

## Risk Factors Comparison 2024-12-17 to 2023-12-07 Form: 10-K

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

- We have produced limited revenue. This makes it difficult to evaluate our future prospects and increase the risk that we will not be successful.
- There is substantial doubt relating to our ability to continue as a going concern.
- ~~Our opportunities to work with customers to develop pharmaceuticals and biologics will require substantial additional funding. Our customers may not be successful in their efforts to create a pipeline of product candidates, to develop commercially successful products, or to develop commercially successful biologic production.~~ • We may not successfully implement our business strategies, including achieving our growth objectives, **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~~ **Common stock** ~~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 our operating results have been and could be adversely affected by refine our business strategy, including a possible divestiture reduction in business with our or significant customers.**
- **We may encounter difficulties in managing closing of our DNA Tagging and Security Products and Services and / our or MDx Testing Services segments** growth and these difficulties could impair our profitability.
- Our current emphasis on Therapeutic DNA Production Services may reduce our ability to maintain and expand our existing MDX Testing Services and DNA Tagging and Security Products and Services businesses.
- ~~If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop, commercialize and have our customers adopt our Therapeutic DNA Production Services.~~ • **If we are unable to expand our DNA manufacturing capacity, we could lose revenue and our business could suffer.**
- Rapidly changing technology and extensive competition in synthetic biology could make the services or products we are developing obsolete or non-competitive unless we continue to develop new and improved services or products and pursue new market opportunities. • **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. • ~~We will need to develop and maintain manufacturing facilities that meet GMP.~~ • Pharmaceutical and biologic- related revenue will be dependent on our collaborators' and customers' demand for our manufacturing services.
- ~~Our safeCircle™ COVID-19 testing service could become obsolete or its utility could be significantly diminished, including in light of significantly decreasing demand for COVID-19 testing services.~~ • We may be unable to consistently manufacture or source our products to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels.
- The markets for drug and biologic candidates and synthetic DNA are very competitive, and we may be unable to continue to compete effectively in these industries in the future.
- The markets for our supply chain security and product authentication solutions are very competitive, and we may be unable ~~to continue~~ to compete effectively in these industries in the future.
- We compete with life science, pharmaceutical and biotechnology companies, some of whom are our customers, who are substantially larger than we are and potentially capable of developing new approaches that could make our products and technology obsolete or develop their own internal capabilities that compete with our products.
- Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand.
- Pharmaceutical and biologic- related revenue is generally dependent on regulatory approval, oversight and compliance.
- If the FDA were to begin to enforce regulation of LDTs, we could incur substantial costs and delays associated with trying to obtain pre- market clearance or approval and costs associated with complying with post- market requirements **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.
- ~~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.~~ 18
- 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~~ **Common stock** ~~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~~ **Common stock** ~~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~~ **Common stock** ~~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~~ **increased 18** from \$ 1.9 million in fiscal 2020 to \$ 18.2 million in fiscal 2022, primarily as a result of our COVID-19 testing revenues, in fiscal 2023 our revenues declined to \$ 13.4 million and ~~are expected to decline~~ **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 \$ ~~302,309~~, ~~447,672~~, ~~147,755~~ as of September 30, ~~2023~~ **2024**. We have incurred a net loss of \$ ~~10,702,088~~, ~~916,306~~ for the ~~fiscal year twelve-month period~~ ended September 30, ~~2023~~ **2024**. At September 30, ~~2023~~ **2024**, we had cash and cash equivalents of \$ ~~7,615,431~~, ~~800,095~~. 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** ~~Our opportunities to work with customers to develop drug and biologics will require substantial additional funding. Our customers may not be successful in their efforts~~ **Note M** to create **our consolidated financial statements, on October 31, 2024, we closed on a registered direct offering** pipeline of product candidates, to develop commercially successful products, or to develop commercially successful drug or biologic products. If our customers fail to successfully identify, finance and **received net proceeds** develop drug and / or biologic candidates incorporating our lineDNA platform, commercial opportunities in drugs **after deducting placement agent fees** and biologics may be limited. We do not plan to market any drug or biologic, except with respect to products in the **other estimated offering expenses payable by** veterinary health market, nor do we have any drug or biologic products approved for commercial sale and have not generated any revenue from drug or biologic product sales, or manufacturing. Identifying, developing, obtaining regulatory approval and commercializing drug and biologic product candidates and biologic production will require substantial funding on the part of our customers, and will also require us, to obtain substantial additional funding beyond our current available resources. Such endeavors are prone to the risks of failure inherent in drug **approximately \$ 5.8 million. As a result of this offering, or our consolidated cash balance** biologic development. Developing product candidates is expensive, and we expect to spend substantial amounts as we work with our customers to fund our early-stage research projects and work with our customers to advance program candidates through preclinical development and clinical trials. Investment in drug and biologic product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that our customers will be able to successfully advance any product candidates through the development process or, if approved, successfully commercialize any product candidates. Even if our customers receive regulatory approval to market product candidates incorporating our lineDNA platform technology, or if we receive regulatory approval to market any veterinary health products, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or be more effective than other commercially-available alternatives. Even if our customers are able to generate revenue from the sale of **November 30, 2024 was approximately \$ 10** we may not become profitable and may need to obtain additional funding to continue operations. **1 million** Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of lineDNA products and veterinary health product candidates or continue our operations, and cause a decline in the value of our common stock, all or any of which may adversely affect our viability. We may not successfully implement our business strategies, including achieving our growth objectives. We may not be able to fully implement our business strategies or realize, in whole or in part within the expected time frames, the anticipated benefits of our various growth or other initiatives. Our various business strategies and initiatives, including our growth, operational and management initiatives and the development in particular of our Therapeutic DNA Production Services, are subject to business, economic and competitive uncertainties and contingencies, many of which are beyond our control. The execution of our business strategy and our financial performance will continue to depend in significant part on our ability to obtain sufficient financing and on our executive management team and other key management personnel, our ability to identify and complete suitable acquisitions and, our executive management team’s ability to execute

new operational initiatives, **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. ~~20~~**We may modify and refine our business strategy, including a possible divestiture 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 divestiture 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 the existing stockholders. Furthermore, if we raise funds in 19 in equity transactions through the issuance of convertible securities which are convertible at the time of conversion at a discount to the prevailing market price, substantial dilution is likely to occur resulting in a material decline in the price of ~~your~~ **our shares common stock**. Our public offerings completed in November 2014, April 2015, December 2018, November 2019 and, August 2022 **and May 2024**, our registered direct offerings ~~during~~ **completed in December 2017**, January 2021 and February 2022, our registered direct public offering and concurrent private placement ~~during~~ **completed in November 2015, January 2024 and October 2024, and** our private placements completed in November 2016, June 2017, and August 2019, ~~and our registered direct offering in December 2017~~ resulted in dilution to investors and future offerings of securities could result in further dilution to investors. If we are unable to maintain and implement effective internal controls over financial reporting and disclosure, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected. As a public company, we are required to maintain internal control over financial reporting and our disclosure controls and to report any material weaknesses in such internal control and our disclosure controls. Section 404 of the Sarbanes- Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements and disclosure may be materially misstated. We have implemented various systems, processes and documentation necessary to comply with Section 404 of the Sarbanes- Oxley Act. We will need to maintain and enhance these processes and controls as we grow, and we will require additional management and staff resources to do so. Additionally, even if we conclude our internal controls or disclosure controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls or disclosure controls, in which case our management will be unable to conclude that our internal control over financial reporting or disclosure controls are effective. Even if our management concludes that our internal control over financial reporting and our disclosure controls are effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. In addition, if we lose our status as a "smaller reporting company," we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. If we are unable to conclude that our internal control over financial reporting or our disclosure controls are effective, ~~or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting~~ because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results. We expect that compliance with these requirements will continue to increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will continue to need to divert attention from operational and other business matters to devote substantial time to these public company requirements. We also expect that it will continue to be expensive for us to maintain director and officer liability insurance. If we fail to maintain an effective system of internal control over financial reporting or our disclosure, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting. This, in turn, could have an adverse impact on trading prices for our common stock. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting or disclosure that are deemed to be material weaknesses, the market price of our stock could decline, our ability to access the capital markets could be reduced and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources. ~~21~~**Our operating results could be adversely affected by a reduction in business with our significant customers. Our revenue earned from the sale of**

products and services for the fiscal year ended September 30, 2023 included an aggregate of 65 % and 14 % of our total revenue from two customers within our MDx Testing Services segment. 65 % and 58 % of the revenues earned for the fiscal years ended September 30, 2023 and 2022, respectively were derived from the COVID-19 testing contract with CUNY that terminated during June 2023. At September 30, 2023, three customers accounted for an aggregate of 60 % of our total accounts receivable. Our revenue earned from the sale of products and services for the fiscal year ended September 30, 2022 included an aggregate of 58 % of our total revenues from one customer within our MDx Testing Services segment. At September 30, 2022, two customers accounted for an aggregate of 89 % of our total accounts receivable. Generally, our customers do not have an obligation to make purchases from us and may stop ordering our products and services or may terminate existing orders or contracts at any time with little or no financial penalty. The loss of any of our significant customers, any substantial decline in sales to these customers, or any significant change in the timing or volume of purchases by our customers has resulted in and could result in lower revenues and could harm our business, financial condition or results of operations. Fluctuations in quarterly results may cause a decline in the price of our common stock. Our revenues and profitability are difficult to predict due to the nature of the markets in which we compete, as well as our recent entry into new markets and products, fluctuating user demand, the uncertainty of current and future global economic conditions, and for many other reasons, including that our operating results are highly dependent on the volume and timing of orders received during a quarter, which are difficult to forecast. Customers generally order on an as-needed basis and we typically do not obtain firm, long-term purchase commitments from our customers. The quarterly fluctuations in operating results described above may cause a decline in the price of our common stock. **The ongoing military conflicts between Russia and Ukraine and, Israel and Hamas has 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 and, 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 **conflict** **conflicts in** between Russia and 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 **diagnostics, veterinary and human therapeutics, diagnostics** and the product security sectors. These diversified operations and activities place significant demands on our limited resources and require us to substantially expand the capabilities of our technical, administrative, and operational resources. **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.** **21** 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 current emphasis 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** 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 -- **business disruption, negative publicity,** -- Our current emphasis on Therapeutic DNA Production Services may divert funding and **brand damage, violation** our limited managerial and other resources from our existing MDX Testing Services and DNA Tagging and Security Products and Services businesses. This may have the effect of **privacy laws,** reducing opportunities to grow or maintain revenues in our existing businesses while at the same time we may fail to achieve the revenues and growth we seek in our Therapeutic DNA Production Services. We have yet to achieve substantial revenues and have incurred losses -- **loss of** from our Therapeutic DNA Production Services. If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop our Therapeutic DNA Production Services without raising additional capital. If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop, commercialize and have our customers adopt our Therapeutic DNA Production Services, **potential liability** including the expansion of our CDMO operation for the manufacture of DNA for use in our nucleic acid-based therapies in veterinary health and **competitive disadvantage** the development of our customers' nucleic acid-based therapy candidates. In such event, and if we are unable to raise additional capital, we would have to scale back our Therapeutic DNA Production Services which would have a material adverse effect on our business, financial condition and results of operations. 23 Risks -- **Risks** Relating to Manufacturing, Development, and Industries: If we are unable to expand our DNA manufacturing capacity, we could lose revenue and our business could suffer. In order to expand our manufacturing capacity for our DNA production, including our **Linea Linea DNA DNA platform and GMP Site 1 and GMP Site 2,** we need to **either** build additional internal manufacturing capacity **that will require additional capital expenditures and additional financing**, **contract with one or more partners, or both.** Our technology and the production process for our DNA production are complex, involving specialized parts, and we may encounter unexpected difficulties in the manufacture, improvement or increasing the capacity of our DNA production, and addressing these difficulties may cause us to divert our time and resources from our other product offerings. There is no assurance that we will be able to continue to increase manufacturing capacity **internally or that we will find one or more suitable partners to help us towards this objective,** in order to meet the volume and quality requirements necessary for success in our existing and potential markets. Manufacturing and product quality issues may arise as we continue to increase the scale of our production. If our DNA manufacturing equipment and tools do not consistently produce DNA products that meet our customers' performance expectations, our reputation may be harmed, and we may be unable to generate sufficient revenue to become profitable. Any delay or inability in expanding our manufacturing capacity could diminish our ability to develop or sell our DNA products, which could result in lost revenue and materially harm our business, financial condition and results of operations. Rapidly changing technology and extensive competition in synthetic DNA could make the services or products we are developing obsolete or non-competitive unless we continue to develop and manufacture new and improved services or products and pursue new market opportunities. The synthetic DNA industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry demands and standards. Our future success will depend on our ability to continually improve the services we are developing and producing, to develop and introduce new services that address the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand, and the utility and value of new products and services developed by us may not be accepted in the markets served by the new services. Our inability to gain market acceptance of existing products and services in new markets or market acceptance of new products and services could harm our future operating results. Our future success also depends on our ability to manufacture these new and improved products and services to meet customer demand in a timely and cost-effective manner, including our ability to resolve manufacturing issues that may arise as we commence production of any new products and services we develop. In addition, there is extensive competition in the synthetic DNA industry, and our future success will depend on our ability to maintain a competitive position with respect to technological advances. Technological development by others may result in our technologies, as well as products developed using our technologies, becoming obsolete. Our ability to compete successfully will depend on our ability to develop proprietary technologies and services that are technologically superior to and / or are less expensive than our competitors' technologies and products. Our competitors may be able to develop competing and / or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time. Pharmaceutical and biologic products and services are highly complex, and if we or our collaborators and customers are unable to provide quality and timely offerings to our respective customers, our business could suffer. The process of manufacturing pharmaceutical and biologics and their components is complex, highly-regulated and subject to multiple risks. **Manufacturing 22 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. ~~24Our~~ **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. ~~25Some~~ **23Some** pharmaceutical manufacturers are also subject to extensive pre- and post- marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is being studied or marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with GMP requirements. If we are a registered facility and an FDA inspection of our facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations or a " Form FDA 483 ". If observations in the Form FDA 483 are not addressed in a timely manner and to the FDA' s satisfaction, the FDA may issue a Warning Letter or pursue other forms of enforcement action. Any failure by us or ~~another~~ **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.

**26H** If the FDA were to begin to enforce regulation of laboratory-developed tests ("LDTs"), we could incur substantial costs and delays associated with trying to obtain pre-market clearance or approval and costs associated with complying with post-market requirements. **Our** As laboratory-developed tests ("LDTs"), our MDx Testing Services **utilize LDTs developed and validated** are currently subject to enforcement discretion by the FDA **Company**. In addition, 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 September **April 29, 2023-2024**, however, the FDA published a proposed **final** rule on LDTs, in which **the** FDA **proposes outlines its plans** to end enforcement discretion for **many virtually all** LDTs in five stages over a four-year period **from the date FDA publishes a final rule**. In Phase 1 (effective **May 6, 2025** **one year post-finalization**), **labs would 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** **two years post-finalization**), **labs would clinical laboratories will** be required to comply with all other device requirements (e.g., registration / listing, labeling, investigational use), except for **quality systems the remaining QSR requirements** and premarket review. In Phase 3 (effective **May 6, 2027** **three years post-finalization**), **labs would clinical laboratories will** be required to comply with **quality systems all remaining applicable QSR** requirements. In Phase 4 (effective **November 6** **three and a half years post-finalization, but not before October 1, 2027**), **labs would 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** **four years post-finalization, but not before April 1, 2028**), **labs would 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).

**24** **Under** Unlike previous proposals, **the proposed rule does not "grandfather" existing tests. The content and timing of any final rule on, several types of tests will be eligible for some degree of continued enforcement discretion. For example, LDTs is 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 uncertain-- 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, **then in June 2021, Spring 2022, 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 **have allowed-- 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 **have limited experience producing and supplying our products. We may be unable to consistently manufacture or source our products to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels. As we continue to scale commercially and develop new products, and as our products incorporate increasingly sophisticated technology, it will become more difficult to ensure our products are produced in the necessary quantities while maintaining quality. There is no assurance that we or our third-party manufacturers will be able to continue to manufacture our products so that our technology**

consistently achieves the product specifications and produces results with acceptable quality. Any future design issues, unforeseen manufacturing problems, such as contamination of our or our manufacturers' facilities, equipment malfunctions, aging components, quality issues with components and materials sourced from third-party suppliers, or failures to strictly follow procedures or meet specifications, may have a material adverse effect on our brand, business, reputation, results of operations and financial condition and could result in us or our third-party manufacturers losing International Organization for Standardization (ISO) or quality management certifications. If our third-party manufacturers fail to maintain ISO quality management certifications, our customers might choose not to purchase products from us. In addition, as we scale our commercial operations, we will also need to make corresponding improvements to other operational functions, such as our customer support, service and billing systems, compliance programs and internal quality assurance programs. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As we develop additional products, we may need to bring new equipment online, implement new systems, technology, controls and procedures and hire personnel with different qualifications. ~~27~~An inability to manufacture products and components that consistently meet specifications, in necessary quantities, at commercially acceptable costs and without significant delays, may have a material adverse effect on our business, results of operations, financial condition and prospects. We must continue to secure and maintain sufficient and stable supplies of components and raw materials. Certain disruptions in supply of, and changes in the competitive environment for, components and raw materials integral to the manufacturing of our products may adversely affect our profitability. We use a broad range of materials and supplies in our products. A significant disruption in the supply of these materials could decrease production and shipping levels, materially increase our operating costs and materially and adversely affect our revenues and profit margins. Shortages of materials or interruptions in transportation systems, labor strikes, work stoppages, war, acts of terrorism or other interruptions to or difficulties in the employment of labor or transportation in the markets in which we purchase materials, components and supplies for the production of our products, in each case, may adversely affect our ability to maintain production of our products and achieve profitability. Unforeseen discontinuation or unavailability of certain components, such as enzymes (e. g., DNAP and RNAP), nucleotides, or synthetic DNA templates, which are available from multiple suppliers, but some of which we currently primarily source from a single supplier, could cause production delays as we modify our product specifications to accommodate replacement components. If we were to experience a significant or prolonged shortage of critical components from any of our suppliers and could not procure the components from other sources, we would be unable to manufacture our products and ship them to our customers in a timely fashion, or at all, which would adversely affect our sales, margins and customer relations. The markets for the synthetic DNA produced via our Therapeutic DNA Production Services are very competitive, and we may be unable to continue to compete effectively in these industries in the future. The principal markets for synthetic DNA are intensely competitive. We compete with many existing suppliers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing products that are more effective than the product candidates that we have or may develop and may be more successful than us in producing and marketing their existing products. Some of our competitors that operate in the nucleic-acid based therapeutic, biologics and DNA manufacturing markets include **, 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-25Co~~, 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. ~~28~~The **The** markets for our supply chain security and product authentication solutions are very competitive, and we may be unable ~~to continue~~ to compete effectively in these industries in the future. The principal markets for our supply chain security and product authentication offerings are intensely competitive. We compete with many existing suppliers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing products that are more effective than the products that we have or may develop and may be more successful than us in producing and marketing their existing products. Some of our competitors that operate in the supply chain security and product authentication markets include: Digimarc Corporation, Haelixa Ltd., ICA Bremen GmbH, IEH Corporation, Orbitain Global Limited, SafeTraces, Inc., DeterTech (acquired SmartWater Technology, Inc.), Sun Chemical Corporation, TraceTag International Ltd., TruTag Technologies, Inc., and Tailorlux gmbH. We expect this competition to continue and intensify in the future. The market for our MDx Testing Services is very competitive, and we may be unable ~~to continue~~ to compete effectively in this industry in the

future. The principal market for molecular diagnostics testing services is intensely competitive. We compete with many existing testing service providers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing testing services that are more effective than the testing services that we have or may develop and may be more successful than us in producing and marketing their existing testing services. Some of our competitors that operate in the molecular diagnostics testing markets include: 23andMe, Inc., Laboratory Corporation of America (LabCorp); Quest Diagnostics Inc., Myriad Genetics, Inc., ARUP Laboratories, Sonic Healthcare USA, 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~~ **26** 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; ~~29~~ • larger and more established distribution networks; • additional product and service lines and the ability to bundle products and services to offer higher discounts or other incentives to gain a competitive advantage; • more experience in conducting research and development, manufacturing and marketing; • more experience in entering into collaborations or other strategic partnership arrangements; and • more financial, manufacturing and human resources to support product development, sales and marketing and patent and other intellectual property litigation. These factors, among others, may enable our competitors to market their products and services at lower prices or on terms more advantageous to customers than we can offer. Competition may result in price reductions, reduced gross margins and loss of market share, any of which could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. Additionally, our current and future competitors, including certain of our customers, may at any time develop additional products and services that compete with our products and new approaches by these competitors may make our products, technologies and methodologies obsolete or noncompetitive. We may not be able to compete effectively against these organizations. In addition, to develop and market our new products, services, technologies and methodologies successfully, we must accurately assess and meet customers' needs, make significant capital expenditures, optimize our development and manufacturing processes to predict and control costs, hire, train and retain the necessary personnel, increase customer awareness and acceptance of such services, provide high quality services in a timely manner, price our products and services competitively and effectively integrate customer feedback into our business planning. If we fail to create demand for our new products, services or technologies, our future business could be harmed. ~~The animal health industry is highly competitive. The animal health industry is highly competitive. Our competitors include standalone animal health businesses, the animal health businesses of large pharmaceutical companies, specialty animal health businesses and companies that mainly produce generic products. We believe many of our competitors are conducting R & D activities in areas in which we are developing products. Several new start-up companies also compete in the animal health industry. These competitors may have access to greater financial, marketing, technical and other resources. As a result, they may be able to devote more resources to developing, manufacturing, marketing and selling their products, initiating or withstanding substantial price competition or more readily taking advantage of acquisitions or other opportunities. Further, consolidation in the animal health industry could result in existing competitors realizing additional efficiencies or improving portfolio bundling opportunities, thereby potentially increasing their market share and pricing power, which could lead to an increase in competition. In addition to competition from established market participants, new entrants to the animal health medicines and vaccines industry could substantially reduce our market share, render our products obsolete or disrupt our business model. To the extent that any of our competitors are more successful with respect to any key competitive factor, our business, financial condition and results of operations could be materially adversely affected. Competitive pressure could arise from, among other things, more favorable safety and efficacy product profiles, limited demand growth or a significant number of additional competitive products being introduced into a particular market, price~~

reductions by competitors, the ability of competitors to capitalize on their economies of scale, the ability of competitors to produce or otherwise procure animal health products at lower costs than us and the ability of competitors to access more or newer technology than us. 30 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 27 In addition, research, development, and commercialization of our Therapeutic DNA Production Services and veterinary biologic products are inherently risky. We cannot give any assurance that any future customers and / or collaborators of our Therapeutic DNA Production Services will receive regulatory approval for their pharmaceutical and biotherapeutic product candidates. In addition, we cannot give any assurance that any of our synthetic DNA performance characteristics own veterinary biologic product candidates will meet or exceed DNA produced by our competitors receive regulatory approval, which is necessary before they can be commercialized.

Risks Related to Our Intellectual Property: Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand. Our patents, trademarks, trade secrets, copyrights and all of our other intellectual property rights are important assets for us. There are events that are outside of our control that pose a threat to our intellectual property rights as well as to our products and services. For example, effective intellectual property protection may not be available in every country in which our products and services are distributed. The efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights could harm our business or our ability to compete. Protecting our intellectual property rights is costly and time consuming. Any increase in the unauthorized use of our intellectual property could make it more expensive to do business and harm our operating results. Although we seek to obtain patent protection for our innovations, it is possible we may not be able to protect all or some of these innovations. Given the costs of obtaining patent protection, we may choose not to protect certain innovations that later turn out to be important. There is always the possibility that the scope of the protection gained from one of our issued patents will be insufficient or deemed invalid or unenforceable. We also seek to maintain certain intellectual property as trade secrets. The secrecy could be developed independently, compromised by third parties, or disclosed, intentionally or accidentally, by our employees which would cause us to lose the competitive advantage resulting from these trade secrets. Intellectual property litigation could harm our business, financial condition and results of operations. Litigation regarding patents and other intellectual property rights is extensive in the drug and biotechnology industry. In the event of an intellectual property dispute, we may be forced to litigate. This litigation could involve proceedings instituted by the U. S. Patent and Trademark Office or the International Trade Commission, as well as proceedings brought directly by affected third parties. Intellectual property litigation can be extremely expensive, and these expenses, as well as the consequences should we not prevail, could seriously harm our business. 31 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 28 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. **32A cybersecurity incident and other technology disruptions....., potential liability and competitive disadvantage.**

Risks Related to Regulatory Approval of Our Customer and Collaborator’s Pharmaceutical and Biotherapeutic Product Candidates and Other Legal Compliance Matters: Revenue from our Therapeutic DNA Production Services will be highly dependent on our collaborators’ and customers’ success in obtaining regulatory approval and commercializing their drug and / or biologic products. The DNA produced via our Therapeutic DNA Production Services may be incorporated into our customers’ products in the drug and / or biologic markets that are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. In the United States, to obtain approval from the FDA to market any future drug or biologic product that incorporates or utilizes our Therapeutic DNA Production Services, our collaborators or customers will be required to submit an NDA or BLA. The process of obtaining such regulatory approvals is expensive, often takes many years if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidate involved. Changes in the regulatory approval process during the development period, changes in or the enactment of additional statutes or regulations, or changes in the regulatory review process may cause delays in the approval or rejection of an application. There is no guarantee that our collaborators and customers will ever be successful in obtaining regulatory approval for any product that incorporates our products or technology. Even if regulatory approval is received, the manufacturing processes, post approval clinical data, labeling, advertising and promotional activities for any such product will be subject to continual requirements of and review by the FDA and other regulatory bodies. Our business may be materially harmed by our collaborators’ and customers’ inability to obtain or maintain regulatory approvals for their products of their failure to comply with applicable regulations. In addition, we will be dependent on, and have no control over, consumer demand for the products into which our ~~Linea LineaDNA DNA~~ technology is incorporated. Consumer demand for our collaborators’ and customers’ products could be adversely affected by, among other things, delays in health regulatory approval, the loss of patent and other intellectual property rights protection, the emergence of competing products, including generic drugs or biosimilars, the degree to which private and government drug plans subsidize payment for a particular product and changes in the marketing strategies for such products. The healthcare industry has changed significantly over time, and we expect the industry to continue to evolve. Some of these changes may have a material adverse effect on our collaborators and customers and thus may have a material adverse effect on our business. If the products into which our ~~Linea LineaDNA DNA~~ is utilized or incorporated do not gain market acceptance, our revenues and profitability may be adversely affected. ~~33The 29The~~ regulatory approval processes of the FDA, ~~USDA~~ and comparable foreign regulatory authorities are lengthy, time consuming, and inherently unpredictable. If our customers are ultimately unable to obtain regulatory approval for products incorporating our Therapeutic DNA Production Services, we will be unable to generate **product meaningful** revenue and our business will be substantially harmed. The time required to obtain approval by the FDA, ~~USDA~~ and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application submitted by one of our customers ~~or by us with respect to the veterinary health market~~. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our customers’ data are insufficient for approval and require additional preclinical, clinical or other studies. We have not submitted for, or plan to obtain regulatory approval for any product candidate ~~(except with respect to the veterinary health market)~~, and it is possible that none of our, or our customers’ existing product candidates or any product candidates that we or our customers may seek to develop in the future that incorporate or utilize our Therapeutic DNA Production Services will ever obtain regulatory approval. Applications for our customers’ product candidates could fail to receive regulatory approval for a variety of reasons. This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in failing to obtain regulatory approval to market any of such product candidates, which would significantly harm our business, results of operations, and prospects. Even if our customers obtain regulatory approval for a product candidate, our Therapeutic DNA Production Services will remain subject to extensive regulatory scrutiny. If any of our customers’ product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Ongoing regulatory requirements include ensuring that quality control and manufacturing and production procedures conform to applicable cGMP regulations, and we will be subject to potential continual review and inspections to assess compliance with applicable cGMP regulations and adherence to commitments made in any regulatory filings. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance. Any regulatory approvals that our customers receive for their products that incorporate our- 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 In addition, veterinary DNA vaccines and therapeutics in the United States are subject to review and regulatory approval by the USDA. The USDA’s Center for Veterinary Biologies is responsible for the regulation of animal health vaccines, including certain immunotherapeutics. All manufacturers of animal health biologics must show their products to be pure, safe, effective and produced by a consistent method of manufacture as defined under the Virus Serum Toxin Act. Post- approval monitoring of products is required. Reports of product quality defects, adverse events or unexpected results are submitted in accordance with the agency requirements. 34If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product, our customer or us, including, but not limited to, requiring withdrawal or recall of the product from the market, imposing civil or criminal penalties, and imposing restrictions on our or our customers’ ability to continue to manufacture the product (s). Any government investigation of alleged violations of law could require our customers or us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our customers’ ability to commercialize and generate revenue from our customers’ products and demand for our synthetic DNA for their products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected related to the demand for those customers’ products or our products in the case of the veterinary health market. In 30In 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. ~~35~~ 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~~ ~~31~~ ~~outside~~ the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

**Risks Related to Personnel:** Our failure to manage our growth in operations and acquisitions of new product lines and new businesses could harm our business. The forecasted change in our strategic focus could place a significant strain on our current management resources. We have a limited number of personnel and expect to continue to have a limited number of personnel for the foreseeable future. To manage such growth, we may need to improve our: • operations and financial systems; • procedures and controls; and • training and management of our employees. If we are unable to continue to retain the services of Dr. Hayward, we may not be able to continue our operations. Our success depends to a significant extent upon the continued service of Dr. James A. Hayward, our CEO. On July 28, 2016, we entered into an employment agreement with Dr. Hayward. The initial term was from July 1, 2016 through June 30, 2017, with automatic one-year renewal periods. As of June 30, ~~2023~~ ~~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~~ ~~Common~~ ~~stock~~ ~~Stock~~ underlying our outstanding options and warrants and the sale of these shares may depress the market price of our ~~common~~ ~~Common~~ ~~stock~~ ~~Stock~~ and cause immediate and substantial dilution to our existing stockholders. As of December 4 ~~13~~, ~~2023~~ ~~2024~~, we had ~~13~~ ~~52~~, ~~687~~ ~~294~~, ~~420~~ ~~359~~ shares of ~~common~~ ~~Common~~ ~~stock~~ ~~Stock~~ issued and outstanding, outstanding options to purchase ~~2~~ ~~108~~, ~~176~~ ~~191~~, ~~535~~ shares of ~~common~~ ~~Common~~ ~~stock~~ ~~Stock~~, outstanding warrants to purchase ~~5~~ ~~136~~, ~~220~~ ~~325~~, ~~588~~ ~~980~~ shares of ~~common~~ ~~Common~~ ~~stock~~ ~~Stock~~, ~~282~~, ~~640~~ unvested restricted stock units, and ~~1~~ ~~269~~, ~~069~~ ~~340~~, ~~948~~ shares available for grant under our 2005 and 2020 Equity Incentive Plans. The issuance of shares upon exercise of our outstanding options and warrants will cause immediate and substantial dilution to our stockholders and any sale thereof may depress the market price of our common stock. **We 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. 33In 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 warrant holders 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~~ Common stock-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~~ **Common stock 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~~ **Common stock Stock**. The Nasdaq Stock Market LLC ("Nasdaq") Listing Rule 5550 (a) (2) (the "Minimum Bid Price Requirement") requires that the Company's ~~common~~ **Common stock Stock** maintain a closing bid price for 30 consecutive business days of \$ 1.00 per share. On ~~December 1~~ **November 12, 2023-2024**, the Company received a letter (the "Notice") from Nasdaq notifying the Company that, because the closing bid price for its ~~common~~ **Common stock 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~~ **Common stock 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~~ **Common stock Stock** will continue to be listed and traded on **34** ~~The Nasdaq Capital Market. To regain compliance, the closing bid price of the Company's common stock must meet or exceed \$ 1.00 per share for a minimum of ten consecutive business days during the 180-day compliance period. The Company intends to actively monitor the bid price for its common stock and will consider available options, including effecting a reverse stock split, to regain compliance with the Minimum Bid Price Requirement. If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets but will lack the market efficiencies associated with Nasdaq. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than \$ 5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets. Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees and customers, the loss of institutional investor interest and fewer business development opportunities.~~ 37