Risk Factors Comparison 2023-12-07 to 2022-12-14 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. ●** We may require additional financing which may in turn require the issuance of additional shares of common stock, preferred stock or other debt or equity securities (including convertible securities) and which would dilute the ownership held by or stockholders. ● ~~We have identified a material weakness in our internal control over financial reporting. ●~~ Our operating results **have been and** could be adversely affected by a reduction in business with our significant customers. ● We may encounter difficulties in managing our growth and these difficulties could impair our profitability. ● Our ~~new~~ **current** emphasis on Therapeutic DNA Production Services may reduce our ability to maintain and expand our existing MDX Testing Services and DNA Tagging and Security Products and Services businesses. ● If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop, commercialize and have our customers adopt our Therapeutic DNA Production Services. ● If we are unable to expand our DNA manufacturing capacity, we could lose revenue and our business could suffer. ● Rapidly changing technology and extensive competition in synthetic biology could make the services or products we are developing obsolete or non- competitive unless we continue to develop new and improved services or products and pursue new market opportunities. ● Pharmaceutical and biologic products are highly complex, and if we or our collaborators and customers are unable to provide quality and timely offerings to our respective customers, our business could suffer. ● We will need to develop and maintain manufacturing facilities that meet ~~cGMP~~ **GMP** . ● Pharmaceutical and biologic- related revenue will be dependent on our collaborators' and customers' demand for our manufacturing services. ● Our safeCircleTM COVID- 19 testing service could become obsolete or its utility could be significantly diminished **, including in light of significantly decreasing demand for COVID- 19 testing services** . ● We may be unable to consistently manufacture or source our products to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels. ● The markets for drug and biologic candidates and synthetic DNA are very competitive, and we may be unable to continue to compete effectively in these industries in the future. ● The markets for our supply chain security and product authentication solutions are very competitive, and we may be unable to continue to compete effectively in these industries in the future. ● We compete with life science, pharmaceutical and biotechnology companies, some of whom are our customers, who are substantially larger than we are and potentially capable of developing new approaches that could make our products and technology obsolete or develop their own internal capabilities that compete with our products. ● Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand. ● Pharmaceutical and biologic- related revenue is generally dependent on regulatory approval, oversight and compliance. ● If the FDA were to begin to enforce regulation of LDTs, we could incur substantial costs and delays associated with trying to obtain pre- market clearance or approval and costs associated with complying with post- market requirements. ● If we fail to comply with laboratory licensing requirements, we could lose the ability to offer our clinical testing services or experience disruptions to our business. ● If we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected. ● If we are unable to continue to retain the services of Dr. Hayward, we may not be able to continue our operations. **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. ~~20~~ ● There are a large number of shares of common stock underlying our outstanding options and warrants and the sale of these shares may depress the market price of our common stock and cause immediate and substantial dilution to our existing stockholders. ● ~~If~~ **We have received written notice from Nasdaq that** we ~~fail to comply~~ **are not in compliance** with **Nasdaq' s minimum bid requirements and if we are unable to regain compliance with** the **Nasdaq** continued listing standards ~~of Nasdaq~~ , **which may require effecting a reverse stock split of** our ~~securities~~ **common stock, we** could be delisted **from The Nasdaq Stock Market** , which ~~could~~ **would** ~~limit investors' negatively impact our business, our~~ ability to **raise capital, and the** ~~make~~ **market** ~~transactions in~~ **price and liquidity of** our common stock ~~and subject us to additional trading restrictions~~ . ● In addition to the above key factors, as well as other variables affecting our operating results and financial condition, past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. The following are important factors that could cause actual results or events to differ materially from those contained in any forward- looking statements made by us or on our behalf. The risks and uncertainties described below are not the only ones we face. In addition to the factors discussed elsewhere in this report and our other reports and documents filed with the SEC, risks and uncertainties not presently known to us or that we may currently deem immaterial also may impair our business, financial condition, operating results and / or stock price. If any of the following risks or such other risks actually occurs, our business, financial condition, operating results and / or stock price could be harmed. In the following factors, " volatility in our share price ", " adverse impact on the price (or value) of our shares ", " decline in the price of our common stock " and similar terms also refer to our warrants

and shares to be received upon exercise of our warrants. Risks Relating to Our Business: We have produced only limited revenues. This makes it difficult to evaluate our future prospects and increases the risk that we will not be successful. Our operations since inception have produced limited revenues and may not produce significant revenues in the near term, or at all, which may harm our ability to obtain additional financing and may require us to reduce or discontinue our operations. **While our revenues increased from $ 1. 9 million in fiscal 2020 to $ 18. 2 million in fiscal 2022, primarily as a result of our COVID- 19 testing revenues, in fiscal 2023 our revenues declined to $ 13. 4 million and are expected to decline further in fiscal 2024.** You must consider our business and prospects in light of the risks and difficulties we will encounter as a company operating in a rapidly evolving industry. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results, and financial condition. **There is substantial doubt relating to our ability to continue as a going concern. We have recurring net losses, which have resulted in an accumulated deficit of $ 302, 447, 147 as of September 30, 2023. We have incurred a net loss of $ 10, 022, 916 for the twelve- month period ended September 30, 2023. At September 30, 2023, we had cash and cash equivalents of $ 7, 151, 800. We have concluded that these factors raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the financial statements. We will continue to seek to raise additional working capital through public equity, private equity or debt financings. If we fail to raise additional working capital, or do so on commercially unfavorable terms, it would materially and adversely affect our business, prospects, financial condition and results of operations, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.** ~~Our~~ **19Our** opportunities to work with customers to develop ~~pharmaceuticals~~ **drug** and biologics will require substantial additional funding. Our customers may not be successful in their efforts to create a pipeline of product candidates, to develop commercially successful products, or to develop commercially successful **drug or** biologic ~~production~~ **products** . If our customers fail to successfully identify, finance and develop ~~product~~ **drug and / or biologic** candidates ~~and / or fail to develop commercially successful biologic production~~ incorporating our ~~linearDNA~~ **lineaDNA** platform, commercial opportunities in ~~pharmaceuticals~~ **drugs** and biologics may be limited. We do not plan to market **any drug or biologic** , except with respect to products in the veterinary health market, nor do we have any ~~pharmaceutical~~ **drug** or biologic products approved for commercial sale and have not generated any revenue from ~~pharmaceutical~~ **drug** or biologic product sales, or manufacturing. Identifying, developing, obtaining regulatory approval and commercializing ~~pharmaceutical~~ **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** ~~, will require substantial funding on the part of our customers, and is~~ prone to the risks of failure inherent in drug or biologic development. Developing product candidates ~~and biologic production~~ is expensive, and we expect to spend substantial amounts as we work with our customers to fund our early- stage research projects ~~, engage in preclinical development of early- stage programs~~ and ~~, in particular,~~ work with our customers to advance program candidates through preclinical development and clinical trials. Investment in ~~pharmaceutical~~ **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 ~~linearDNA~~ **lineaDNA** platform technology, or if we receive regulatory approval to market any veterinary health products, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or be more effective than other commercially- available alternatives. ~~21Even~~ **Even** if our customers are able to generate revenue from the sale of any approved ~~pharmaceutical~~ **drug** and biologic products or we are able to generate revenue from the sale of any veterinary health products, we may not become profitable and may need to obtain additional funding to continue operations. Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of ~~linearDNA~~ **lineaDNA** products and veterinary health product candidates or continue our operations, and cause a decline in the value of our common stock, all or any of which may adversely affect our viability. We **may not successfully implement our business strategies, including achieving our growth objectives. We may not be able to fully implement our business strategies or realize, in whole or in part within the expected time frames, the anticipated benefits of our various growth or other initiatives. Our various business strategies and initiatives, including our growth, operational and management initiatives and the development in particular of our Therapeutic DNA Production Services, are subject to business, economic and competitive uncertainties and contingencies, many of which are beyond our control. The execution of our business strategy and our financial performance will continue to depend in significant part our ability to obtain sufficient financing and on our executive management team and other key management personnel, our ability to identify and complete suitable acquisitions and our executive management team' s ability to execute new operational initiatives. In addition, we may incur certain costs as we pursue our growth, operational and management initiatives, and we may not meet anticipated implementation timetables or stay within budgeted costs. As these initiatives are undertaken, we may not fully achieve our expected efficiency improvements or growth rates, or these initiatives could adversely impact our customer retention, supplier relationships or operations. Also, our business strategies may change from time to time in light of our ability to implement our business initiatives, competitive pressures, economic uncertainties or developments, or other factors. 20We** may require additional financing which may in turn require the issuance of additional shares of common stock, preferred stock or other debt or equity securities (including convertible securities) and which would dilute the ownership held by our stockholders. We may need to raise funds through either debt or

the sale of our shares of our common stock in order to achieve our business goals. Any additional shares issued would further dilute the percentage ownership held by the stockholders. Furthermore, if we raise funds in equity transactions through the issuance of convertible securities which are convertible at the time of conversion at a discount to the prevailing market price, substantial dilution is likely to occur resulting in a material decline in the price of your shares. Our public offerings completed in November 2014, April 2015, December 2018, November 2019 and August 2022, our registered direct offerings during January 2021 and February 2022, our registered direct public offering and concurrent private placement during November 2015, our private placements completed in November 2016, June 2017, and August 2019, and our registered direct offering in December 2017 resulted in dilution to investors and future offerings of securities could result in further dilution to investors. If we are unable to maintain and implement effective internal controls over financial reporting and disclosure, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected. As a public company, we are required to maintain internal control over financial reporting and our disclosure controls and to report any material weaknesses in such internal control and our disclosure controls. Section 404 of the Sarbanes- Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements and disclosure may be materially misstated. We have implemented various systems, processes and documentation necessary to comply with Section 404 of the Sarbanes- Oxley Act. We will need to maintain and enhance these processes and controls as we grow, and we will require additional management and staff resources to do so. Additionally, even if we conclude our internal controls or disclosure controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls or disclosure controls, in which case our management will be unable to conclude that our internal control over financial reporting or disclosure controls are effective. ~~Please see the following risk factor " We have identified a material weakness in our internal control over financial reporting. "~~ Even if our management concludes that our internal control over financial reporting and our disclosure controls are effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. In addition, if we lose our status as a " smaller reporting company, " we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting. If we are unable to conclude that our internal control over financial reporting or our disclosure controls are effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results. We expect that compliance with these requirements will continue to increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will continue to need to divert attention from operational and other business matters to devote substantial time to these public company requirements. We also expect that it will continue to be expensive for us to maintain director and officer liability insurance. If we fail to maintain an effective system of internal control over financial reporting or our disclosure, we may not be able to accurately report our financial results, and current and potential stockholders may lose confidence in our financial reporting. This, in turn, could have an adverse impact on trading prices for our common stock. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting or disclosure that are deemed to be material weaknesses, the market price of ~~22our~~ -- **our** stock could decline, our ability to access the capital markets could be reduced and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources. ~~We have identified a material weakness in our internal control over financial reporting. In connection with the audit of our consolidated financial statements for the fiscal years ended September 30, 2022 and 2021, we identified a material weakness in our internal control over financial reporting (see Item 9A of this report for further information). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness in our case related to the controls around accounting for complex financial instruments, as it relates to the accounting for our outstanding warrants and the related tax impact. If we are unable to remedy this or a similar material weakness that may arise in the future, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price. Furthermore, future deficiencies could result in future non- compliance with Section 404 of the Sarbanes- Oxley Act of 2002. Such non-compliance could subject us to a variety of administrative sanctions, including review by the SEC or other regulatory authorities.~~ ~~Our~~ **21Our** operating results could be adversely affected by a reduction in business with our significant customers. Our revenue earned from the sale of ~~product~~ **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 ~~revenue~~ **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. ~~Our revenue earned from the sale of products and services for the fiscal year ended September 30, 2021~~

~~included an aggregate of 31 % of our total revenues from two customers within our MDx Testing Services segment. At September 30, 2021, two customers accounted for an aggregate of 67 % of our total accounts receivable.~~ Generally, our customers do not have an obligation to make purchases from us and may stop ordering our products and services or may terminate existing orders or contracts at any time with little or no financial penalty. The loss of any of our significant customers, any substantial decline in sales to these customers, or any significant change in the timing or volume of purchases by our customers **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 ~~conflict~~ **conflicts** between Russia and Ukraine **and Israel and Hamas** has caused geopolitical instability, economic uncertainty, financial markets volatility and capital markets disruption. Our business, financial condition and results of operations may be materially adversely affected by any negative impact on the capital markets resulting from the ~~conflict~~ **conflicts** in Ukraine **and the Middle East** or any other geopolitical tensions. In late February 2022, Russia invaded Ukraine, significantly amplifying already existing geopolitical tensions among Russia and other countries in the region and in the west, including the United States. Russia' s invasion, the responses of countries and political bodies to Russia' s actions, the larger overarching tensions, and Ukraine' s military response and the potential for wider conflict have resulted in inflation, financial market volatility and capital markets disruption, potentially increasing in magnitude, and could have severe adverse effects on regional and global economic markets and international relations. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. **Further, on October 7, 2023, Hamas, a U. S. designated Foreign Terrorist Organization, launched terrorist attacks against Israel. Israel then declared war on Hamas and there is currently an armed conflict in Israel and the Gaza Strip. The extent and duration of the wars in Ukraine and Israel / Gaza and expanding geopolitical tensions and any resulting market disruptions could be significant and could potentially have a substantial impact on the global economy, market volatility and our business for an unknown period of time. Any of the above- mentioned factors could materially adversely affect our business, financial condition, and results of operations.** Third parties may use our products in ways that could damage our reputation. After our customers have received our products, we do not have any control over their use and our customers may use them in ways that are harmful to our reputation as a supplier of synthetic DNA products. In addition, while we plan to establish a biosecurity program ~~23designed --~~ **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~~ **22Our** business could be adversely impacted by inflation. Increases in inflation may have an adverse effect on our business. Current and future inflationary effects may be driven by, among other things, supply chain disruptions and governmental stimulus or fiscal policies as well as the ongoing military conflict between Russia and Ukraine. Continuing increases in inflation could impact the overall demand for our products, our costs for labor, material and services, and the margins we are able to realize on our products, all of which could have an adverse impact on our business, financial position, results of operations and cash flows. We may encounter difficulties in managing our growth, and these difficulties could impair our profitability. Currently, we are working simultaneously on multiple projects, expanding our DNA manufacturing capacity as well as targeting several market sectors, including activities in the diagnostics, veterinary and human therapeutics, and the product security sectors. These diversified operations and activities place significant demands on our limited resources and require us to substantially expand the capabilities of our technical, administrative, and operational resources. If we are unable to manage this growth effectively, our shipments to our customers could be impacted, our time and resources could be diverted from other products and offerings and our business and operating results could suffer. Our ability to manage our operations and costs, including research and development, costs of components, manufacturing, sales and marketing, requires us to continue to enhance our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. Failure to attract and retain sufficient numbers of talented employees will further strain our human resources and could impede our growth. Our ~~new~~ **current** emphasis on Therapeutic DNA Production Services may reduce our ability to maintain and expand our existing MDx Testing Services and DNA Tagging and Security Products and Services businesses. Our ~~new~~ **current** emphasis on Therapeutic DNA Production Services may divert funding and our limited managerial and other resources from our existing MDX Testing Services and DNA Tagging and Security Products and Services businesses. This may have the effect of reducing opportunities to grow or maintain revenues in our existing businesses while at the same time we may fail to achieve the revenues and growth we seek in our Therapeutic DNA Production Services. We have yet to achieve substantial revenues and have incurred losses from our Therapeutic DNA Production Services. If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop our Therapeutic DNA Production Services **without raising additional capital** . If in the future our MDX Testing Services and DNA Tagging and Security Products and Services businesses do not generate significant cash flows, we may not have sufficient capital to develop, commercialize and have our customers adopt our Therapeutic DNA Production Services, including the expansion of our CDMO operation for the manufacture of DNA for use in our nucleic acid- based therapies in veterinary health and the development of our customers' nucleic acid- based therapy candidates. In such event, and if we are unable to raise additional capital, we would have to scale back our Therapeutic DNA Production Services which would have a material adverse effect on our business,

financial condition and results of operations. ~~Risks~~ **23Risks** Relating to Manufacturing, Development, and Industries: If we are unable to expand our DNA manufacturing capacity, we could lose revenue and our business could suffer. In order to expand our manufacturing capacity for our DNA production, including our ~~linearDNA~~ **Linea DNA** platform, we need to either build additional internal manufacturing capacity, contract with one or more partners, or both. Our technology and the production process for our DNA production are complex, involving specialized parts, and we may encounter unexpected difficulties in the manufacture, improvement or increasing the capacity of our DNA production, and addressing these difficulties may cause us to divert our time and resources from our other product offerings. There is no assurance that we will be able to continue to increase manufacturing capacity ~~24internally~~ -- **internally** or that we will find one or more suitable partners to help us towards this objective, in order to meet the volume and quality requirements necessary for success in our existing and potential markets. Manufacturing and product quality issues may arise as we continue to increase the scale of our production. If our DNA manufacturing equipment and tools do not consistently produce DNA products that meet our customers' performance expectations, our reputation may be harmed, and we may be unable to generate sufficient revenue to become profitable. Any delay or inability in expanding our manufacturing capacity could diminish our ability to develop or sell our DNA products, which could result in lost revenue and materially harm our business, financial condition and results of operations. Rapidly changing technology and extensive competition in synthetic DNA could make the services or products we are developing obsolete or non- competitive unless we continue to develop and manufacture new and improved services or products and pursue new market opportunities. The synthetic DNA industry is characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry demands and standards. Our future success will depend on our ability to continually improve the services we are developing and producing, to develop and introduce new services that address the evolving needs of our customers on a timely and cost- effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand, and the utility and value of new products and services developed by us may not be accepted in the markets served by the new services. Our inability to gain market acceptance of existing products and services in new markets or market acceptance of new products and services could harm our future operating results. Our future success also depends on our ability to manufacture these new and improved products and services to meet customer demand in a timely and cost- effective manner, including our ability to resolve manufacturing issues that may arise as we commence production of any new products and services we develop. In addition, there is extensive competition in the synthetic DNA industry, and our future success will depend on our ability to maintain a competitive position with respect to technological advances. Technological development by others may result in our technologies, as well as products developed using our technologies, becoming obsolete. Our ability to compete successfully will depend on our ability to develop proprietary technologies and services that are technologically superior to and / or are less expensive than our competitors' technologies and products. Our competitors may be able to develop competing and / or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time. Pharmaceutical and biologic products and services are highly complex, and if we or our collaborators and customers are unable to provide quality and timely offerings to our respective customers, our business could suffer. The process of manufacturing pharmaceutical and biologics and their components is complex, highly- regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. ~~Our~~ **24Our** 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 ~~25suffieient~~ -- **sufficient** supply of product candidate (s) or we may be delayed in doing so. Such failure or substantial delay could materially harm our business. Our customers will rely on us for synthetic DNA and other biological materials that are used in their discovery and development programs. These materials can be difficult to produce and occasionally have variability from the product specifications. Any disruption in the supply of these biological materials consistent with our product specifications could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. We may also have lower yields in manufacturing batches, which can increase our costs and slow our development timelines. Improper storage of these materials, by us or any third- party storage facilities, may require us to destroy some of our biological raw materials or product candidates. We also face risks that we may fail to synthesize and manufacture our customers' product candidates in accordance with their product specifications, and the possibility of termination or nonrenewal of the agreement by our customers at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our products be manufactured according to ~~eGMP~~ - **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. ~~Pharmaceutical manufacturers are~~ **Depending on the type and intended use of the synthetic DNA produced by the Company we may be** required to register ~~their~~ **our** facilities and list ~~their~~ **our** products manufactured after beginning ~~drug~~ manufacturing and then annually thereafter with the FDA and certain state and foreign agencies. If the FDA or a comparable foreign regulatory authority does not approve our customers' product candidates at any of our proposed contract manufacturer' s facilities, or if we fail to maintain a compliance status acceptable to the FDA or a comparable foreign authority, our customers may need to find alternative manufacturing facilities, which would significantly impact our ability to supply our customers' product candidates, if approved. Any discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners, may result in restrictions on the product or on the manufacturing or laboratory facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of such incidents. If we were unable to provide a solution in time, our customers' clinical trials could be delayed, thereby limiting our commercial activities associated with those products. The sale of our customers' products could contain other defects could adversely affect our business, financial condition, and results of operations. Any failure by us or another third- party manufacturers to comply with **applicable** ~~cGMP~~ **GMP regulations** or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of ~~product candidates~~ **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** ~~Pharmaceutical~~ **pharmaceutical** manufacturers are also subject to extensive pre- and post- marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where the product is being studied or marketed, which include periodic unannounced and announced inspections by the FDA to assess compliance with ~~cGMP~~ **GMP** requirements. If **we are a registered facility and** an FDA inspection of our facilities reveals conditions that the FDA determines not to comply with applicable regulatory requirements, the FDA may issue observations through a Notice of Inspectional Observations or a " Form FDA 483 ". If observations in the Form FDA 483 are not addressed in a timely manner and to the FDA' s satisfaction, the FDA may issue a Warning Letter or pursue other forms of enforcement action. Any failure by us or another contract manufacturers to comply with ~~cGMP~~ **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 ~~pharmaceutical~~ **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 ~~cGMP~~ **GMP** regulations, the FDA may deny NDA or BLA approval until the deficiencies are corrected. ~~26Even~~ **Even** if our collaborators or customers obtain regulatory approval for any of their product candidates, there is no assurance that they will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our collaborators or customers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Pharmaceutical and biologic- related revenue will be dependent on our collaborators' and customers' demand for our manufacturing services. The amount of customer spending on pharmaceutical and biologic development and manufacturing will have an impact on our sales and profitability in the pharmaceutical and biologic market. Our collaborators and customers determine the amounts that they will spend based upon, among other things, available resources, access to capital, and their need to develop new products, which, in turn, are dependent upon a number of factors, including their competitors' research, development and product initiatives and the anticipated market uptake, and clinical and reimbursement scenarios for specific products and therapeutic areas. Consolidation in the pharmaceutical and biologic industry may impact such spending as customers integrate acquired operations, including research and development (" R & D ") departments and manufacturing operations. Any reduction in spending on pharmaceutical and biotechnology development and related services as a result of these and other factors could have a material adverse effect on our business, results of operations and financial condition. ~~Our safeCircleTM COVID 19 testing service~~ **26If the FDA were to begin to enforce regulation of laboratory developed tests (" LDTs "), we** could ~~become obsolete~~ **incur substantial costs and delays associated with trying to obtain pre- market clearance or approval and costs associated with complying with post- market requirements. As laboratory- developed tests (" LDTs "), ~~or~~ our MDx ~~its utility could be significantly diminished. Surveillance testing~~ Testing ~~is not generally regulated~~ Services are currently subject to enforcement discretion** by the FDA ~~and CMS has stated that CLIA certification is not required to conduct surveillance testing for non- patient- specific tests~~. **In addition,** ADCL is ~~offering~~ **currently subject to NYSDOH oversight as a CLEP- permitted and CLIA- certified laboratory. On September 29, 2023, however, the FDA published a proposed rule on LDTs, in which FDA proposes to end enforcement discretion for virtually all LDTs in five stages over a four- year period from the date FDA publishes a final rule. In Phase 1 (effective one year post- finalization), labs would be required to comply with medical device (adverse event) reporting and correction / removal reporting requirements. In Phase 2 (effective two years post-**

finalization), labs would be required to comply with all other device requirements (e. g., registration / listing, labeling, investigational use), except for quality systems and premarket review. In Phase 3 (effective three years post-finalization), labs would be required to comply with quality systems requirements. In Phase 4 (effective three and a half years post- finalization, but not before October 1, 2027), labs would be required to comply with premarket review requirements for high- risk tests (i. e., tests subject to premarket approval (PMA) requirement). Finally, in Phase 5 (effective four years post- finalization, but not before April 1, 2028), labs would be required to comply with premarket review requirements for moderate- and low- risk tests (i. e., tests subject to de novo or 510 (k) requirement). Unlike previous proposals, the proposed rule does not " grandfather " existing tests. The content and timing of any final rule on LDTs is uncertain at this time. Congress is also working on legislative language that would clarify FDA' s authority with respect to LDTs. In this regard, most recently, the " Verifying Accurate Leading- edge IVCT Development Act, " or VALID Act, was introduced in March 2020, then in June 2021, Spring 2022, and March 2023. The bill proposes a risk-based approach that would subject many LDTs to FDA regulation by creating a new in vitro clinical test, or IVCT, category of regulated products. As proposed, the bill would grandfather many existing LDTs from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would require such tests to comply with other regulatory requirements (e. g., registration and listing, adverse event reporting). To market a high- risk IVCT, reasonable assurance of analytical and clinical validity for the intended use would be needed to be established. Under VALID, a precertification process would be established that would have allowed a laboratory to establish that the facilities, methods, and controls used in the development of its ~~safeCircleTM surveillance testing in compliance with current CDC~~ **IVCTs meet quality system requirements. If pre- certified** , ~~FDA~~ **low- risk IVCTs** , ~~CMS and NYSDOH recommendations~~ **developed by the laboratory would not be subject to pre- market review** . The **new** regulatory framework ~~or recommendations regarding COVID~~ **would include quality control and post** - ~~19 Surveillance Testing~~ **market reporting requirements. The FDA** ~~could~~ **would** ~~change at~~ **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 ~~time. In addition, our pooled COVID- 19 screening testing is conducted via a NYSDOH conditionally approved LDT. In the~~ **other bill)** ~~event that NYSDOH revokes the conditional approval or declines to fully approve the LDT, ADCL~~ will be **enacted in its** ~~required to utilize a third- party EUA- authorized COVID- 19 assay and potentially stop utilizing pooled testing. Further, our COVID- 19 testing may become obsolete for a variety of reasons, including an end to the~~ current **(or any** ~~pandemic, mutations in the~~ **other)** ~~genome of the SARS- CoV- 2 virus, or the development and widespread distribution of a vaccine, including the vaccines developed by Pfizer- BioNTech, Moderna, and Johnson & Johnson for~~ **form** ~~which~~ **and cannot quantify** the **effect of such proposals on** ~~FDA has granted emergency use authorization or~~ **our business** ~~approval. In addition, the utility of these services will also diminish if positivity rates reach levels high enough to render surveillance testing ineffective or inefficient~~ . We have limited experience producing and supplying our products. We may be unable to consistently manufacture or source our products to the necessary specifications or in quantities necessary to meet demand on a timely basis and at acceptable performance and cost levels. As we continue to scale commercially and develop new products, and as our products incorporate increasingly sophisticated technology, it will become more difficult to ensure our products are produced in the necessary quantities while maintaining quality. There is no assurance that we or our third- party manufacturers will be able to continue to manufacture our products so that our technology consistently achieves the product specifications and produces results with acceptable quality. Any future design issues, unforeseen manufacturing problems, such as contamination of our or our manufacturers' facilities, equipment malfunctions, aging components, quality issues with components and materials sourced from third- party suppliers, or failures to strictly follow procedures or meet specifications, may have a material adverse effect on our brand, business, reputation, results of operations and financial condition and could result in us or our third- party manufacturers losing International Organization for Standardization (ISO) or quality management certifications. If our third- party manufacturers fail to maintain ISO quality management certifications, our customers might choose not to purchase products from us. In addition, as we scale our commercial operations, we will also need to make corresponding improvements to other operational functions, such as our customer support, service and billing systems, compliance programs and internal quality assurance programs. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that ~~27appropriate~~ -- **appropriate** personnel will be available. As we develop additional products, we may need to bring new equipment online, implement new systems, technology, controls and procedures and hire personnel with different qualifications. ~~An~~ **27An** 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**) ~~or~~ **,** nucleotides, ~~each~~ **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** ~~our drug and biologic candidates and~~ 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 ~~our drug and biologic candidates and~~ synthetic DNA are intensely competitive. We compete with many existing suppliers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing products that are more effective than the product candidates that we have or may develop and may be more successful than us in producing and marketing their existing products. Some of our competitors that operate in the nucleic- acid based therapeutic, biologics and DNA manufacturing markets include: Precigen, Inc., Aldevron, LLC, Cobra Biologics, Limited, Integrated DNA Technologies, Inc., 4basebio PLC, Ziopharm Oncology, Inc., MaxCyte, Inc., Touchlight Genetics Ltd., Generation Bio, Co., Novartis AG, Kite Pharma, Inc., Juno Therapeutics, Inc., Promega Corporation, OriGene Technologies, Inc., Blue Heron Biotech, LLC, Gene Art, GenScript Biotech Corporation, and others. We expect this competition to continue and intensify in the future. Our competitors also compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize **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 ~~drug and biologic candidates and linearDNA~~ - **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 ~~potential drug and biologic candidates and linearDNA~~ - **LineaDNA** uneconomical or obsolete, and we may not be successful in marketing any drug and biologic candidates and ~~linearDNA~~ - **LineaDNA** we may develop against competitors. If any of these risks occur, our business, financial condition and results of operations could be significantly harmed. ~~The~~ **28The** 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 ~~28elsewhere~~ -- **elsewhere** , are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing products that are more effective than the products that we have or may develop and may be more successful than us in producing and marketing their existing products. Some of our competitors that operate in the supply chain security and product authentication markets include: ~~AlpVision Sa, Authentix, Inc., Brandwatch Technologies, Inc., Chromologic LLC, Collectors Universe, Inc., DataDot Technology Limited, De La Rue Plc.,~~ Digimarc Corporation ~~, DNA Technologies, Inc.~~, Haelixa Ltd., ICA Bremen GmbH, IEH Corporation, ~~Informium AG, opSec Security Group plc., MicroTag Temed Ltd., Nanotech Security Corp., Nokomis, Inc.,~~ Oritain Global Limited, SafeTraces, Inc., **DeterTech (acquired** ~~Selectamark Security Systems plc,~~ SmartWater Technology, Inc. **)** , Sun Chemical Corporation, TraceTag International Ltd., TruTag Technologies, Inc., **and** Tailorlux gmbH ~~and YottaMark, Inc~~ . We expect this competition to continue and intensify in the future. The market for our MDx Testing Services is very competitive, and we may be unable to continue to compete effectively in this industry in the future. The principal market for molecular diagnostics testing services is intensely competitive. We compete with many existing testing service providers and new competitors continue to enter the market. Many of our competitors, both in the United States and elsewhere, are major pharmaceutical, chemical and biotechnology companies, or have strategic alliances with such companies, and many of them have substantially greater capital resources, marketing experience, research and development staff, and facilities than we do. Any of these companies could succeed in developing testing services that are more effective than the testing services that we have or may develop and may be more successful than us in producing and marketing their existing testing services. Some of our competitors that operate in the molecular diagnostics testing markets include: 23andMe, Inc., Laboratory Corporation of America (LabCorp); Quest Diagnostics Inc., Myriad Genetics, Inc., ARUP Laboratories, Sonic Healthcare USA, Everly Well, Inc., and Fulgent Genetics, Inc. Our MDx Testing Services provide higher education institutions, private clients, and businesses located in New York State with COVID- 19 testing services, including test scheduling, sample collection and automated results reporting. **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** ~~and grow the number of~~ customers who will avail themselves of our testing services, or how regularly we will be able to obtain a flow of business from existing customers. If we are unable ~~to increase sales of our testing services or~~ to successfully develop, validate and commercialize other diagnostic tests and services, our MDx Testing Services may not produce sufficient revenues to become profitable. We compete with life science, pharmaceutical and biotechnology companies, some of whom are our customers, who are substantially larger than we are and potentially capable of developing new approaches that could make our products and technology obsolete or develop their own internal capabilities that compete with our products. The market for biologics **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; ~~29~~ ● additional product and service lines and the ability to bundle products and services to offer higher discounts or other incentives to gain a competitive advantage; ● more experience in conducting research and development, manufacturing and marketing; ● more experience in entering into collaborations or other strategic partnership arrangements; and ● more financial, manufacturing and human resources to support product development, sales and marketing and patent and other intellectual property litigation. These factors, among others, may enable our competitors to market their products and services at lower prices or on terms more advantageous to customers than we can offer. Competition may result in price reductions, reduced gross margins and loss of market share, any of which could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. Additionally, our current and future competitors, including certain of our customers, may at any time develop additional products and services that compete with our products and new approaches by these competitors may make our products, technologies and methodologies obsolete or noncompetitive. We may not be able to compete effectively against these organizations. In addition, to develop and market our new products, services, technologies and methodologies successfully, we must accurately assess and meet customers' needs, make significant capital expenditures, optimize our development and manufacturing processes to predict and control costs, hire, train and retain the necessary personnel, increase customer awareness and acceptance of such services, provide high quality services in a timely manner, price our products and services competitively and effectively integrate customer feedback into our business planning. If we fail to create demand for our new products, services or technologies, our future business could be harmed. The animal health industry is highly competitive. The animal health industry is highly competitive. Our competitors include standalone animal health businesses, the animal health businesses of large pharmaceutical companies, specialty animal health businesses and companies that mainly produce generic products. We believe many of our competitors are conducting R & D activities in areas in which we are developing products. Several new start- up companies also compete in the animal health industry. These competitors may have access to greater financial, marketing, technical and other resources. As a result, they may be able to devote more resources to developing, manufacturing, marketing and selling their products, initiating or withstanding substantial price competition or more readily taking advantage of acquisitions or other opportunities. Further, consolidation in the animal health industry could result in existing competitors realizing additional efficiencies or improving portfolio bundling opportunities, thereby potentially increasing their market share and pricing power, which could lead to an increase in competition. In addition to competition from established market participants, new entrants to the animal health medicines and vaccines industry could substantially reduce our market share, render our products obsolete or disrupt our business model. To the extent that any of our competitors are more successful with respect to any key competitive factor, our business, financial condition and results of operations could be materially adversely affected. Competitive pressure could arise from, among other things, more favorable safety and efficacy product profiles, limited demand growth or a significant number of additional competitive products being introduced into a particular market, price reductions by competitors, the ability of competitors to capitalize on their economies of scale, the ability of competitors to produce or otherwise procure animal health products at lower costs than us and the ability of competitors to access more or newer technology than us. ~~Our~~ **30Our** 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. ~~30In~~ **In** addition, research, development, and commercialization of our Therapeutic DNA Production Services and veterinary biologic products are inherently risky. We cannot give any assurance that any future customers and / or collaborators of our Therapeutic DNA Production Services will receive regulatory approval for their pharmaceutical and biotherapeutic product candidates. In addition, we cannot give any assurance that any of our own veterinary biologic product candidates will receive regulatory approval, which is necessary before they can be commercialized. Risks Related to Our Intellectual Property: Our intellectual property rights are valuable, and any inability to protect them could reduce the value of our products, services and brand. Our patents, trademarks, trade secrets, copyrights and all of our other intellectual property rights are important assets for us. There are events that are outside of our control that pose a threat to our intellectual property rights as well as to our products and services. For example, effective intellectual property protection may not be available in every country in which our products and services are distributed. The efforts we have taken to protect our proprietary rights may not be sufficient or effective. Any significant impairment of our intellectual property rights could harm our business or our ability to compete. Protecting our intellectual property rights is costly and time consuming. Any increase in the unauthorized use of our intellectual property could make it more expensive to do business and harm our operating results. Although we seek to obtain patent protection for our innovations, it is possible we may not be able to protect all or some of these

innovations. Given the costs of obtaining patent protection, we may choose not to protect certain innovations that later turn out to be important. There is always the possibility that the scope of the protection gained from one of our issued patents will be insufficient or deemed invalid or unenforceable. We also seek to maintain certain intellectual property as trade secrets. The secrecy could be developed independently, compromised by third parties, or disclosed, intentionally or accidentally, by our employees which would cause us to lose the competitive advantage resulting from these trade secrets. Intellectual property litigation could harm our business, financial condition and results of operations. Litigation regarding patents and other intellectual property rights is extensive in the drug and biotechnology industry. In the event of an intellectual property dispute, we may be forced to litigate. This litigation could involve proceedings instituted by the U. S. Patent and Trademark Office or the International Trade Commission, as well as proceedings brought directly by affected third parties. Intellectual property litigation can be extremely expensive, and these expenses, as well as the consequences should we not prevail, could seriously harm our business. ~~If~~ **31If** 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 ~~31may~~ -- **may** have to participate in an interference proceeding declared by the U. S. Patent and Trademark Office (" USPTO ") to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. Moreover, the scope, validity and enforceability of granted claims can be challenged in a variety of proceedings. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, outside of the context of litigation per se. Such mechanisms include ex parte re- examination, inter partes review, post- grant review, derivation and pre- and post- grant opposition proceedings. Furthermore, the courts have held that patent claims that recite laws of nature are not patent eligible, but patent claims that recite sufficient additional features that provide practical assurance that claimed processes are genuine inventive applications of those laws may be patent eligible. But what constitutes a " sufficient " additional feature is the subject of uncertainty. The USPTO has published and continues to revise and publish guidelines for patent examiners to apply when examining claims for patent eligibility as the case law continues to evolve. Patent eligibility is also an area of the law under continual development in other jurisdictions around the world. In addition, U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. ~~A~~ **32A** cybersecurity incident and other technology disruptions could negatively affect our business and our relationships with customers. We use technology in substantially all aspects of our business operations. The widespread use of technology, including mobile devices, cloud computing, and the internet, ~~give~~ **gives** rise to cybersecurity risks, including security ~~breach~~ **breaches** , espionage, system disruption, theft and inadvertent release of information. Our business involves the storage and transmission of numerous classes of sensitive and / or confidential information and intellectual property, including information relating to customers and suppliers, private information about employees, and financial and strategic information about us and our business partners. If we fail to effectively assess and identify cybersecurity risks associated with the use of technology in our business operations, we may become increasingly vulnerable to such risks. Additionally, while we have implemented measures to prevent security breaches and cyber incidents, our preventative measures and incident response efforts may not be entirely effective. The theft, destruction, loss, misappropriation, or release of sensitive and / or confidential

information or intellectual property, or interference with our information technology systems or the technology systems of third parties on which we rely, could result in business disruption, negative publicity, brand damage, violation of privacy laws, loss of customers, potential liability and competitive disadvantage. Risks Related to Regulatory Approval of Our Customer and Collaborator' s Pharmaceutical and Biotherapeutic Product Candidates and Other Legal Compliance Matters: ~~Pharmaceutical and biologic- related revenue~~ **Revenue from our** ~~is generally dependent on regulatory approval, oversight and compliance. Our~~ Therapeutic DNA Production Services will ~~generally~~ be ~~subject to~~ **highly dependent on our collaborators' and customers' success in obtaining** regulatory approval and **commercializing their drug** ~~oversight, potentially including approval~~ and / or ~~oversight in various foreign jurisdictions. In addition, our pharmaceutical and~~ biologic products ~~and~~ **. The DNA produced via our Therapeutic DNA Production** ~~services~~ **Services** may be incorporated into **our customers'** products **in the drug and / or biologic markets** that ~~cannot be marketed~~ **are subject to comprehensive regulation by the FDA and other regulatory agencies** in the United States **and** ~~or in many other jurisdictions without approval~~ by ~~the FDA or~~ comparable ~~agencies of~~ **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** ~~or~~ **our** ~~regions~~ **Therapeutic DNA Production Services, our collaborators or customers will be required to submit an NDA or BLA** . **The process of** ~~Obtaining~~ **obtaining** such regulatory approvals is ~~costly~~ **expensive** , ~~time- consuming~~ **often takes many years if approval is obtained at all** , ~~uncertain,~~ and ~~subject to unanticipated~~ **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** . ~~When,~~ **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 ~~ever~~ **regulatory approval is received** , **the manufacturing processes, post approval clinical data, labeling, advertising and promotional activities for any** such ~~approvals~~ **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** ~~obtained~~ -- **obtain or maintain regulatory approvals for their products of their failure to comply with applicable regulations. In addition, we will be dependent on, and have no control over, consumer demand for the products into which our Linea DNA technology** is ~~unknown~~ **incorporated** . ~~Our~~ Consumer demand for our collaborators' and customers' products could be adversely affected by,among other things,delays in health regulatory approval,the loss of patent and other intellectual property rights protection,the emergence of competing products,including generic drugs or biosimilars,the degree to which private and government drug plans subsidize payment for a particular product and changes in the marketing strategies for such products.The healthcare industry has changed significantly over time,and we expect the industry to continue to evolve.Some of these changes may have a material adverse effect on our collaborators and customers and thus may have a material adverse effect on our business.If the products into which our ~~products are~~ **Linea DNA is utilized or** incorporated do not gain market acceptance,our revenues and profitability may be adversely affected. ~~The~~ **33The** regulatory approval processes of the FDA,USDA and comparable foreign regulatory authorities are lengthy,time consuming,and inherently unpredictable.If ~~we or~~ our customers are ultimately unable to obtain regulatory approval for products incorporating our Therapeutic DNA Production Services,we will be unable to generate product ~~revenue~~ revenue ~~in the pharmaceutical~~ and ~~biologic markets~~ **our business will be substantially harmed. The time required to obtain approval by the FDA, USDA and comparable foreign regulatory authorities** is ~~highly~~ **unpredictable, typically takes many years following the commencement of clinical trials, and** ~~dependent~~ **depends** upon ~~obtaining such~~ **numerous factors, including the type, complexity and novelty of the product candidates involved. In addition,** approval **policies** ~~. Federal agencies~~ , ~~including~~ **regulations, or** the ~~FDA~~ **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** ~~and~~ - **an** ~~FTC 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 and~~ our customers' product candidates could fail to receive regulatory approval for a variety of reasons.This lengthy approval process , as well as ~~state, local, and foreign authorities, also exercise ongoing review and control of~~ the **unpredictability** ~~manufacturing, packaging, labeling, advertising, sale, distribution, and monitoring~~ of ~~pharmaceutical and biologic~~ **the results of clinical trials, may result in failing to obtain regulatory approval to market any of such** ~~products~~ **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 ~~32our or~~ **any of** our customers' ~~pharmaceutical or biologic~~ product candidates **are approved, they will be subject to ongoing regulatory requirements** ~~or~~ **for** ~~pharmaceutical ' 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 ~~products~~ **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~~ or biologic **safety issues could result in delays in product development or commercialization, or increased costs to assure manufacturing compliance. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of** products ~~incorporating our products~~ **to ensure that they** are ~~ever~~ **manufactured, marketed and distributed only for the** approved ~~, failure to comply~~ **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** ~~any~~ **an** ~~of these regulations~~ **approved NDA must submit new or supplemental applications and obtain approval** ~~or~~ **for certain changes to** ~~other~~ **the** ~~requirements~~ **approved product, product labeling, or manufacturing process. We** could also ~~have~~ **be asked to conduct post- marketing manufacturing changes to verify the safety** ~~an~~ **and** ~~adverse~~ **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** ~~effect~~ **affect** ~~on our revenue in~~ the ~~pharmaceutical and biologic markets~~ **need for our manufacturing services** . In addition, veterinary DNA vaccines and therapeutics in the United States are subject to review and regulatory approval by the USDA. The USDA’ s Center for Veterinary Biologics is responsible for the regulation of animal health vaccines, including certain immunotherapeutics. All manufacturers of animal health biologicals must show their products to be pure, safe, effective and produced by a consistent method of manufacture as defined under the Virus Serum Toxin Act. Post- approval monitoring of products is required. Reports of product quality defects, adverse events or unexpected results are submitted in accordance with the agency requirements. **34If** Revenue from our Therapeutic DNA Production Services..... accordance with the agency requirements. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product, our customer or us, including, but not limited to, requiring withdrawal or recall of the product from the market, imposing civil or criminal penalties, and imposing restrictions on our or our customers’ ability to continue to manufacture the product (s). Any government investigation of alleged violations of law could require our customers or us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our customers’ ability to commercialize and generate ~~34revenue~~ **revenue** from our customers’ products and demand for our synthetic DNA for their products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected related to the demand for those customers’ products or our products in the case of the veterinary health market. In addition, the FDA’ s regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could further restrict or regulate our post- approval manufacturing activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action. If our customers or we are not able to achieve and maintain regulatory compliance, we may not be permitted to continue manufacturing synthetic DNA products for our customers’ products and / or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability ~~. If the FDA were to begin to enforce regulation of LDTs, we could incur substantial costs and delays associated with trying to obtain pre- market clearance or approval and costs associated with complying with post- market requirements. As an LDT, our MDx Testing Services are currently subject to enforcement discretion by the FDA. While FDA has issued various guidance documents proposing a framework to regulate LDTs, the FDA appears to be waiting for a legislative solution. In this regard, most recently, the “ Verifying Accurate Leading- edge IVCT Development Act of 2020, ” or VALID Act, was introduced in March 2020, then in June 2021, and Spring 2022. A modified version of the VALID Act was added to the reauthorization bill for the Medical Device User Fee Act (“ MDUFA ”) V but then was removed to permit a more rapid passage of MDUFA V to prevent worker layoffs. The bill proposed a risk- based approach that would have subjected many LDTs to FDA regulation by creating a new in vitro clinical test, or IVCT, category of regulated products. As proposed, the bill would have grandfathered many existing LDTs from the proposed premarket approval, quality systems, and labeling requirements, respectively, but would have required such tests to comply with other regulatory requirements (e. g., registration and listing, adverse event reporting). To market a high- risk IVCT, reasonable assurance of analytical and clinical validity for the intended use would have needed to be established. Under VALID, a precertification process would have been established that would have allowed a laboratory to establish that the facilities, methods, and controls used in the development of its IVCTs meet quality system requirements. If pre- certified, low- risk IVCTs, developed by the laboratory would not have been subject to pre- market review. The new regulatory framework would have included quality control and post- market reporting requirements. The FDA would have had the authority to withdraw approvals for IVCTs for various reasons, including (for example) if there were a reasonable likelihood that the test would cause death or serious adverse health consequences. However, with bill language being removed from MDUFA V, we cannot predict if this (or any other bill) will be enacted in its current (or any other) form and cannot quantify the effect of such proposals on our business~~ . If we fail to comply with laboratory licensing requirements, we could lose the ability to offer our clinical testing services or experience disruptions to our business. CLIA is a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency

testing, patient test management, quality control, quality assurance and inspections. Clinical laboratories must be certified under CLIA in order to perform testing on human specimens, unless they fall within an exception to CLIA certification, such as research laboratories that test human specimens but do not report patient- specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients. CLIA certification is also required to be eligible to bill Federal and State healthcare programs, as well as many private third- party payers, for diagnostic testing and services. ~~Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations. Third party payors are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in the United States in 2010, the ACA was enacted. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The repeal of or changes in some or all of the ACA and complying with any new legislation or reversing changes implemented under the ACA could be time- intensive and expensive, resulting in a material adverse effect on our business. 35There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect the demand for our customer' s product candidates, if our customers obtain regulatory approval, including: our ability to receive or set a price that we believe is fair for our products; our ability to generate revenue and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive from any customer. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.~~ Our employees, independent contractors, consultants, commercial partners, customers and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners, customers and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with applicable laws and regulations of the FDA and other comparable foreign regulatory authorities; provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If our customers obtain FDA approval of any of their products and begin commercializing those products in the United States, our potential exposure under such laws may increase significantly, and our costs associated with compliance with such laws as a result of our relationship with our customers may also increase. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. ~~If~~ **35If** we fail to comply with healthcare laws, we could face substantial penalties and our business, operations and financial conditions could be adversely affected. Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of any product candidates for which our customers may obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including activities that potentially harm consumers and analogous state and foreign laws and regulations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could, despite our efforts to comply, be subject to challenge under one or more of such laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our customers' product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. ~~36Risks --~~ **Risks** Related to Personnel: Our failure to manage our growth in operations and acquisitions of new product lines and new businesses could harm our business. The ~~recent growth~~ **forecasted change** in our ~~operations~~ **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, ~~2022~~ **2023** , the employment contract automatically renewed for an additional year. Loss of the services of Dr. Hayward could significantly harm our business, results of operations and financial condition. We do not maintain key- person insurance on the life of Dr. Hayward. We may have conflicts of interest with our affiliates and related parties, and in the past we have engaged in transactions and entered into agreements with affiliates that were not negotiated at arms' length. We have engaged, and may in the future engage, in transactions with affiliates and other related parties. These transactions may not have been, and may not be, on terms as favorable to us as they could have been if obtained from non- affiliated persons. While an effort has been made, and will continue to be made, to enter into transactions with affiliated persons and other related parties at rates and on terms as favorable as would be charged by others, there will always be an inherent conflict of interest between our interests and those of our affiliates and related parties. The Company may be adversely impacted if any related party agreement or transaction is made on unfavorable terms. ~~Risks~~ **36Risks** Relating to Our Common Stock and Other Securities: There are a large number of shares of common stock underlying our outstanding options and warrants and the sale of these shares may depress the market price of our common stock and cause immediate and substantial dilution to our existing stockholders. As of December ~~9~~ **4** , ~~2022~~ **2023** , we had ~~12~~ **13** , ~~908~~ **687** , ~~520~~ **420** shares of common stock issued and outstanding, outstanding options to purchase ~~1~~ **2** , ~~061~~ **191** , ~~810~~ **535** shares of common stock, outstanding warrants to purchase ~~7~~ **5** , ~~313~~ **220** , ~~963~~ **588** shares of common stock, **282** ~~and 2~~ , ~~767~~ **640 unvested restricted stock units** , ~~568~~ **and 1, 340, 948** shares available for grant under our 2005 and 2020 Equity Incentive Plans. The issuance of shares upon exercise of our outstanding options and warrants will cause immediate and substantial dilution to our stockholders and any sale thereof may depress the market price of our common stock. We may be required to repurchase certain of our warrants. Under our warrants sold privately that have registration rights, in the event of a " Fundamental Transaction " (as defined in the related warrant agreement, which generally includes any merger with another entity, the sale, transfer or other disposition of all or substantially all of our assets to another entity, or the acquisition by a person of more than 50 % of our common stock), each warrant holder will have the right at any time prior to the consummation of the Fundamental Transaction to require us to repurchase the warrant for a purchase price in cash equal to the Black Scholes value (as calculated under the warrant agreement) of the then remaining unexercised portion of such warrant on the date of such Fundamental Transaction, which may materially adversely affect our financial condition and / or results of operations and may prevent or deter a third party from acquiring us. **We have received written notice from Nasdaq that we are not in compliance with Nasdaq' s minimum bid price requirements and if we are unable to regain compliance with Nasdaq continued listing standards, which may require effecting a reverse stock split of our common stock, we could be delisted from The Nasdaq Stock Market, which would negatively impact our business, our ability to raise capital, and the market price and liquidity of our common stock. The Nasdaq Stock Market LLC (" Nasdaq ") Listing Rule 5550 (a) (2) (the " Minimum Bid Price Requirement ") requires that the Company' s common stock maintain a closing bid price for 30 consecutive business days of $ 1. 00 per share. On December 1, 2023, the Company received a letter (the " Notice ") from Nasdaq notifying the Company that, because the closing bid price for its common stock has been below $ 1. 00 per share for 30 consecutive business days, it no longer complies with the Minimum Bid Price Requirement for continued listing on The Nasdaq Capital Market. There is no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement. The Notice had no immediate effect on the listing of the Company' s common stock on The Nasdaq Capital Market. The Company has been provided an initial compliance period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement. During the compliance period, the Company' s shares of common stock will continue to be listed and traded on The Nasdaq Capital Market. To regain compliance, the closing bid price of the Company' s common stock must meet or exceed $ 1. 00 per share for a minimum of ten consecutive business days during the 180- day compliance period. The Company intends to actively monitor the bid price for its common stock and will consider available options, including effecting a reverse stock split, to regain compliance with the Minimum Bid Price Requirement. If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over- the- counter quotation system or on the pink sheets but will lack the market efficiencies associated with Nasdaq. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $ 5. 00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of stockholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets. Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees and customers, the loss of institutional investor interest and fewer business development opportunities.** 37