following is a discussion of our employment agreement with Dr. Hayward as of December 13, 2024 and, where indicated, compensation actions prior to such date.

The Chairman and Chief Executive Officer is the only named executive officer with an employment agreement. Effective as of January 1, 2024, Dr. Hayward voluntarily reduced his salary to $250,000 in response to the then current cash position of the Company. This voluntary reduction was effective until May 25, 2024.

The initial term of Dr. Hayward's employment agreement was from July 1, 2016 to July 1, 2017, and the term of the employment agreement renews automatically on an annual basis thereafter, unless either party provides the other with 90 days' advance written notice of non-renewal. The employment agreement provides for an annual base salary, which is described above in the section entitled "Base Salary," and the Board of Directors, acting in its discretion, may also grant annual bonuses and annual equity awards to Dr. Hayward, provided that Dr. Hayward may not be treated less favorably with respect to annual bonuses or annual equity awards than other executives of the Company. Dr. Hayward will be eligible to participate in retirement, welfare and incentive plans available to the Company's other employees. The employment agreement also provides for the following limited perquisites: an automobile allowance of up to $1,500 per month, a gas allowance, the use of an outside driver for up to 20 hours per week, a gym membership and an airline club membership.

The employment agreement with Dr. Hayward also provides that if he is terminated by the company without "cause" (as defined in the employment agreement and summarized below) or if Dr. Hayward terminates his employment for "good reason" (as defined in the employment agreement and summarized below), then, in addition to payment or provision of any earned and unpaid base salary, bonus and benefits, and subject to his delivery of an executed general release and continuing compliance with restrictive covenants, Dr. Hayward will be entitled to receive: (i) a pro rata portion (based on the number of days elapsed from the beginning of the Company's fiscal year to the date of his termination of employment) of the greater of (A) the annual bonus he would have received if his employment had continued through the end of the fiscal year of termination and (B) the prior year's annual bonus; (ii) installment payments for two years following termination in an aggregate amount equal to the greater of (A) 2.99 times Dr. Hayward's base salary and (B) two times the sum of (I) Dr. Hayward's base salary and Dr. Hayward's prior year's annual bonus (or, if greater, Dr. Hayward's target bonus (if any) for the fiscal year of termination); (iii) Company-paid COBRA continuation coverage for 18 months post-termination; (iv) continuing life insurance benefits (if any) for two years post-termination; and (v) extended exercisability of any outstanding vested stock options and stock appreciation rights (until three years from the termination date or, if earlier, until the expiration of the fixed stock option or stock appreciation right term).

If termination of Dr. Hayward's employment is triggered by the Company without cause or by

Dr. Hayward for good reason, in each case, within six months before or two years after a "change in control of the Company" (as defined in the employment agreement), then, the severance payments that would otherwise have been paid in installments will be paid in a lump sum. Further, unless assumed or continued by the acquiror, all of Dr. Hayward's outstanding stock options and other equity incentive awards will become fully vested upon the occurrence of a change in control of the Company (whether or not his employment is terminated in connection with such change in control). The exercisability period of outstanding stock options and stock appreciation rights would be extended until three years following the change in control (or, if later, until three years following a qualifying termination after a change in control), or, if earlier, until the earlier expiration of the fixed stock option or stock appreciation right term. In addition, the employment agreement provides that if the payments and benefits due to Dr. Hayward in connection with a change in control would be subject to an excise tax under Section 280G of the Code, they will be reduced to the maximum amount that would not trigger the excise tax, unless Dr. Hayward would be better off (on an after- tax basis) receiving all of the payments and benefits and paying all necessary applicable taxes. Additionally, if, following a change in control, the Company fails to comply with any of its obligations under the employment agreement or the Company takes any action to declare the employment agreement void or unenforceable or institutes any litigation or other legal action designed to deny, diminish or to recover from Dr. Hayward (or his beneficiary) the payments and benefits intended to be provided, then Dr. Hayward (or his beneficiary, as the case may be) shall be entitled to select and retain counsel at the expense of the Company to represent him (or his beneficiary) in connection with the good faith initiation or defense of any litigation or other legal action, whether by or against the Company or any director, officer, stockholder or other person affiliated with the Company or any successor thereto in any jurisdiction.

Upon a termination of his employment due to death or "disability" (as defined in the employment agreement), Dr. Hayward 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, other than the installment payments and the continuing life insurance benefits, and additionally, the extended exercisability provisions would apply to any outstanding stock options only.

For purposes of the employment agreement, “cause” means Dr. Hayward: (i) is convicted of or pleads nolo contendere to a felony, (ii) commits fraud or a material act or omission involving dishonesty affecting the assets, business or reputation of the Company or any of its subsidiaries or affiliates, (iii) willfully fails or refuses to carry out the material responsibilities of his employment, as reasonably determined by the Board of Directors, (iv) engages in gross negligence, willful misconduct or a pattern of behavior that has had or is reasonably likely to have a significant adverse effect on the Company or his ability to perform the duties and responsibilities of his employment, or (v) willfully engages in any act or omission that is in material violation of Company policy, including, without limitation, Company policy on business ethics and conduct, and Company policy on the use of inside information and insider trading; provided, however, that, if the conduct giving rise to termination for Cause is curable without material harm to the business or assets of the Company, Dr. Hayward will be afforded an opportunity to effect such a cure within 30 days after notice of termination and thereby avoid a termination for Cause based upon such conduct.

For purposes of the employment agreement, “good reason” is defined as any of the following: (i) a material adverse change by the Company of Dr. Hayward’s status or position as the Chief Executive Officer, including, without limitation, a material diminution of his position, duties, responsibilities or authority or the assignment to him of duties or responsibilities that are materially inconsistent with his status or position; (ii) a non-voluntary reduction by the Company of his annual base salary or failure to pay same; (iii) a breach by the Company of any of its material obligations under the employment agreement; (iv) relocation of Dr. Hayward without his consent beyond a 75-mile radius of his then principal place of employment in violation of the employment agreement; or (v) in connection with a change in control, the failure or refusal by the successor or acquiring company to expressly assume the obligations of the Company under the employment agreement. As a condition to terminating his employment for Good Reason, Dr. Hayward must, within 60 days after the occurrence of the event or condition giving rise to such termination, provide written notice to the Company (or the successor or acquiring company) of his desire to terminate for Good Reason, specifying the nature of the act or omission that he deems to constitute Good Reason. The Company shall have 30 days after receipt of such notice to review and, if required, correct the situation (and thus prevent his termination for Good Reason).

Dr. Hayward is subject to standard restrictive covenants, including a two-year post-employment non- compete and a two-year post-employment non-solicit of employees or customers. In his capacity as a Chief Executive Officer, Dr. Hayward’s position at the Company is a policy-making position in which he has the authority to make policy decisions that control significant aspects of the Company.

Director Compensation: Fiscal 2024

Due to the financial state of the Company, the Board waived their compensation for fiscal 2024.

None of the members of our Board of Directors received any other compensation in respect of fiscal 2024.

Name	Option Awards ($)	Total ($)
Sanford R. Simon	—	—
Yacov A. Shamash	—	—
Joseph D. Ceccoli	—	—
Robert C. Catell	—	—
Elizabeth M. Schmalz Shaheen	—	—

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

Equity Compensation Plan Information

The following table provides information as of September 30, 2024 with respect to shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights	Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the first Column)
Equity compensation plans approved by security holders			
Applied DNA Sciences, Inc.2005 Incentive Stock Plan, as amended	11,629	$ 1,229.27	2,218
Applied DNA Sciences, Inc. 2020 Incentive Plan	97,006	60.36	266,392
Equity compensation plans not approved by security holders	—	—	—
TOTAL	108,635	$ 185.78	268,610

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the shares of our Common Stock beneficially owned as of December 12, 2024, by (i) each person, or group of affiliated persons, who is known to us to beneficially own 5% or more of the outstanding Common Stock, (ii) each of our named executive officers and current executive officers, (iii) each of our directors and (iv) all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC, and thus it represents sole or shared voting or investment power with respect to our securities. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. The information does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Exchange Act of 1934, as amended (the "*Exchange Act*").

We have based our calculation of the percentage of beneficial ownership on 51,545,359 shares of our Common Stock outstanding as of December 12, 2024. We have deemed shares of Common Stock subject to stock options or warrants that are currently exercisable or exercisable within 60 days of December 12, 2024 to be outstanding and to be beneficially owned by the person holding the stock option or warrant, as applicable, for the purpose of computing the percentage ownership of that person. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated below, the address of each beneficial owner listed in the table below is c/o 50 Health Sciences Drive, Stony Brook, New York 11790. The information in the table below is based solely on a review of Schedules 13D and 13G and information provided by certain investors as well as the Company's knowledge of holdings with respect to its employees and directors.

	Title of Class	Number of Shares Owned[1]	Percentage of Class[2]
Executive Officers and Directors:			
James A. Hayward	Common Stock	25,212 (3)	*
Yacov A. Shamash	Common Stock	8,994 (4)	*
Joseph D. Ceccoli	Common Stock	8,554 (5)	*
Sanford R. Simon	Common Stock	8,356 (6)	*
Robert B. Catell	Common Stock	8,436 (7)	*
Elizabeth Schmalz Shaheen	Common Stock	8,373 (8)	*
Beth M. Jantzen	Common Stock	6,911 (9) (12)	*
Judith Murrah	Common Stock	7,721 (10) (12)	*
Clay Shorrock	Common Stock	6,305 (11) (12)	*
All directors and officers as a group (9 persons)	Common Stock	88,862 (13)	*
5% Stockholder:			
Altium Growth Fund, LP	Common Stock	21,048,579 (14) (15)	31.08 %
Anson Master Funds	Common Stock	19,955,769 (16) (17)	29.31 %
Michael Bigger	Common Stock	19,723,289 (18) (19)	29.21 %
L1 Capital Global Opportunities Master Fund	Common Stock	18,555,128 (20) (21)	27.70 %
Sabby Volatility Warrant Master Fund, Ltd.	Common Stock	19,471,005 (22) (23)	29.17 %
S.H.N. Financial Investments Ltd	Common Stock	18,955,127 (24) (25)	28.41 %

* indicates less than one percent

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the shares shown. Except as indicated by footnote and subject to community property laws where applicable, to our knowledge, the stockholders named in the table have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them. A person is deemed to be the beneficial owner of securities that can be acquired by such person within 60 days upon the exercise of options, warrants or convertible securities (in any case, the "Currently Exercisable Options").

(2) Based upon 51,545,359 shares of Common Stock outstanding as of December 12, 2024. Each beneficial owner's percentage ownership is determined by assuming that the Currently Exercisable Options that are beneficially held by such person (but not those held by any other person) have been exercised and converted.

(3) Includes 18,503 shares underlying currently exercisable options.

(4) Includes 8,915 shares underlying currently exercisable options.

(5) Includes 8,526 shares underlying currently exercisable options.

(6) Includes 8,352 shares underlying currently exercisable options.

(7) Includes 8,339 shares underlying currently exercisable options.

(8) Includes 8,334 shares underlying currently exercisable options.

(9) Includes 4,861 shares underlying currently exercisable options.

(10) Includes 5,384 shares underlying currently exercisable options.

(11) Includes 3,507 shares underlying currently exercisable options.

(12) Excludes 3,752, 3,752 and 4,064 shares underlying options for Ms. Jantzen, Mr. Shorrock and Ms. Murrah, respectively that were granted on March 23, 2023 and vest 25% per year commencing on the first anniversary of grant date.

(13) Includes 74,721 shares underlying currently exercisable options.

(14) The securities are directly held as of November 6, 2024, by Altium Growth Fund, LP ("Altium"), and may be deemed to be beneficially owned by Jacob Gottlieb, who exercises investment and voting control over the securities. The address of Altium is c/o Altium Capital Management, LP, 152 West 57th Street, 20th Floor, New York, NY 10019.

(15) Consists of (i) 4,877,375 shares of Common Stock, (ii) warrants to purchase up to 15,846,791 shares of Common Stock and (iii) Pre-Funded Warrants to purchase up to 324,413 shares of Common Stock. Certain of the warrants held by Altium are subject to a beneficial ownership limitation of 4.99% or 9.99%, as applicable, which such limitation restricts Altium from exercising that portion of the warrants that would result in Altium and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The beneficial ownership of Altium reported in this table does not reflect this limitation. Excludes (i) Series C Warrants to purchase up to 3,750,000 shares of Common Stock and (ii) Series D Warrants to purchase up to 3,750,000 shares of Common Stock, whose exercise are subject to Warrant Stockholder Approval.

(16) The securities are directly held as of November 6, 2024, by (i) Anson East Master Fund LP ("Anson East") and (ii) Anson Investments Master Fund LP ("Anson Investments", and, collectively with Anson East, the "Anson Master Funds"). Anson Advisors Inc and Anson Funds Management LP, the Co-Investment Advisers of the Anson Master Funds, hold voting and dispositive power over the shares of Common Stock held by the Anson Master Funds. Tony Moore is the managing member of Anson Management GP LLC, which is the general partner of Anson Funds Management LP. Moez Kassam and Amin Nathoo are directors of Anson Advisors Inc. Mr. Moore, Mr. Kassam and Mr. Nathoo each disclaim beneficial ownership of these shares of Common Stock except to the extent of their pecuniary interest therein. The principal business address of the Anson Master Funds is Maples Corporate Services Limited, PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

(17) Consists of (i) 3,425,587 shares of Common Stock, (ii) warrants to purchase up to 16,205,769 shares of Common Stock and (iii) Pre-Funded Warrants to purchase up to 324,413 shares of Common Stock. Certain of the warrants held by the Anson Master Funds are subject to a beneficial ownership limitation of 4.99% or 9.99%, as applicable, which such limitation restrict the Anson Master Funds from exercising that portion of the warrants that would result in the Anson Master Funds and their affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The beneficial ownership of the Anson Master Funds reported in this table do not reflect this limitation. Excludes (i) Series C Warrants to purchase up to 3,750,000 shares of Common Stock and (ii) Series D Warrants to purchase up to 3,750,000 shares of Common Stock, whose exercise are subject to Warrant Stockholder Approval.

(18) The securities are directly held as of November 6, 2024, by (i) Bigger Capital Fund, LP ("Bigger") and (ii) District 2 Capital Fund LP ("District 2"), and may be deemed to be beneficially owned by Michael Bigger, who exercises investment and voting control over the securities. The address of Bigger is 11700 W. Charleston Blvd. 170-659, Las Vegas, NV 89135, and the address of District 2 is 14 Wall Street, Huntington, NY 11743.

(19) Consists of (i) 3,750,000 shares of Common Stock and (ii) warrants to purchase up to 15,973,289 shares of Common Stock. Certain of the warrants held by Bigger and District 2 are subject to a beneficial ownership limitation of 4.99% or 9.99%, as applicable, which such limitation restrict Bigger and District 2 from exercising that portion of the warrants that would result in Bigger and District 2 and their affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The beneficial ownership of Bigger and District 2 reported in this table do not reflect this limitation. Excludes (i) Series C Warrants to purchase up to 3,750,000 shares of Common Stock and (ii) Series D Warrants to purchase up to 3,750,000 shares of Common Stock, whose exercise are subject to Warrant Stockholder Approval.

(20) The securities are directly held as of November 6, 2024, by L1 Capital Global Opportunities Master Fund ("L1"), and may be deemed to be beneficially owned by David Feldman and Joel Arber. The address of L1 is 161A Shedden Road, 1 Artillery Court, PO Box 10085, Grand Cayman KY1-1001, Cayman Islands.

(21) Consists of (i) 3,125,000 shares of Common Stock and (ii) warrants to purchase up to 15,430,128 shares of Common Stock. Certain of the warrants held by L1 are subject to a beneficial ownership limitation of 4.99% or 9.99%, as applicable, which such limitation restrict L1 from exercising that portion of the warrants that would result in L1 and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The beneficial ownership of L1 reported in this table does not reflect this limitation. Excludes (i) Series C Warrants to purchase up to 3,125,000 shares of Common Stock and (ii) Series D Warrants to purchase up to 3,125,000 shares of Common Stock, whose exercise are subject to Warrant Stockholder Approval.

(22) The securities are directly held as of November 7, 2024, by Sabby Volatility Warrant Master Fund, Ltd. ("Sabby"). Sabby Management, LLC is the investment manager of Sabby and shares voting and investment power with respect to these shares in this capacity. As manager of Sabby Management, LLC, Hal Mintz also shares voting and investment power on behalf of Sabby. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities listed except to the extent of their pecuniary interest therein. The address of Sabby is Captiva (Cayman) Ltd., Governors Square, Bld. 4, 2nd Floor, 23 Lime Tree Bay Avenue, P.O. Box 32315, Grand Cayman KY1-1209, Cayman Islands.

(23) Consists of (i) 4,259,627 shares of Common Stock and (ii) warrants to purchase up to 15,211,378 shares of Common Stock. Certain of the warrants held by Sabby are subject to a beneficial ownership limitation of 4.99% or 9.99%, as applicable, which such limitation restrict Sabby from exercising that portion of the warrants that would result in Sabby and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The beneficial ownership of Sabby reported in this table does not reflect this limitation. Excludes (i) Series C Warrants to purchase up to 3,750,000 shares of Common Stock and (ii) Series D Warrants to purchase up to 3,750,000 shares of Common Stock, whose exercise are subject to Warrant Stockholder Approval.

(24) The securities are directly held as of November 6, 2024, by S.H.N. Financial Investments Ltd. ("SHN"), and may be deemed to be beneficially owned by Nir Shamir and Hadar Shamir. The address of SHN is Arik Einstein 3, Herzliya, Israel.

(25) Consists of (i) 3,775,000 shares of Common Stock and (ii) warrants to purchase up to 15,180,127 shares of Common Stock. Certain of the warrants held by SHN are subject to a beneficial ownership limitation of 4.99% or 9.99%, as applicable, which such limitation restricts SHN from exercising that portion of the warrants that would result in SHN and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation. The beneficial ownership of SHN reported in this table does not reflect this limitation. Excludes (i) Series C Warrants to purchase up to 2,187,500 shares of Common Stock and (ii) Series D Warrants to purchase up to 2,187,500 shares of Common Stock, whose exercise are subject to Warrant Stockholder Approval.

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

Director Independence

The Board of Directors has determined that at all times during the fiscal year ended September 30, 2024, each of our directors other than Dr. Hayward — consisting of Robert B. Catell, Joseph D. Ceccoli, Yacov A. Shamash, Sanford R. Simon, and Elizabeth M. Schmalz Shaheen — are and were "independent" as defined by the listing standards of Nasdaq, constituting a majority of independent directors on our Board of Directors as required by the rules of Nasdaq. The Board of Directors considers in its evaluation of independence whether any director has a relationship with us that would interfere with the exercise of independent judgment in carrying out his or her responsibilities of a director.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit and Other Fees

The following table sets forth fees billed to us by our current independent auditors during the fiscal years ended September 30, 2024 and 2023 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements, (ii) services by our auditor that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees, (iii) services rendered in connection with tax compliance, tax advice and tax planning, and (iv) all other fees for services rendered.

Marcum LLP	**Fiscal year ended September 30, 2024**	**Fiscal year ended September 30, 2023**
(i) Audit Fees	$ 460,204	$ 278,105
(ii) Audit-Related Fees	—	—
(iii) Tax Fees	50,985	26,265
(iv) All Other Fees	—	—
Total Fees	$ 511,189	$ 304,370

Audit Fees — Consists of fees billed for professional services rendered for the audit of our consolidated financial statements, review of the interim consolidated financial statements included in quarterly reports, and services that are normally provided by our independent auditors in connection with statutory and regulatory filings or engagements, including registration statements.

Audit-Related Fees — Consists of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements and are not reported under “Audit Fees,” such as accounting consultation and audits in connection with acquisitions.

Tax Fees — Consists of fees billed for professional services for tax compliance, tax advice and tax planning.

All Other Fees — Consists of fees for products and services other than the services reported above.

The Audit Committee of the Board of Directors has considered whether the provision of non-audit services is compatible with maintaining the principal accountant’s independence and has determined that independence has been maintained.

Audit Committee Pre-Approval Policy

Our audit committee is responsible for approving all audit, audit-related, tax and other services. The audit committee pre-approves all auditing services and permitted non-audit services, including all fees and terms to be performed for us by our independent auditor at the beginning of the fiscal year. Non-audit services are reviewed and pre-approved by project at the beginning of the fiscal year. Any additional non-audit services contemplated by us after the beginning of the fiscal year are submitted to the chairman of our audit committee for pre-approval prior to engaging our independent auditor for such services. These interim pre-approvals are reviewed with the full audit committee at its next meeting for ratification. During the fiscal years ended September 30, 2024 and 2023, all services performed by Marcum LLP were pre-approved by our audit committee in accordance with these policies and applicable SEC regulations.

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, 2024 and 2023 and for the years ended September 30, 2024 and 2023, 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 17, 2024

/s/ James A. Hayward
By: James A. Hayward
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*), Chairman of the Board of Directors and Director	December 17, 2024
/s/ BETH M. JANTZEN Beth M. Jantzen	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	December 17, 2024
/s/ **ROBERT CATELL** Robert Catell	Director	December 17, 2024
/s/ **JOSEPH D. CECCOLI** Joseph D. Ceccoli	Director	December 17, 2024
/s/ **YACOV A. SHAMASH** Yacov A. Shamash	Director	December 17, 2024
/s/ **SANFORD R. SIMON** Sanford R. Simon	Director	December 17, 2024
/s/ **ELIZABETH M. SCHMALZ SHAHEEN** Elizabeth M. Schmalz Shaheen	Director	December 17, 2024

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	Conformed version of By-Laws, as amended by the Certificate of Amendment to the By-Laws, effective November 7, 2024.	S-1	3.2	333-283315	11/19/2024	
4.1	Description of Securities	10-K	4.1	001-36745	12/9/2021	
4.2	Form of Pre-Funded Common Stock Purchase Warrant	8-K	4.1	001-36745	2/23/2022	
4.3	Form of Common Stock Purchase Warrant	8-K	4.2	001-36745	2/23/2022	
4.4	Form of Series A Warrant	8-K	4.1	001-36745	8/9/2022	
4.5	Form of Series B Warrant	8-K	4.2	001-36745	8/9/2022	
4.6	Form of Prefunded Warrant	8-K	4.3	001-36745	8/9/2022	
4.7	Form of Pre-Funded Warrant.	8-K	4.1	001-36745	02/01/2024	
4.8	Form of Private Common Warrant.	8-K	4.2	001-36745	02/01/2024	
4.9	Form of Pre-Funded Warrant	8-K	4.4	001-36745	05/29/2024	
4.10	Form of Series A Warrant	8-K	4.2	001-36745	05/29/2024	
4.11	Form of Series B Warrant	8-K	4.3	001-36745	05/29/2024	
4.12	Form of Placement Agent Warrant	8-K	4.1	001-36745	05/29/2024	
4.13	Form of Pre-Funded Warrant	8-K	4.1	001-36745	10/30/2024	
4.14	Form of Series C Common Stock Purchase Warrant	8-K	4.2	001-36745	10/30/2024	
4.15	Form of Series D Common Stock Purchase Warrant	8-K	4.3	001-36745	10/30/2024	
4.16	Form of Placement Agent Warrant	8-K	4.4	001-36745	10/30/2024	
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*	License Agreement with Himatsingka America, Inc. dated June 23, 2017	10-Q	10.1	001-36745	8/10/2017
10.9+	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
10.10	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
10.11	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
10.12	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
10.13	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
10.14†	Letter Agreement, dated January 4, 2024, by and between Applied DNA Sciences, Inc. and James A. Hayward.	8-K	10.1	001-36745	1/5/2024
10.15†	Letter Agreement, dated January 4, 2024, by and between Applied DNA Sciences, Inc. and Judith Murrah.	8-K	10.2	001-36745	1/5/2024
10.16	Amended and Restated Lease Agreement, dated February 24, 2023, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc. (Office Lease).	8-K	10.1	001-36745	02/28/2023
10.17	Amended and Restated Lease Agreement, dated February 24, 2023, by and between Long Island High Technology Incubator, Inc. and Applied DNA Sciences, Inc. (Laboratory Lease).	8-K	10.2	001-36745	02/28/2023
10.18	Lease Renewal Agreement dated January 10, 2024 (Laboratory Lease).	10-Q	10.3	001-36745	02/08/2024
10.19	Placement Agency Agreement by and between Applied DNA Sciences, Inc. and	8-K	10.1	001-36745	02/01/2024

	Maxim Group LLC, dated January 31, 2024.					
10.20	Form of Securities Purchase Agreement, dated January 31, 2024, by and between Applied DNA Sciences, Inc. and the parties thereto.	8-K	10.2	001-36745	02/01/2024	
10.21	Form of Purchase Warrant Amendment	8-K	10.1	001-36745	04/19/2024	
10.22	Form of Book-Entry Warrant Amendment	8-K	10.2	001-36745	04/19/2024	
10.23	Form of Placement Agency Agreement by and between Applied DNA Sciences, Inc. Craig-Hallum Capital Group LLC and Laidlaw & Company (UK) Ltd.	8-K	10.1	001-36745	05/29/2024	
10.24	Form of Securities Purchase Agreement, dated October 30, 2024, by and between Applied DNA Sciences, Inc. and the parties thereto.	8-K	10.1	001-36745	10/30/2024	
10.25	Form of Warrant Amendment	8-K	10.2	001-36745	10/30/2024	
10.26	Waiver of Negative Covenant	8-K	10.3	001-36745	10/30/2024	
14.1	Code of Business Conduct and Ethics.	10-K	14.1	001-36745	12/14/2022	
19.1	Insider Trading Policy					Filed
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
97.1	Clawback Policy					Filed
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 ExtensionDefinition 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. and Subsidiaries (the "Company") as of September 30, 2024 and 2023, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended September 30, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended September 30, 2024, 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 17, 2024

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
SEPTEMBER 30, 2024 AND 2023

	September 30, 2024	September 30, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,431,095	$ 7,151,800
Accounts receivable, net of allowance for credit losses of $ 75,000 at September 30, 2024 and 2023	362,013	255,502
Inventories	438,592	330,027
Prepaid expenses and other current assets	815,970	389,241
Total current assets	8,047,670	8,126,570
Property and equipment, net	553,233	838,270
Other assets:		
Restricted cash	750,000	750,000
Intangible assets	2,698,975	2,698,975
Operating right of use asset	739,162	1,237,762
Total assets	$ 12,789,040	$ 13,651,577
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 1,793,427	$ 2,270,388
Operating lease liability, current	545,912	498,598
Deferred revenue	58,785	76,435
Total current liabilities	2,398,124	2,845,421
Long term accrued liabilities	31,467	31,467
Deferred revenue, long term	194,000	194,000
Operating lease liability, long term	193,249	739,162
Deferred tax liability, net	684,115	684,115
Warrants classified as a liability	320,000	4,285,000
Total liabilities	3,820,955	8,779,165
Commitments and contingencies (Note G)		
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, 2024 and 2023	—	—
Series A Preferred stock, par value $ 0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2024 and 2023	—	—
Series B Preferred stock, par value $ 0.001 per share; 10,000,000 shares authorized; -0- issued and outstanding as of September 30, 2024 and 2023	—	—
Common stock, par value $0.001 per share; 200,000,000 shares authorized as of September 30, 2024 and 2023, 10,311,885 and 682,926 shares issued and outstanding as of September 30, 2024 and 2023, respectively	10,314	683
Additional paid in capital	318,805,058	307,397,623
Accumulated deficit	(309,672,755)	(302,447,147)
Applied DNA Sciences, Inc. stockholders' equity	9,142,617	4,951,159
Noncontrolling interest	(174,532)	(78,747)
Total equity	8,968,085	4,872,412
Total liabilities and equity	$ 12,789,040	$ 13,651,577

See the accompanying notes to the consolidated financial statements.

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE FISCAL YEARS ENDED SEPTEMBER 30, 2024 AND 2023

	Fiscal Years Ended September 30,	
	2024	2023
Revenues		
Product revenues	$ 1,074,813	$ 1,218,185
Service revenues	1,038,677	996,866
Clinical laboratory service revenues	1,317,930	11,152,392
Total revenues	3,431,420	13,367,443
Cost of product revenues	1,138,650	1,308,620
Cost of clinical laboratory service revenues	1,275,891	6,525,391
Total cost of revenues	2,414,541	7,834,011
Gross profit	1,016,879	5,533,432
Operating expenses:		
Selling, general and administrative	11,447,894	12,751,644
Research and development	3,593,750	3,735,078
Total operating expenses	15,041,644	16,486,722
LOSS FROM OPERATIONS	(14,024,765)	(10,953,290)
Interest income	176,301	75,332
Transaction costs allocated to warrant liabilities	(633,198)	—
Unrealized gain on change in fair value of warrants classified as a liability	9,430,000	854,400
Unrealized loss on change in fair value of warrants classified as a liability - warrant modification	(394,000)	—
Loss on issuance of warrants	(1,633,767)	—
Other (expense) income, net	(8,877)	642
Loss before provision for income taxes	(7,088,306)	(10,022,916)
Provision for income taxes	—	—
NET LOSS	$ (7,088,306)	$ (10,022,916)
Less: Net loss attributable to noncontrolling interest	95,785	75,857
NET LOSS attributable to Applied DNA Sciences, Inc.	$ (6,992,521)	$ (9,947,059)
Deemed dividend related to warrant modifications	(233,087)	—
NET LOSS attributable to common stockholders	$ (7,225,608)	$ (9,947,059)
Net loss per share attributable to common stockholders-basic and diluted	$ (1.82)	$ (15.21)
Weighted average shares outstanding-basic and diluted	3,966,026	653,771

See the accompanying notes to the consolidated financial statements.

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
FOR THE FISCAL YEARS ENDED SEPTEMBER 30, 2024 AND 2023

	Common Shares	Common Stock Amount	Additional Paid in Capital	Accumulated Deficit	Noncontrolling Interest	Total
Balance, October 1, 2022	645,426	$ 645	$305,411,272	$(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	37,500	38	952,462	—	—	952,500
Net loss	—	—	—	(9,947,059)	(75,857)	(10,022,916)
Balance, October 1, 2023	682,926	683	307,397,623	(302,447,147)	(78,747)	4,872,412
Exercise of warrants, cashlessly	105	1	(1)	—	—	—
Stock based compensation expense	—	—	572,293	—	—	572,293
Common stock issued in ATM, net of offering costs	4,502	5	64,392	—	—	64,397
Deemed dividend - warrant repricing	—	—	233,087	(233,087)	—	—
Common stock issued in Registered direct offering, net of offering costs	161,403	161	—	—	—	161
Share issued upon restricted stock vesting	14,132	14	(14)	—	—	—
Common stock and pre-funded warrants issued in public offering, net of offering costs	724,923	725	10,524,338	—	—	10,525,063
Share issued upon warrant exercises	8,626,333	8,627	(3,687)	—	—	4,940
Adjustment for reverse split	85,061	85	(85)	—	—	—
Common stock issued, Spindle earnout	12,500	13	17,112	—	—	17,125
Net loss	—	—	—	(6,992,521)	(95,785)	(7,088,306)
Balance, September 30, 2024	10,311,885	10,314	318,805,058	(309,672,755)	(174,532)	8,968,085

See the accompanying notes to the consolidated financial statements.

APPLIED DNA SCIENCES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE FISCAL YEARS ENDED SEPTEMBER 30, 2024 AND 2023

	Years Ended September 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (7,088,306)	$ (10,022,916)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	696,425	1,362,249
Gain on sale of property and equipment	—	(6,083)
Write-off of property and equipment	—	62,000
Shares issued Spindle earnout	17,125	—
Unrealized gain on change in fair value of warrants classified as a liability	(9,430,000)	(854,400)
Unrealized loss on change in fair value of warrants classified as a liability-warrant modification	394,000	—
Transaction costs allocated to warrant liabilities	633,198	—
Loss on issuance of warrants	1,633,767	—
Stock-based compensation	572,293	1,033,889
Change in provision for bad debts	—	(239,043)
Change in operating assets and liabilities:		
Accounts receivable	(106,511)	3,051,083
Inventories	(108,565)	272,217
Prepaid expenses, other current assets and deposits	(426,729)	767,812
Accounts payable and accrued liabilities	(480,444)	(1,351,363)
Deferred revenue	(17,650)	(293,122)
Net cash used in operating activities	(13,711,397)	(6,217,677)
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	(407,904)	(78,448)
Net cash used in investing activities	(407,904)	(1,095,808)
Cash flows from financing activities:		
Net proceeds from exercise of warrants	394	—
Net proceeds from issuance of common stock	13,398,202	—
Net cash provided by financing activities	13,398,596	—
Net decrease in cash, cash equivalents and restricted cash	(720,705)	(7,313,485)
Cash, cash equivalents and restricted cash at beginning of period	7,901,800	15,215,285
Cash, cash equivalents and restricted cash at end of period	$ 7,181,095	$ 7,901,800
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:		
Common stock issued for Spindle asset purchase	$ —	$ 952,500
Deemed dividend warrant modifications	$ 233,087	$ —
Deferred tax liability for Spindle asset purchase	$ —	$ 684,115
Leased assets obtained in exchange for new operating lease liabilities	$ —	$ 1,545,916
Property and equipment acquired and included in accounts payable	$ 3,484	$ —

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 (including biologics and drugs), as well as the development and sale of a proprietary RNA polymerase (“RNAP”) for use in the production of messenger RNA (“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 chains and security services (“DNA Tagging and Security Products and Services”).

On April 24, 2024, the Company filed a Certificate of Amendment of its Certificate of Incorporation with the Secretary of State of the State of Delaware that effected a one-for-twenty (1:20) reverse stock split of its common stock, par value $ 0.001 per share (the “Common Stock”), effective 12:01 A.M. April 25, 2024 (the “April 2024 Reverse Stock Split”). All warrant, option, share, and per share information in the condensed consolidated financial statements gives retroactive effect to a one-for-twenty reverse stock split that was affected on April 25, 2024. Please see Note E for more information.

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 $ 309,672,755 as of September 30, 2024. The Company incurred a net loss of $7,088,306 and incurred negative operating cash flow of $ 13,711,397 for the fiscal year ended September 30, 2024.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.

As discussed below in Note M, on October 31, 2024, we closed on a registered direct offering and received net proceeds, after deducting placement agent fees and other estimated offering expenses payable by the Company, of approximately $5.8 million. As a result of this offering, the Company’s consolidated cash balance as of November 30, 2024 was approximately $10.1 million.

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 Biotech, Inc. (“Spindle”) and its 98% majority–owned subsidiary, LineaRx, Inc. (“LRx”). Significant inter-company transactions and balances have been eliminated in consolidation. To facilitate comparison of information across periods, certain reclassifications have been made to prior year amounts to conform to the current year’s presentation.

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

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, fair value calculations for warrants, contingencies, and management's anticipated liquidity. Management reviews its estimates on a regular basis and the effects of any material revisions are reflected in the consolidated financial statements in the period they are deemed necessary. Accordingly, actual results could differ from those estimates.

Revenue Recognition

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

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

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

Product Revenues

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.

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

Research and Development Services

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

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

Disaggregation of Revenue

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

	Fiscal Years Ended: September 30,	
	2024	2023
Research and development services (over-time)	$ 311,238	$ 421,585
Clinical laboratory testing services (point-in-time)	32,610	7,612,975
Clinical laboratory services (over-time)	1,285,320	3,540,456
Product and authentication services (point-in-time):		
Supply chain	1,208,696	827,603
Large Scale DNA Production	584,115	653,015
Asset marking	9,441	311,809
Total	$ 3,431,420	$ 13,367,443

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

Contract balances

As of September 30, 2024, 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, 2023	September 30, 2024	$ change
Contract liabilities	Deferred revenue	$ 270,435	$ 252,785	$ 17,650

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

For the fiscal year ended September 30, 2024, the Company recognized $ 40,035 of revenue that was included in contract liabilities as of October 1, 2023.

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.

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.

	September 30, 2024	September 30, 2023
Cash and cash equivalents	$ 6,431,095	$ 7,151,800
Restricted cash	750,000	750,000
Total cash, cash equivalents and restricted cash	$ 7,181,095	$ 7,901,800

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

Accounts Receivable

The Company provides an allowance for credit losses 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 credit losses 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.

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

	Balance sheet classification	October 1, 2023	September 30, 2024	$ change
Contract receivable	Accounts receivable	$ 255,502	$ 362,013	$ 106,511

	Balance sheet classification	October 1, 2022	September 30, 2023	$ change
Contract receivable	Accounts receivable	$ 3,067,544	$ 255,502	$ (2,812,042)

At September 30, 2024 and 2023, the Company has an allowance for credit losses of $ 75,000. 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, 2024 and 2023, the Company incurred losses from operations. Based upon these results and the trends in the Company's performance projected for fiscal year 2025, 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, 2024 and 2023. Tax years 2020 through 2023 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,	
	2024	2023
Lab equipment	$ 4,480,947	$ 4,069,175
Vehicles	56,471	56,471
Leasehold improvements	124,825	124,825
Total	4,662,243	4,250,471
Accumulated depreciation	4,109,010	3,412,201
Property and equipment, net	$ 553,233	$ 838,270

As of September 30, 2024 and 2023, there was $ 167,342 and $0 of construction in progress, respectively that was included in lab equipment. Depreciation expense for the fiscal years ended September 30, 2024 and 2023 were $696,425 and $1,362,249, 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 loss 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, 2024 and 2023 are as follows:

	2024	2023
Warrants	19,748,143	261,029
Restricted Stock Units	—	14,132
Options	108,635	110,537
	19,856,778	385,698

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.

Warrant Liabilities

The Company evaluates its 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 certain of its warrant agreements, the instruments do not qualify for equity treatment. As such, the Common Warrants, Series A Warrants and Private Common Warrants were recorded as a liability on the condensed 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.

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, 2024, the Company had cash and cash equivalents of approximately $6.1 million in excess of the FDIC insurance limit.

The Company's revenues earned from the sale of products and services for the fiscal year ended September 30, 2024 included an aggregate of 26% and 17%, from one customer within the MDx Testing Services segment and one customer within the Therapeutic DNA Production Services segment, respectively.

The Company's revenues earned from the 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.

At September 30, 2024, four customers accounted for 59% of the Company's accounts receivable. At September 30, 2023, three customers accounted for 60% of the Company's accounts receivable.

Research and Development

The Company accounts for research and development costs in accordance with the ASC 730, Research and Development ("ASC 730"). Under ASC 730, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and development costs are expensed when the contracted work has been performed. 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, 2024 and 2023, the Company incurred research and development expenses of 3,593,750 and $3,735,078, respectively.

Advertising

The Company follows the policy of charging the costs of advertising to expense as incurred. The Company charged to operations $124,036 and $185,115, as advertising costs for the fiscal years ended September 30, 2024 and 2023, 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, 2024, the Company performed its qualitative assessment and indicated that there was no impairment.

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 public offering (See Note G), offering costs in the aggregate of $633,198 were incurred, and were allocated to the liability classified warrants, and are included in other expense in the accompanying consolidated statement of operations for the fiscal year ended September 30, 2024.

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, 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 offers pharmacogenomics testing services that were approved by the New York State Department of Health during June 2024.

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

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

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

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 — Unadjusted 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, 2024, 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 December 2023, the FASB issued Accounting Standards Update (ASU) No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, that enhances the transparency of income tax disclosures by expanding annual disclosure requirements related to the rate reconciliation and income taxes paid. The guidance is effective for fiscal years beginning after December 15, 2024, with early adoption permitted, and should be applied prospectively with the option of retrospective application. The Company is currently evaluating the impact of adopting this ASU on its disclosures.

In November 2023, the FASB issued ASU No. 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure." The ASU updates reportable segment disclosure requirements, primarily through requiring enhanced disclosures about significant segment expenses and information used to assess segment performance. These disclosures are required quarterly. The ASU is effective for fiscal years beginning after December 15, 2023 and interim periods beginning after December 15, 2024, with early adoption permitted. It is required to be adopted retrospectively for all prior periods presented in the financial statements The Company is currently evaluating the impact of adopting this ASU on its disclosures.

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, 2024 and 2023:

	2024	2023
Raw materials	$ 81,008	$ 212,079
Work in progress	221,250	19,859
Finished goods	136,334	98,089
Total	$ 438,592	$ 330,027

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 37,500 restricted shares of the Company's Common Stock, in addition to future contingent consideration of up to 50,000 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
37,500 Company shares at $25.40/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, 2024 and 2023 are as follows:

	2024	2023
Accounts payable	$ 1,165,727	$ 1,072,161
Accrued salaries payable	509,281	1,138,235
Other accrued expenses	118,419	59,992
Total	$ 1,793,427	$ 2,270,388

NOTE G – CAPITAL STOCK

Common Stock Transactions during the Fiscal Year Ended September 30, 2024:

April 2024 Reverse Stock Split

On April 15, 2024, the Company held the special meeting of stockholders (the "April 2024 Special Meeting") where its stockholders approved the April 2024 Reverse Split (the "Reverse Split Proposal"). The Company's Board of Directors determined on April 21, 2024 that the split ratio of the April 2024 Reverse Stock Split should be one-for-twenty shares.

The April 2024 Reverse Stock Split was effected as of 12:01 a.m. Eastern Time on Thursday, April 25, 2024 and combined each twenty shares of the Company's outstanding Common Stock into one share of Common Stock, without any change in the par value per share. Moreover, the April 2024 Reverse Stock Split correspondingly adjusted, a) the per share exercise price and the number of shares issuable upon the exercise of all outstanding options, and b) the number of shares underlying any of our outstanding warrants by adjusting the conversion ratio for each instrument and increasing the applicable exercise price or conversion price in accordance with the terms of each instrument and based on the reverse stock split ratio. No fractional shares were issued in connection with the April 2024 Reverse Stock Split. Any fractional shares resulting from the April 2024 Reverse Stock Split were rounded up to the nearest whole share.

Public Offering

On May 28, 2024, the Company entered into a placement agency agreement (the "May 2024 Placement Agreement") with Craig-Hallum Capital Group LLC ("Craig Hallum") and Laidlaw & Company (UK) Ltd. ("Laidlaw", and with Craig-Hallum, the "May 2024 Placement Agents") pursuant to which the May 2024 Placement Agents agreed to serve as the co-placement agents, on a "reasonable best efforts" basis, in connection with the issuance and sale (the "May 2024 Offering") of 9,230,769 units (the "Units"), with each Unit consisting of either (A) one share of the Company's Common Stock, and one Series A warrant (the " May 2024 Series A Warrant") to purchase one share of Common Stock and one Series B warrant to purchase one share of Common Stock (the "May 2024 Series B Warrant" and, together with the May 2024 Series A Warrant, the "May 2024 Series Warrants"), or (B) one pre-funded warrant (each, a "May 2024 Pre-Funded Warrant") to purchase one share of Common Stock and one May 2024 Series A Warrant and one May 2024 Series B Warrant. In connection with the May 2024 Offering, the Company also issued placement agent warrants ("May 2024 Placement Agent Warrants") to purchase up to 461,538 shares of Common Stock. The May 2024 Offering closed on May 29, 2024. The purchase price of each Unit was $1.30, except for Units which include May 2024 Pre-Funded Warrants, which had a purchase price of $1.2999. The Units had no stand-alone rights and will not be certificated or issued as stand-alone securities.

The Company received net proceeds from the May 2024 Offering, after deducting placement agent fees and other offering expenses payable by the Company, of approximately $10.5 million.

The exercisability of the May 2024 Series Warrants was available only upon receipt of such stockholder approval as may be required by the applicable rules and regulations of the Nasdaq Capital Market (the "May 2024 Warrant Stockholder Approval"). Each May 2024 Series A Warrant offered would become exercisable beginning on the date of the May 2024Warrant Stockholder Approval at an exercise price of $1.99 per share of Common Stock, and would expire five years from the date of the May 2024 Warrant Stockholder Approval. Each May 2024 Series B Warrant offered would become exercisable beginning on the date of the May 2024Warrant Stockholder Approval at an exercise price of $1.99 per share of Common Stock, and will expire one year from the date of the May 2024 Warrant Stockholder Approval. The May 2024 Warrant Stockholder Approval was obtained at the Company's annual meeting, which was held on September 30, 2024.

Under the alternate cashless exercise option of the May 2024 Series B Warrants, the holder of the May 2024 Series B Warrant has the right to receive an aggregate number of shares equal to the product of (x) the aggregate number of shares of Common Stock that would be issuable upon a cash exercise of the May 2024 Series B Warrant and (y) 3.0. In addition, the May 2024 Series A Warrants and May 2024 Series B Warrants include a provision that resets their respective exercise price in the event of a reverse split of the Company's Common Stock, to a price equal to the lesser of (i) the then exercise price and (ii) lowest volume weighted average price (VWAP) during the period commencing five trading days immediately preceding and the five trading days commencing on the date the Company effects a reverse stock split in the future with a proportionate adjustment to the number of shares underlying the May 2024 Series A Warrants and May 2024 Series B Warrants.

NOTE G – CAPITAL STOCK, continued

Public Offering, continued

Subject to certain exceptions, the May 2024 Series A Warrants provide for an adjustment to the exercise price and number of shares underlying the May 2024 Series A Warrants upon the Company's issuance of Common Stock or Common Stock equivalents at a price per share that is less than the exercise price of the May 2024 Series A Warrants (the "Price Reset Mechanism").

In connection with the October Registered Direct Offering (see Note M), the Price Reset Mechanism in the May 2024 Series A Warrants was triggered, which resulted in the number of shares of Common Stock issuable upon exercise of the May 2024 Series A Warrants increasing from 9,230,769 to 91,890,698. The exercise price of the May 2024 Series A Warrants was adjusted from $ 1.99 per share to $0.20 per share with respect to the May 2024 Series A Warrants amended by the Warrant Amendment, and to $ 0.19 with respect to the May 2024 Series A Warrants not amended by the Warrant Amendment.

The Common Stock and May 2024 Pre-Funded Warrants were only sold with the accompanying May 2024 Series A Warrants and May 2024 Series B Warrants that are part of a Unit, but the components of the Units were immediately separable and were issued separately in this Offering. During the three-month period ended June 30, 2024, all of the May 2024 Pre-Funded Warrants were exercised.

Registered Direct Offering

On February 2, 2024, the Company closed on a registered direct public offering (the "RDO") of 161,403 shares of the Company's Common Stock and pre-funded warrants ("RDO Pre-Funded Warrants") to purchase up to 120,800 shares of Common Stock, and in a concurrent private placement, unregistered common warrants ("Private Common Warrants") to purchase up to 564,407 shares of Common Stock. In connection with the RDO, the Company entered into securities purchase agreements (the "RDO Purchase Agreements") with certain institutional investors (each, a "RDO Purchaser" and, collectively, the "RDO Purchasers"). The Company received net proceeds from the RDO, after deducting placement agent fees and other estimated offering expenses payable by the Company, of approximately $2.8 million.

The RDO Pre-Funded Warrants have an exercise price of $ 0.0001 per share and are immediately exercisable and can be exercised at any time after their original issuance until such RDO Pre-Funded Warrants are exercised in full. Each share was sold at an offering price of $12.18 and each RDO Pre-Funded Warrant was sold at an offering price of $ 12.18 (equal to the purchase price per share of Common Stock minus the exercise price of the RDO Pre-Funded Warrant). Pursuant to the RDO Purchase Agreements, the Company also agreed to issue to the RDO Purchasers, in a concurrent private placement, the Private Common Warrants. Each Private Common Warrant has an exercise price of $12.18 per share, and became exercisable following shareholder approval obtained on April 15, 2024 and will expire on April 15, 2029. During the fiscal year ended September 30, 2024, all of the 120,800 RDO Pre-Funded Warrants were exercised.

The Private Common Warrants and the shares of Common Stock issuable upon the exercise of the Private Common Warrants are not registered under the Securities Act. The Private Common Warrants and the shares of Common Stock issuable upon exercise thereof were issued or will be issued, respectively, in reliance on the exemptions from registration provided by Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder, for transactions not involving a public offering. Pursuant to the RDO Purchase Agreements, within 45 calendar days from the date of the RDO Purchase Agreements, the Company agreed to file a registration statement on Form S-3 (or other appropriate form if the Company is not then S-3 eligible) providing for the resale by the RDO Purchasers of the shares of Common Stock issuable upon exercise of the Private Common Warrants. The Company agreed to use commercially reasonable efforts to cause such registration statement to become effective within 90 days following the closing date of the RDO Purchase Agreements and to keep such registration statement effective at all times until no RDO Purchaser owns any Private Common Warrants or shares of Common Stock issuable upon exercise thereof. The Company filed the registration statement on March 12, 2024, and the registration statement was declared effective on March 20, 2024.

The Private 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 L). Additionally, the Company incurred $ 633,198 of transaction costs related to the RDO which is included in the consolidated statement of operations for the fiscal year ended September 30, 2024.

NOTE G – CAPITAL STOCK, continued

Registered Direct Offering, continued

In connection with the RDO and the RDO Purchase Agreements, the Company agreed to reduce the exercise price of warrants previously issued to the RDO Purchasers with exercise prices ranging from $25.80 to $80.00 per warrant to $12.18 per warrant. The Company also agreed to extend the expiration dates for such warrants to August 2028. In addition, 2,904 outstanding common stock warrants held by other investors who did not participate in the RDO had their exercise price reduced to $12.18 per warrant share and had their warrant expiration dates extended to August 2028. The foregoing reductions of the exercise price and extension of expiration dates of such warrants were approved by shareholders on April 15, 2024. The incremental change in fair value as a result of the modification for the warrants that are recorded as a liability was $1,633,767 and is recorded as a unrealized loss on the change in fair value of warrants classified as a liability in the consolidated statement of operations for the fiscal year ended September 30, 2024. The incremental change in fair value as a result of the modification for the warrants that are recorded to equity was $155,330 and is recorded as a deemed dividend in the consolidated statement of operations for the fiscal year ended September 30, 2024.

ATM

On November 7, 2023, the Company entered into an Equity Distribution Agreement (the “Equity Distribution 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 in an aggregate offering price of up to $6,397,939 through the Agent.

The offer and sales of the shares of Common Stock made pursuant to the Equity Distribution Agreement, was made under the Company’s effective “shelf” registration statement on Form S-3. Under the terms of the Equity Distribution Agreement, the Agent may sell the shares of Common Stock 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 September 30, 2024, the Company has issued 4,501 shares of its Common Stock for net proceeds of approximately $64,397 under this Equity Distribution Agreement. Effective January 30, 2024, the Company terminated the Equity Distribution Agreement by providing notice of termination to the Agent in accordance with the terms of the Equity Distribution Agreement. As a result of terminating the Equity Distribution Agreement, the $ 217,000 of capitalized transaction costs were written off and are included in the consolidated statement of operations for the fiscal year ended September 30, 2024.

As a result of the issuance of Common Stock under this Equity Distribution Agreement, the exercise price of the 22,891 remaining warrants issued during November 2019 was reduced to $29.40 per share, the exercise price of 7,950 warrants issued during October 2020 was reduced to $30.20 per share and the exercise prices of 5,000 warrants issued during December 2020 was reduced to an exercise price of $26.20 per share for 2,500 warrants and an exercise price of $25.80 per share for the remaining 2,500 warrants. These exercise price adjustments are in accordance with the adjustment provisions contained in the respective warrant agreements. The incremental change in fair value of these warrants as a result of the triggering event was $77,757 and is recorded as a deemed dividend in the consolidated statement of operations for the fiscal year ended September 30, 2024.

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, 2023	261,029	$ 3.50
Granted	28,305,629	1.64
Exercised	(8,626,796)	(0.002)
Cancelled or expired	(191,719)	(56.98)
Balance, September 30, 2024	19,748,143	$ 2.78

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, 2024, a total of 14,477 shares have been issued and options to purchase 81,257 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, 2023	110,537	$ 201.27		
Granted	—	—		
Exercised	—	—		
Forfeited	(866)	21.60		
Expired	(1,036)	2,006.38		
Outstanding at September 30, 2024	108,635	185.48		
Vested at September 30, 2024	92,634	213.60	—	7.23
Non-vested at September 30, 2024	16,001	22.71	—	8.47

For the fiscal year ended September 30, 2024, the Company did not grant stock options to officers or employees of the Company.

For the fiscal year 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 fiscal year 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.

The fair value of options granted during the fiscal year ended September 30, 2023 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:

Stock price	$ 1.27
Exercise price	$ 1.27
Expected term	5.75
Dividend yield	—
Volatility	157 %
Risk free rate	3.64 %

The Company recorded $572,293 and $1,033,889 as stock compensation expense within selling, general and administrative for fiscal years ended September 30, 2024 and 2023, respectively. As of September 30, 2024, unrecorded compensation cost related to non-vested awards was $268,476 which is expected to be recognized over a weighted average period of approximately 2.43 years. The weighted average grant date fair value per share for options granted during the fiscal years ended September 30, 2023 was $1.20.

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

Restricted Stock Units

Restricted stock unit awards are valued at the market price of the Company's Common Stock on the grant date. During the fiscal year ended September 30, 2023, the Company granted 14,132 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 of $21.60. These RSUs vested during March 2024. As of September 30, 2024 there were no RSUs outstanding.

NOTE I – INCOME TAXES

The income tax provision (benefit) for the fiscal years ended September 30, 2024 and 2023 consists of the following:

	2024	2023
Federal:		
Current	$ —	$ —
Deferred	5,874,000	(3,249,000)
	5,874,000	(3,249,000)
State and local:		
Current	—	—
Deferred	417,000	(1,161,000)
	417,000	(1,161,000)
Foreign:		
Current	—	—
Deferred	(11,000)	(121,000)
	—	—
Change in valuation allowance	(6,280,000)	4,531,000
Income tax provision (benefit)	$ —	$ —

The provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory rate to losses before income tax expense for the years ended September 30, 2024 and 2023 as follows:

	2024	2023
Statutory federal income tax rate	21.00 %	21.00 %
Statutory state and local income tax rate (1%, as of September 30, 2024 and 2023), net of federal benefit	10.19 %	9.56 %
Stock based compensation	2.04 %	(1.76)%
Permanent differences related to warrants	20.33 %	1.80 %
Other permanent differences	(2.49)%	1.97 %
Canada NOL	— %	1.28 %
Federal R&D Credit	(2.43)%	9.93 %
Adjustment for prior year's NOLs	(137.65)%	— %
Change in deferred tax rate	(0.81)%	1.67 %
Change in valuation allowance	89.82 %	(45.45)%
Effective tax rate	0.00 %	0.00 %

NOTE I – INCOME TAXES, continued

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

	September 30,	
	2024	2023
Deferred tax assets (liabilities):		
Stock based compensation	$ 1,309,000	$ 993,000
Depreciation and amortization	333,000	440,000
Net operating loss carry forward	18,463,000	25,250,000
Impairment of intangibles	222,000	227,000
Capitalized research and development	1,386,000	726,000
Lease liability	200,000	342,000
Tax credits	2,885,000	3,060,000
Other	141,000	324,000
Deferred tax assets	24,939,000	31,362,000
Intellectual property	(684,000)	(684,000)
ROU asset	(200,000)	(342,000)
	(884,000)	(1,026,000)
Less: valuation allowance	(24,739,000)	(31,020,000)
Net deferred tax liability	$ (684,000)	$ (684,000)

As of September 30, 2024, the Company has approximately $ 71,634,000 of Federal and $ 49,169,000 of State net operating loss “NOL” carryforwards available. 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. The annual limitation ranges between $44,000 and $1,529,000 and any unused amounts can be carried forward to subsequent years. Based on a study of Section 382 of the Internal Revenue code conducted by the Company at September 30, 2024, the deferred tax asset related to Federal net operating loss carryforwards is decreased by $40,477,000 and the state net operating loss carryforwards is decreased by $16,849,000. The write off of the deferred tax asset and the corresponding reduction in valuation allowance has no impact to the consolidated balance sheet or statement of operations. The Federal NOLs generated in tax years beginning after 12/31/2017 have no expiration period due to the TCJA that was enacted in March 2020.

The Company has provided a full valuation allowance against all of the net deferred tax assets based on management’s determination that it is more likely than not that the net deferred tax assets will not be realized in the future. The valuation allowance decreased by 6,281,000.

The Company has Federal research and development credits of approximately $ 2,369,000 that will begin to expire after 2034. The Company also has state investment tax credits of $469,000 that will begin to expire after 2029.

On August 16, 2022, President Biden signed the Inflation Reduction Act, which is effective for tax years beginning on or after January 1, 2023 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, 2024. 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 on February 1, 2023. The initial lease term for the laboratory space is one year from the commencement date and was extended until January 31, 2025. The lease requires monthly payments of $10,417. 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 Company has ceased operations of its testing facility in India and vacated this lease on August 31, 2024. The total rent expense for the fiscal years ended September 30, 2024 and 2023 were $722,332 and $663,513, respectively.

The components of lease expense are as follows:

	Fiscal year ended September 30,	
Lease Cost	**2024**	**2023**
Operating lease cost	$ 597,670	$ 560,841
Short-term lease cost	124,662	102,672
Total lease cost	$ 722,332	$ 663,513

Other Information	
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 586,334
Right-of-use assets obtained in exchange for new operating lease liabilities	—
Weighted-average remaining lease term — operating leases	1.3 years
Weighted-average discount rate — operating leases	9.1 %

NOTE J – COMMITMENTS AND CONTINGENCIES, continued

Operating leases, continued

Maturities of operating lease liabilities were as follows:

Maturity of Lease Liabilities	Fiscal year ended September 30, Operating Leases
2025	586,334
2026	195,445
Total lease payments	781,779
Less: interest	(42,615)
Present value of lease liabilities	$ 739,164

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 unless either party provides the other with 90 days' advance written notice of non - renewal. 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, 2024. 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.

NOTE J – COMMITMENTS AND CONTINGENCIES, continued

Employment Agreement, continued

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. On January 4, 2024, in connection with certain cost management efforts, the Company entered into a letter agreement with the CEO to amend the CEO's employment agreement with the Company and to provide for a temporary 45% reduction to the CEO's annual base salary, from $ 450,000 to $250,000, for a period of three months, effective as of January 1, 2024 through March 31, 2024. On April 1, 2024, the CEO extended the voluntary salary reduction with all terms and conditions withstanding until May 15, 2024. The CEO also agreed to waive any right to resign for "good reason" under his employment agreement with the Company as a result of the foregoing salary reduction. The CEO's salary was restored to $450,000 on May 25, 2024. While the compensation committee determined that the CEO was eligible to receive a discretionary bonus in the amount of $500,000 with respect to his performance for fiscal 2023, on January 19, 2024, the CEO elected not to receive any cash incentive or other bonus for fiscal 2023, in light of the Company's cash position.

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, 2024 is as follows:

	Therapeutic DNA Production	MDx Testing Services	DNA Tagging and Security Products	Consolidated
Revenues:				
Product revenues	$ 560,000	$ —	$ 514,813	$ 1,074,813
Service revenues	335,354	—	703,323	1,038,677
Clinical laboratory service revenues	—	1,330,850	—	1,330,850
Less intersegment revenues	—	(12,920)	—	(12,920)
Total revenues	$ 895,354	$ 1,317,930	$ 1,218,136	$ 3,431,420
Gross profit	$ 678,166	$ (49,830)	$ 388,543	$ 1,016,879
(Loss) income from segment operations (a)	$ (4,789,268)	$ (1,489,220)	$ (2,551,983)	$ (8,830,471)

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)

Reconciliation of segment loss from operations to corporate loss:

	September 30,	
	2024	2023
Loss from operations of reportable segments	$ (8,830,471)	$ (6,137,013)
General corporate expenses (b)	(5,194,294)	(4,816,277)
Interest income	176,301	75,332
Unrealized gain on change in fair value of warrants classified as a liability	9,430,000	—
Unrealized loss on change in fair value of warrants classified as a liability - warrant modification	(394,000)	—
Transaction costs allocated to registered direct offering	(633,198)	854,400
Transaction costs allocated to warrant liabilities	—	—
Loss on issuance of warrants	(1,633,767)	—
Other income (expense), net	(8,877)	$ 642
Consolidated loss before provision for income taxes	$ (7,088,306)	$ (10,022,916)

(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,	
	2024	2023
Americas	$ 2,269,826	$ 12,222,650
Europe	172,368	258,355
Asia and other	989,226	886,438
Total	$ 3,431,420	$ 13,367,443

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 (loss) on change in fair value of the warrants classified as a liability in the consolidated statements of operations. For additional disclosures regarding methods and assumptions used in estimating fair values of these financial instruments, see Note B.

The following table presents the fair value of the Company's financial instruments as of September 30, 2024 and summarizes the significant unobservable inputs in fair value measurement of Level 3 financial assets and liabilities as of September 30, 2024. The Company did not have any assets or liabilities categorized as Level 1 or 2 as of September 30, 2024.

	Fair value at September 30, 2024	Valuation Technique	Unobservable Input	Volatility Input
Liabilities:				
Common Warrants	$ 27,000	Monte Carlo simulation	Annualized volatility	157.50 %
Series A Warrants	$ 15,000	Monte Carlo simulation	Annualized volatility	167.50 %
Series A Warrants - modified	$ 16,000	Monte Carlo simulation	Annualized volatility	157.50 %
Private Common Warrants	$ 262,000	Monte Carlo simulation	Annualized volatility	167.50 %

The change in fair value of the Common Warrants for the fiscal year ended September 30, 2024 is summarized as follows:

	Common Warrants	Series A Warrants	Series A Warrants-modified	Private Common Warrants	Totals
Fair value at October 1, 2023	$ 1,468,000	$ 1,971,900	$ 845,100	$ —	$ 4,285,000
Fair value at February 2, 2024	—	—	—	5,071,000	5,071,000
Change in fair value-warrant modification	230,000	—	164,000	—	394,000
Change in fair value	(1,671,000)	(1,956,900)	(993,100)	(4,809,000)	(9,430,000)
Fair Value at September 30, 2024	$ 27,000	$ 15,000	$ 16,000	$ 262,000	$ 320,000

NOTE M — SUBSEQUENT EVENTS

Registered Direct Offering and Concurrent Private Placement

On October 31, 2024, the Company closed a registered direct offering (the "October Registered Direct Offering") in which, pursuant to the Securities Purchase Agreement dated October 31, 2024 (the "October Purchase Agreement"), by and between the Company and certain institutional investors (the "October Purchasers"), the Company issued and sold 19,247,498 shares of the Company's Common Stock, and pre-funded warrants ("October Pre-Funded Warrants") to purchase up to 1,065,002 shares of Common Stock, and (ii) in a concurrent private placement (the "October Private Placement", and together with the October Registered Direct Offering the "October Offering"), unregistered Series C Common Stock Purchase Warrants ("October Series C Warrants") to purchase up to 20,312,500 shares of Common Stock and unregistered Series D Common Stock Purchase Warrants ("October Series D Warrants", and together with the October Series C Warrants, the "October Series Warrants", and, together with the October Pre-Funded Warrants and the October Series C Warrants, the "October Warrants") to purchase up to 20,312,500 shares of Common Stock. The purchase price for each share of Common Stock and accompanying October Series C Warrant and October Series D Warrant was $0.32 and the purchase price for each October Pre-Funded Warrant and accompanying October Series C Warrant and October Series D Warrant was $0.3199. Craig-Hallum acted as placement agent in connection with the October Offering.

The Company received gross proceeds from the October Offering, before deducting placement agent fees and other estimated offering expenses payable by the Company, of approximately $6.5 million.

The exercisability of the October Series Warrants and the October Placement Agent Warrants will be available only upon receipt of such stockholder approval ("Warrant Stockholder Approval") as may be required by the applicable rules and regulations of The Nasdaq Stock Market LLC. Each October Series C Warrant has an exercise price of $0.32 per share of Common Stock, will become exercisable upon the first trading day (the "Stockholder Approval Date") following the Company's notice to warrantholders of Warrant Stockholder Approval, and will expire on the five-year anniversary of the Stockholder Approval Date. Each October Series D Warrant has an exercise price of $0.32 per share of Common Stock, will become exercisable upon the Stockholder Approval Date, and will expire on the 18-month anniversary of the Stockholder Approval Date. Each October Placement Agent warrant has an exercise price of $ 0.32, will become exercisable upon the Stockholder Approval date and will expire on October 30, 2029.

Pursuant to that certain engagement letter, dated August 23, 2024, by and between the Company and Craig-Hallum, the Company agreed to pay the Craig-Hallum a cash placement fee equal to 6.0% of the aggregate gross proceeds raised in the October Offering from sales arranged for by the Craig-Hallum. Subject to certain conditions, the Company also agreed to reimburse certain expenses of the Placement Agent in connection with the Offering, including but not limited to legal fees, up to a maximum of $100,000. The Company also agreed to issue to the Placement Agent, or its respective designees, October Placement Agent Warrants ("Placement Agent Warrants") to purchase up to 1,015,625 shares of Common Stock (which equals 5.0% of the number of shares of Common Stock and October Pre-Funded Warrants offered). The Pre-Funded Warrants have an exercise price of $0.0001 per share and are immediately exercisable and can be exercised at any time after their original issuance until such October Pre-Funded Warrants are exercised in full.

The Company has agreed to hold a special meeting of stockholders to obtain the Warrant Stockholder Approval no later than 90 days after the closing of the Offering (the "Special Meeting"). If the Company does not obtain Warrant Stockholder Approval at the first meeting, the Company is obligated to call a meeting every ninety days thereafter to seek Warrant Stockholder Approval until the earlier of the date on which Warrant Stockholder Approval is obtained or the October Series C Warrants and October Series D Warrants are no longer outstanding. The Company agreed to file a preliminary proxy statement with respect to obtaining Warrant Stockholder Approval at the Special Meeting within 20 days following the closing date of the October Purchase Agreement, and filed such preliminary proxy statement with the Securities and Exchange Commission ("SEC") on November 14, 2024.

Under the alternate cashless exercise option of the October Series D Warrants, the holder of an October Series D Warrant, has the right to receive an aggregate number of shares equal to the product of (x) the aggregate number of shares of Common Stock that would be issuable upon a cash exercise of the October Series D Warrant and (y) 1.0. In addition, the October Series D Warrants will include a provision that resets their exercise price in the event of a reverse split of our Common Stock, to a price equal to the lesser of (i) the then exercise price and (ii) lowest volume weighted average price (VWAP) during the period commencing five trading days immediately preceding and the five trading days commencing on the date we effect a reverse stock split in the future with a proportionate adjustment to the number of shares underlying the October Series D Warrants, subject to a floor of $0.0634.

NOTE M — SUBSEQUENT EVENTS, continued

Registered Direct Offering and Concurrent Private Placement , continued

The October Warrants and the shares of Common Stock issuable upon the exercise of the October Warrants are not registered under the Securities Act. The October Warrants were issued, and the shares of Common Stock issuable upon exercise thereof will be issued, in reliance on the exemptions from registration provided by Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder, for transactions not involving a public offering.

Pursuant to the October Purchase Agreement, within 20 calendar days from the date of the October Purchase Agreement, the Company agreed to file a registration statement on Form S-1 providing for the resale by the Purchasers of the shares of Common Stock issuable upon exercise of the October Series Warrants. The Company agreed to use commercially reasonable efforts to cause such registration statement to become effective within 50 calendar days following the closing date of the October Purchase Agreement (or 90 calendar days following the closing date of the October Purchase Agreement in the event that the SEC requires the Company to include its audited year-end financial statements for the fiscal year ended September 30, 2024 in such registration statement) and to keep such registration statement effective at all times until no October Purchaser owns any October Series Warrants or shares of Common Stock issuable upon exercise thereof. The Company filed the registration statement with the SEC on November 19, 2024.

In the event of any fundamental transaction, as described in the October Warrants and generally including any merger with or into another entity, sale of all or substantially all of the Company's assets, tender offer or exchange offer, reclassification of the shares of Common Stock, or the acquisition of greater than 50% of the Company's then outstanding shares of Common Stock by a person or persons, subject to certain exceptions, then upon any subsequent exercise of an October Warrant, the holder will have the right to receive as alternative consideration, for each share of Common Stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of Common Stock of the successor or acquiring corporation of the Company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of Common Stock for which the October Warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders of the October Warrants have the right to require the Company or a successor entity to purchase the October Warrants for cash in the amount of the Black Scholes Value (as defined in the October Warrants) of the unexercised portion of the October Warrants concurrently with or within 30 days following the consummation of a fundamental transaction. However, in the event of a fundamental transaction which is not in the Company's control or in which the consideration payable consists of equity securities of a successor entity that is quoted or listed on a nationally recognized securities exchange, the holders of the October Warrants will only be entitled to receive from the Company or its successor entity, as of the date of consummation of such fundamental transaction the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of the October Warrants that is being offered and paid to the holders of Common Stock in connection with the fundamental transaction, whether that consideration is in the form of cash, stock or any combination of cash and stock, or whether the holders of Common Stock are given the choice to receive alternative forms of consideration in connection with the fundamental transaction.

Amendment to Series A Warrants

On October 30, 2024, the Company entered into the Warrant Amendment with certain holders of an aggregate of 9,153,846 May 2024 Series A Warrants. The Warrant Amendments amended the May 2024 Series A Warrants to revise the Price Reset Mechanism of the May 2024 Series A Warrants such that the Floor Price (as defined in the May 2024 Series A Warrants) shall not be lower than $ 0.20 and revised the definition of "Material Subsidiary" in Section 3(d) of the May 2024 Series A Warrants to clarify that Applied DNA Clinical Labs LLC is not a Material Subsidiary. Please see Note G – Capital Stock for more information.

NOTE M — SUBSEQUENT EVENTS, continued

Waiver of Standstill in Placement Agency Agreement

As disclosed in Note G above, the Company closed the May 2024 Offering on May 29, 2024. As part of the May 2024 Offering, the Company entered into the May Placement Agency Agreement with Craig-Hallum and Laidlaw. The May 2024 Placement Agency Agreement contains a negative covenant which restricts the Company's ability to enter into certain equity sales of its securities for a period of time after the closing of the May 2024 Offering without the prior consent of Craig-Hallum (the "Negative Covenant").

On October 29, 2024, in connection with entering into the October 2024 Offering, the Company and Craig-Hallum entered into a waiver of the Negative Covenant, which permitted the Company to proceed with the October 2024 Offering.

Nasdaq Minimum Bid Price Requirement Deficiency Notification

On November 12, 2024, the Company received written notice (the "Notification Letter") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it is 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. Nasdaq Listing Rule 5550(a)(2) 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 (collectively, the "Bid Price Rule"). Based on the closing bid price of the Company's Common Stock for the thirty-one (31) consecutive business days from September 27, 2024 to November 11, 2024, the Company no longer meets the requirements of the Bid Price Rule.

The Notification Letter does not impact the Company's listing on The Nasdaq Capital Market at this time. The Notification Letter states that the Company has 180 calendar days, or until May 12, 2025, to regain compliance with the Bid Price Rule. To regain compliance, the bid price of the Company's Common Stock must have a closing bid price of at least $1.00 per share for a minimum of ten (10) consecutive business days, with a longer period potentially required by the staff of Nasdaq (the "Staff"). If the Company does not regain compliance with the Bid Price Rule by May 12, 2025, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company 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 Rule, and would need to provide written notice of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary, no later than ten (10) business days prior to May 12, 2025.

However, if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq would notify the Company that its securities would be subject to delisting. In the event of such a notification, the Company may appeal the Staff's determination to delist its securities, but there can be no assurance the Staff would grant the Company's request for continued listing.

Pursuant to the October Purchase Agreement, the Company is required to effect a reverse stock split of its outstanding shares of Common Stock if, at any time after the Stockholder Approval Date, it is not in compliance with Nasdaq's Bid Price Rule and has received a deficiency letter from the Listing Qualifications Department of The Nasdaq Stock Market LLC (the "Reverse Stock Split"). The Company must effect the Reverse Stock Split within 30 days of the Stockholder Approval Date; provided that if within such 30 day period the Company regains compliance with the Bid Price Rule, the Company shall have no obligation to effect the Reverse Stock Split. The Company intends to implement a reverse stock split of its outstanding securities to regain compliance with the Bid Price Rule and to comply with the provisions of the October Purchase Agreement.

Company's Announcement of Exploration of Divestiture of Business Segment and Changes to Management Team

On December 17, 2024, that Company announced its intention to restructure its operations to prioritize its Therapeutic DNA Production Services and is exploring the divestiture of its DNA Tagging and Security Products and Service business segment. The Company also announced that Ms. Murrah was named the President of Applied DNA Sciences, Inc. and Mr. Shorrock was named the President of LineaRx, Inc, effective on December 13, 2024. Concurrently on December 13, 2024, Dr. Hayward stepped down as the President of APDN. Dr. Hayward remains as the CEO and Chairman of the Board.

Exhibit 19.1

APPLIED DNA INSIDER TRADING POLICY

Purpose

The purpose of this Insider Trading Policy is to define those individuals who are designated as “insiders” for the purpose of APDN stock trading restrictions and to outline the obligations of insiders regarding insider trading and federal securities laws. Except where otherwise explicitly stated, this insider trading policy applies to all employees, officers, members of the Board of Directors and consultants of Applied DNA Sciences as well as their spouses, minor children, other relatives who live with them and any trusts, estates or other entities over which they exercise control or in which they have any beneficial interest.

General Prohibition Against Insider Trading and Disclosure of Nonpublic Information

During your work at Applied DNA Sciences, you may become aware of important information – or what the law calls “material” information – about Applied DNA Sciences or other companies that is not available to the public. It is illegal and contrary to company policy for you to buy or sell stock or other securities of any company (including Applied DNA Sciences, Inc.) while you are in possession of such material nonpublic information concerning the relevant company or its securities.

Whenever you possess such material nonpublic information, it is also illegal and contrary to company policy for you to disclose such information to anyone else who might buy or sell securities of the relevant company (including family, friends, or business acquaintances), or to suggest to anyone else that they buy or sell securities of the relevant company. Any of the foregoing conduct can result in severe disciplinary action up to and including termination of your employment and subject both you and the company to civil liability and criminal prosecution. For purposes of this policy, “material” information includes any information that a reasonable investor would consider important in deciding whether to buy, sell or hold the securities involved, or any information that would, if disclosed to the public, likely affect the market price of the securities.

You should resolve any doubts in favor of assuming that non-public information is material.

Some categories of information typically deemed “material” include the following, although this list is not exclusive:

- Information about revenues, earnings, liquidity and other measures of financial position or performance;
- Changes in financial performance or future financial outlook;
- Significant changes in the company’s debt ratings;
- Significant transactions such as mergers, acquisitions and divestitures;
- Key personnel changes, additions or departures;

- Development of significant new products or discontinuations of significant existing products;
- Acquisitions or losses of significant customers or significant orders;
- Anticipated stock splits, company share repurchases, securities offerings or changes in dividend policy or amounts; and
- Significant litigation developments or decisions by government agencies.

Information is generally considered nonpublic unless it has been publicly disseminated through a press release, SEC filing, or other means of wide public distribution. If you have any doubt about whether information you possess is available to the public, you should confirm its public nature by reviewing the company's press releases, SEC filings, and web site before engaging in any securities transactions.

As a general guidance, if you possess material nonpublic information about a company or its securities, you should wait until at least 24 hours after the information has been publicly disseminated before effecting any securities transactions.

Additional Restrictions for Senior Management (Director Level and above), Finance Group and Sales Group– Trading Blackout Periods

In addition to the foregoing prohibition against buying or selling securities at any time when you possess material nonpublic information, the company has adopted certain "Trading Blackout Periods" during which you are prohibited from buying or selling Applied DNA Sciences, Inc. securities even if you do not possess such information. These Trading Blackout Periods are imposed to avoid even the potential appearance that any of us might take advantage of quarterly or annual financial information that has not yet been disclosed to the public.

The four quarterly Trading Blackout Periods begin on the 10th business day of the last month of each fiscal quarter and end at the close of trading on the second full day after issuance of our quarterly earnings release for the corresponding concluded fiscal quarter. The fiscal quarters end on December 31, March 31, June 30 and September 30 of each year.

You should note that if a quarterly earnings release is delayed, the actual ending date of the regular blackout period will be extended. It is your responsibility and obligation to confirm that no regular blackout period is in effect under the Insider trading policy prior to trading in any Company securities that are subject to the Insider Trading Policy.

Special Trading Blackout Periods

On occasion, a nonpublic development or transaction may require the company to impose, without prior notice, a Special Trading Blackout Period applicable to some or all personnel. If you are subject to such a Special Trading Blackout Period, you will be notified by email when the Special

Trading Blackout Period begins and ends, and you may not buy or sell any Applied DNA Sciences, Inc. securities during the period. The imposition of such a Special Trading Blackout Period may itself be deemed material nonpublic information, so you should not disclose its existence to anyone else.

Limited Exceptions to the Foregoing

The foregoing prohibitions, restrictions and Trading Blackout Periods do not apply to the following:

- The acceptance or receipt of stock options, shares of restricted stock or similar grants of securities under one of the company's benefit plans; and

- Exercises of employee stock options, so long as the stock is not sold during a Trading Blackout Period or at a time when you possess material nonpublic information about Applied DNA Sciences, Inc. or its securities.

Investor Communications

Unless explicitly authorized, employees should not respond to any inquiries from analysts or investors. All communications should be referred to Investor Relations. This includes among other things, posting information in message boards and chat rooms and requests for "official comments".

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, 333-266512, 333-277832, 333-278890 and 333-283315), Form S-3 (File Nos. 333-238557, 333-252280, 333-266217 and 333-272267) and Form S-8 (File Nos. 333-182350, 333-205123, 333-231944, 333-249365 and 333-282414) of our report dated December 17, 2024, 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, 2024 and 2023 and for each of the two years in the period ended September 30, 2024, which report is included in this Annual Report on Form 10-K of Applied DNA Sciences, Inc. for the year ended September 30, 2024.

/s/ Marcum LLP

Marcum LLP
Melville, NY
December 17, 2024

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 17, 2024

/s/ James A. Hayward
James A. Hayward
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 17, 2024

/s/ Beth Jantzen
Beth Jantzen, CPA
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James A. Hayward, 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
Chief Executive Officer and Chairman
(Principal Executive Officer)

Date: December 17, 2024

* 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, 2024, 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 and Principal Accounting Officer)

Date: December 17, 2024

* 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 97.1

APPLIED DNA SCIENCES, INC. (the "Company")

COMPENSATION CLAWBACK POLICY

Effective Date: October 2, 2023

1. **Purpose.** The Company has adopted this Policy to comply with Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as codified by Section 10D of the Exchange Act, and Nasdaq Listing Rule 5608, which require the recovery of certain forms of executive compensation in the case of accounting restatements resulting from a material error in an issuer's financial statements or material noncompliance with financial reporting requirements under the federal securities laws.

2. **Administration.** This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee, in which case references herein to the Board shall be deemed references to the Compensation Committee.

3. **Definitions.** For purposes of this Policy, the following capitalized terms shall have the meanings set forth below.

   (a) "**Acknowledgement Form**" shall mean the acknowledgment form attached hereto as Annex A.

   (b) "**Board**" shall mean the Board of Directors of the Company.

   (c) "**Commission**" shall mean the U.S. Securities and Exchange Commission.

   (d) "**Covered Executive**" shall mean the Company's current and former executive officers, and such other employees who may from time to time be deemed subject to this Policy by the Board. For purposes of this Policy, an executive officer means an officer as defined in Rule 16a-1(f) under the Exchange Act.

   (e) "**Erroneously Awarded Compensation**" shall mean, with respect to each Covered Executive in connection with a Restatement, the amount of Incentive-based Compensation that exceeds the amount of Incentive-based Compensation that would have been received by the Covered Executive had it been determined based on the restated amounts, without regard to any taxes paid by the Covered Executive.

   (f) "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended.

   (g) "**Financial Reporting Measures**" shall mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures, including, but not limited to, the achievement of annual revenue targets. Stock price and total shareholder return shall also constitute "Financial Reporting Measures." A Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the Commission.

   (h) "**Incentive-based Compensation**" shall mean any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure, including, but not limited to, cash incentive bonuses, stock option awards and restricted stock unit awards. Incentive-based Compensation shall be deemed to have been received during the fiscal period in which the Financial Reporting Measure specified in the Incentive-based Compensation award is attained, even if such Incentive-based Compensation is paid or granted after the end of such fiscal period. For the avoidance of doubt, Incentive-based Compensation does not include

annual salary, compensation awarded based on completion of a specified period of service, or compensation awarded based on subjective standards, strategic measures, or operational measures.

(i) "**Nasdaq**" shall mean the Nasdaq Stock Market LLC.

(j) "**Policy**" shall mean this compensation clawback policy, as may be amended or restated from time to time.

(k) "**Restatement**" shall mean an accounting restatement due to material noncompliance by the Company with any financial reporting requirement under the federal securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

(l) "**Restatement Date**" shall be the earlier of (i) the date the Board, a committee of the Board, or officer(s) are authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement.

4. **Effective Date.** This Policy shall be effective as of the Effective Date set forth on the first page of this Policy and shall apply to Incentive-based Compensation that is approved, awarded, or granted to Covered Executives on or after that date.

5. **Scope.** This Policy applies to all Incentive-based Compensation received by the Covered Executives (i) after beginning service as an executive officer, (ii) who served as an executive officer at any time during the performance period for such Incentive-based Compensation, and (iii) during the three (3) completed fiscal years immediately preceding a Restatement Date. In addition to these last three (3) completed fiscal years, the Policy applies to any transition period that results from a change in the Company's fiscal year within or immediately following those three (3) completed fiscal years, provided, however, that a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine (9) to twelve (12) months would be deemed a completed fiscal year for purposes of this Policy. For the avoidance of doubt, the Company's obligation to recover Erroneously Awarded Compensation is not dependent on if or when the restated financial statements are filed.

6. **Recovery.** In the event the Company is required to prepare a Restatement, the Company shall, as promptly as reasonably possible, recover any Erroneously Awarded Compensation received by a Covered Executive during the three (3) completed fiscal years immediately preceding the Restatement Date. For Incentive-based Compensation based on stock price or total shareholder return, the Board shall determine the amount of Erroneously Awarded Compensation based on a reasonable estimate of the effect of the Restatement on the stock price or total shareholder return upon which the Incentive-based Compensation was received and the Company shall document such reasonable estimate and provide such documentation to Nasdaq.

   Subsequent changes in a Covered Executive's employment status, including retirement or termination of employment, do not affect the Company's rights to recover Incentive-based Compensation pursuant to this Policy.

The Board shall determine, in its sole discretion, the method of recovering any Incentive-based Compensation pursuant to this Policy. Such methods may include, but are not limited to: (i) direct recovery by reimbursement; (ii) set-off against future compensation; (iii) forfeiture of equity awards; (iv) set-off or cancelation against planned future awards; (v) forfeiture of deferred compensation (subject to compliance with the Internal Revenue Code and related regulations); and/or (vi) any other recovery action approved by the Board and permitted under applicable law.

7. **Impracticability.** The Board shall recover any Erroneously Awarded Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with Rule 10D-1 under the Exchange Act and the listing standards of Nasdaq.

8. **No Indemnification.** The Company shall not indemnify any current or former Covered Executive against the loss of Erroneously Awarded Compensation, and shall not pay, or reimburse any Covered Executives, for any insurance policy to fund such executive's potential recovery obligations.

9. **Acknowledgment.** Each Covered Executive shall sign and return to the Company, within thirty (30) calendar days following the later of (i) the effective date of this Policy first set forth above or (ii) the date the individual becomes a Covered Executive, the Acknowledgement Form, pursuant to which the Covered Executive agrees to be bound by, and to comply with, the terms and conditions of this Policy.

10. **Amendment and Interpretation.** The Board may amend this Policy from time to time in its discretion, and shall amend this Policy as it deems necessary to reflect the regulations adopted by the Commission and to comply with any rules or standards adopted by Nasdaq or such other national securities exchange on which the Company's securities are then listed. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the Commission and Nasdaq, or such other national securities exchange on which the Company's securities are then listed.

11. **Other Recoupment Rights.** This Policy shall be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the effective date shall require a Covered Executive to agree to abide by the terms of this Policy as a condition to the grant of any benefit. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other rights of recoupment or remedies that may be available to the Company pursuant to the terms of any employment agreement, equity award agreement, similar agreement, or policy and any other legal remedies available to the Company.

12. **Successors.** This Policy shall be binding and enforceable against all Covered Executives and their administrators, beneficiaries, executors, heirs, or other legal representatives.

13. **Venue.** All actions arising out of or relating to this Policy shall be brought and determined exclusively in the Court of Chancery of the State of Delaware or, in the event that such court does not have subject matter jurisdiction over such action, in any state or federal court within the State of Delaware.

14. **Governing Law.** This Policy shall be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction).

Annex A

APPLIED DNA SCIENCES, INC.

COMPENSATION CLAWBACK POLICY

ACKNOWLEDGEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Applied DNA Sciences, Inc. (the "**Company**") Compensation Clawback Policy (the "**Policy**"). Capitalized terms used but not defined in this Acknowledgement Form (this "**Acknowledgement Form**") shall have the meanings set forth in the Policy.

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Incentive-based Compensation subject to recovery under the Policy to the Company to the extent required by, and in a manner consistent with, the Policy.

_____
Signature

_____
Print Name

_____
Date