

Risk Factors Comparison 2025-03-31 to 2024-03-25 Form: 10-K

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Our short and long- term success is subject to numerous risks and uncertainties, many of which involve factors that are difficult to predict or beyond our control. As a result, investing in our common stock involves substantial risk. Before deciding to purchase, hold or sell our common stock, stockholders, and potential stockholders should carefully consider the risks and uncertainties described below, in addition to the other information contained in or incorporated by reference into this Report, as well as the other information we file with the SEC. If any of these risks are realized, our business, financial condition, results of operations, and prospects could be materially and adversely affected. In that case, the value of our common stock could decline, and stockholders may lose all or part of their investment. Furthermore, additional risks and uncertainties of which we are currently unaware, or which we currently consider to be immaterial, could have a material adverse effect on our business. Certain statements made in this section constitute “ forward- looking statements, ” which are subject to numerous risks and uncertainties including those described in this section. Refer to the section entitled “ Cautionary Note Regarding Forward- Looking Statements ” within this Report for additional information. Risks Associated with Our Company We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. The summary below, as well as the discussion that follows the summary, highlights some of the risks that may affect future operating results. These are the risks and uncertainties we believe are most important for you to consider. We cannot be certain that we will successfully address these risks. If we are unable to address these risks, among other things, our business may not grow, our stock price may suffer, and we may be unable to stay in business. Additional risks and uncertainties not presently known to us, which we currently deem immaterial, or which are similar to those faced by other companies in our industry or business in general, may also impair our business operations. Risk Factor Summary Risks Related to Our Business and Business Strategy · ~~We have incurred significant losses, and we may never achieve profitability.~~ · We may need to raise additional capital in the future. If we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our plan of operations. · **We have incurred significant losses, and we may never achieve profitability.** · It is difficult to forecast our future performance, which may cause our financial results to fluctuate unpredictably. · The diagnostics market is highly competitive and subject to rapid technological change; accordingly, we will face fierce competition, including from companies with greater resources and experience than us, and our intended products may not achieve significant market penetration and / or may become obsolete. · Our management has broad discretion over the use of our available cash and might not allocate cash in ways that increase the value of your investment. · Our future success depends on our ability to retain our officers and directors, scientists, and other key employees and to attract, retain and motivate qualified personnel. · If any of our facilities or our laboratory equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed. · Failure in our information technology, storage systems or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts and subject us to liability. · Our business and reputation will suffer if we are unable to establish and comply with stringent quality standards to assure that the highest level of quality is observed in the performance of our tests. · Declining global economic or business conditions may have a negative impact on our business. · We may engage in acquisitions that are not successful and which could disrupt our business, cause dilution to our stockholders and reduce our financial resources. 10Risks Related to Product Development, Commercialization and Sales of Our Products · If the marketplace does not accept the products in our development pipeline or any other diagnostic products we might develop, we may be unable to generate sufficient revenue to sustain and grow our business. · Our business is dependent on our ability to successfully develop and commercialize diagnostic products. If we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. · Failure to successfully develop, manufacture, market, and sell our future products will have a material adverse effect on our business, financial condition, and results of operations. · The results of pre- clinical studies and completed clinical trials are not necessarily predictive of future results, and our current product candidates may not have favorable results in later studies or trials which, in turn, could have a material adverse effect on our business. · Our research and development efforts will be hindered if we are not able to obtain samples, contract with third parties for access to samples or complete timely enrollment in future clinical trials. · If the third parties on which we increasingly rely to assist us with our current and anticipated pre- clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance or approval or commercialize our products. · We expect to expand our product development, research and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. · We have limited experience with sales and marketing and any failure to build and manage a sales and marketing team effectively, or to successfully engage third party providers for such services, could have a material adverse effect on our business. · We rely on third parties to manufacture and supply our intended products. Any problems experienced by these third parties could result in a delay or interruption in the supply of our intended products to our customers, which could have a material negative effect on our business. · We depend on third- party distributors to market and sell our products which will subject us to a number of risks. · The manufacturing operations of our third- party manufacturers will likely be dependent upon third- party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business. · Defects in our products may subject us to substantial damages which could materially harm our business or financial condition. Risks Related to Governmental Regulation and Reimbursement · Our failure to obtain necessary regulatory clearances or approvals on a timely basis would significantly impair our ability to distribute and

market our future products on the clinical IVD market. · Reductions or changes in reimbursement policies could limit our ability to sell our products. · If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

Risks Related to Our Intellectual Property · If the patents we rely on to protect our intellectual property prove to be inadequate, our ability to successfully commercialize our products will be harmed and we may never be able to operate our business profitably. · If third parties assert that we have infringed their patents and proprietary rights or challenge the validity of our patents and proprietary rights, we may become involved in intellectual property disputes and litigation that would be costly, time consuming, and delay or prevent the development or commercialization of our products. · If we are unable to protect our trade secrets, we may be unable to protect our interests in proprietary technology, processes and know-how that is not patentable or for which we have elected not to seek patent protection.

Risks Related to Our Securities · The market prices and trading volume of our stock may be volatile. · We have identified material weaknesses in our internal control over financial reporting that have not yet been remediated, and although we are working to address such weaknesses, the failure to address these material weaknesses, or the identification of any others, could impact the reliability of our financial reporting and harm investors' views of us, which could adversely impact our stock price. · We have a "going concern" opinion from our auditors, indicating the possibility that we may not be able to continue to operate.

If we fail to comply with the NYSE American's continued listing requirements, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. · Our Second Amended and Restated Certificate of Incorporation exculpates our officers and directors from certain liability to our Company and our stockholders. · Our corporate governance documents, and certain corporate laws applicable to us, and share ownership by executive officers and directors, could make a takeover attempt, which may be beneficial to our stockholders, more difficult. · We do not expect to pay dividends in the foreseeable future. · We may in the future issue additional shares of our common stock which would reduce investors' ownership interests in the Company, and which may cause our stock price to decline. · Future sales of our common stock could depress the market price of our common stock. · If equity research analysts do not publish research or reports about our business, or if they do publish such reports but issue unfavorable commentary or downgrade our common stock, the price and trading volume of our common stock could decline.

~~If we fail to comply with the NYSE American's continued listing requirements, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.~~ · We are a smaller reporting company and a non-accelerated filer, and we cannot be certain if the reduced disclosure requirements applicable to our filing status, as well as the exemption from the requirement to provide an auditor's attestation report regarding the effectiveness of our internal controls, will make our common stock less attractive to investors.

~~We are a clinical stage company..... value of our common stock will decline.~~ · We may require additional capital to fully fund our current strategic plan, which includes successfully commercializing our Nu. Q[®] pipeline and developing future products. If we incur delays in commercialization of our Nu. Q[®] pipeline or other future products or in achieving significant product revenue, or if we encounter other unforeseen adverse business developments, we may exhaust our capital resources prior to the commencement of commercialization. We cannot be certain that additional capital will be available when needed or that our actual cash requirements will not be greater than anticipated. Financing opportunities may not be available to us, or if available, may not be available on favorable terms. The availability of financing opportunities will depend on various factors, such as market conditions and our financial condition and outlook. In addition, if we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders could be significantly diluted, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders. If we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, and the terms of the debt securities issued could impose significant restrictions on our operations. If we are unable to obtain financing on terms favorable to us, we may be unable to execute our plan of operations and we may be required to cease or reduce development or commercialization of any future products, sell some or all of our technology or assets or merge with another entity.

· We are a clinical stage company and have incurred losses since our formation. As of December 31, 2024-2023, we have an accumulated total deficit of approximately \$ 229-202.5-6 million. As we continue the discovery and development of our future diagnostic products, we expect our expenses to increase significantly. Even as we begin to market and sell our intended products, we expect our losses to continue as a result of ongoing research and development expenses, as well as increased manufacturing, sales and marketing expenses. These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' deficit equity.

· Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict when or if we will become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we are unable to achieve and then maintain profitability, our business, financial condition and results of operations will be negatively affected, and the market value of our common stock will decline.

–12 Our limited operating history and the rapid evolution of the market for diagnostic products make it difficult for us to predict our future performance. A number of factors, many of which are outside of our control, may contribute to fluctuations in our financial results, such as: · our ability to develop or procure antibodies for clinical use in our future products; · our ability to translate preliminary clinical results to larger prospective symptomatic and screening populations; · the demand for our intended products; · our ability to obtain any necessary financing; · our ability to market and sell our future products; · market acceptance of our future products and technology; · performance of any future strategic business partners; · our ability to obtain regulatory clearances or approvals; · our success in collecting payments from third-party payors and customers; · changes in technology that may render our future products uncompetitive or obsolete; · competition with other diagnostics companies; and · adverse changes in the healthcare industry (human and canine). The diagnostics market is extremely competitive and characterized by rapidly evolving industry standards and new product enhancements. Our diagnostic tests are technologically innovative and

require significant planning, design, development, and testing at the technological, product, and manufacturing process levels. These activities require significant capital commitments and investment. There can be no assurance that our intended products or proprietary technologies will remain competitive following the introduction of new products and technologies by competing companies within the industry. Furthermore, there can be no assurance that our competitors will not develop products that render our future products obsolete or that are more effective, accurate or can be produced at lower costs. There can be no assurance that we will be successful in the face of increasing competition from new technologies or products introduced by existing companies in the industry or by new companies entering the market. The market for diagnostics is also significantly affected by new product introductions and other market activities of industry participants. Our competitors include large multinational corporations and their operating units, including Exact Sciences Corporation, Guardant Health, GRAIL Inc., Freenome Holdings Inc, CellMax Life, Archer DX Inc., Foundation Medicine Inc., Oncocyte Corporation, OpKo Health Inc., MDNA Life Sciences Inc., Abbott Laboratories Inc., Cepheid Inc., Hologic Corporation, Agilent Technologies Inc., Qiagen Inc., Thermo Fisher, Illumina, Becton Dickinson, BioMerieux, Siemens, Gen- Probe Incorporated, EpiGenomics AG, MDxHealth SA, Roche Diagnostics, Cytovale Inc. and Immunexpress Inc., and from companies such as ~~PetDx~~, One Health Company (Fidocure) and ~~Vidium Animal Health~~ focused on the veterinary space. There may also be other companies developing products competitive with ours of which we are unaware. Successful commercialization of our services will require that we satisfactorily address the needs of various medical practitioners that constitute a target market to reach customers and to address potential resistance to recommendations for our services. If we are unable to continue to achieve significant market penetration, we will not be able to generate sufficient revenue to become profitable and our products may become obsolete. Many of our competitors have greater resources and experience than us and may enjoy several competitive advantages, including: · significantly greater name recognition; · established relationships with healthcare professionals, companies and consumers; · additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage; · established supply and distribution networks; and · greater resources for product development, sales and marketing, and intellectual property protection. Many of these other companies have developed and will continue to develop new products that will compete directly with our future products. In addition, many of our competitors spend significantly greater funds for the research, development, promotion, and sale of new and existing products. These resources may allow them to respond more quickly to new or emerging technologies and changes in consumer requirements. We also face competition in our search for third parties to assist us with sales and marketing of our product candidates, which may negatively impact our ability to enter into favorable sales and marketing arrangements. For all the foregoing reasons, we may not be able to compete successfully against our competitors, which could jeopardize our ability to recoup research and development expenditures, hurt our reputation and harm our business, results of operations and financial condition. 13As of December 31, ~~2023~~ **2024**, we had approximately \$ ~~20.3~~ **7.3** million in combined cash and cash equivalents compared to approximately \$ ~~10.20~~ **9.7** million as of December 31, ~~2022~~ **2023**. Our management expects to deploy these resources primarily to expand our commercialization activities, to fund our product development efforts and for general corporate and working capital purposes. However, our management has broad discretion to pursue other objectives. Our management might not apply our cash in ways that increase or permit any return of your investment. Our success depends on our ability to attract, retain and motivate highly qualified management and scientific personnel. In particular, we are highly dependent on Cameron Reynolds, our President and Chief Executive Officer, our other officers and directors, scientists and key employees. The loss of any of these persons or their expertise would be difficult to replace and could have a material adverse effect on our ability to achieve our business goals. In addition, the loss of the services of any one of these persons may impede the achievement of our research, development and commercialization objectives by diverting management's attention to the identification of suitable replacements, if any. There can be no assurance that we will be successful in hiring or retaining qualified personnel and our failure to do so could have a material adverse effect on our business, financial condition and results of operations. Recruiting and retaining qualified scientific personnel and, in the future, sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among pharmaceutical, biotechnology and diagnostic companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. We do not maintain "key person" insurance on any of our employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research, development and commercialization strategies. Our consultants and advisors, however, may have other commitments or employment that may limit their availability to us. If our present, or any future facilities, were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, earthquakes, other inclement weather events or natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, it may render it difficult or impossible for us to perform our research and development for some period of time and our business could be severely disrupted. The lead time from ordering to delivery of certain specialized equipment we use can be more than six months and difficult to substitute. Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology systems, which support our operations including our research and development efforts. The integrity and protection of our own data, and that of our customers, clinical trial subjects and employees, is critical to our business. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. IT systems are vulnerable to damage from a variety of sources. High-profile security breaches at other companies and in government agencies have increased in recent years, and cyber- attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclose information or unwittingly provide access to systems or data. While we devote significant resources to security measures to protect our systems and data, these measures cannot provide absolute security. Any breach or interruption of our information technology systems could compromise our networks and the

information stored therein could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, unauthorized access, loss or disclosure could also disrupt our operations, including our ability to: · provide customer assistance services; · conduct research and development activities; · collect, process and prepare company financial information; · provide information about our tests and other patient and healthcare provider education and outreach efforts through our website; and · manage the administrative aspects of our business and damage to our reputation. 14Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the U. S. Health Insurance Portability and Accountability Act of 1996, similar U. S. state data protection regulations, including the California Consumer Privacy Act, the EU' s General Data Protection Regulation, and other regulations, the breach of which could result in significant penalties. Failure to adequately protect and maintain the integrity of our information systems and data, including as a result of a security breach, may result in significant losses and have a material adverse effect on our financial position, results of operations and cash flows. Inherent risks are involved in providing and marketing diagnostic and monitoring tests and related services. Patients and healthcare providers rely on us to provide accurate clinical and diagnostic information that may be used to make critical healthcare decisions. Consequently, users of our tests may have a greater sensitivity to errors than users of some other types of products and services. We must maintain high service standards and other quality controls. Performance or accuracy defects, incomplete or improper process controls, excessively slow turnaround times, unanticipated uses of our tests or mishandling of samples or test results (whether by us, patients, healthcare providers, courier delivery services, or others) can lead to adverse outcomes for patients and interruptions to our services. These events could lead to voluntary or legally mandated safety alerts relating to our tests or our laboratory facilities and could result in the removal of our products and services from the market or the suspension of our laboratories' operations. Insufficient quality controls and any resulting negative outcomes could result in significant costs and litigation, as well as negative publicity that could reduce demand for our tests and payers' willingness to cover our tests. Even if we maintain adequate controls and procedures, damaging and costly errors may occur. Declining global economic conditions may have a negative impact on our business. Concerns over U. S. healthcare reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries, and global inflationary pressures may contribute to increased volatility and diminished expectations for the global economy. If the economic climate deteriorates, our business, including our access to the research use only, or clinical IVD markets for diagnostic tests, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations. The United Kingdom' s withdrawal from the European Union became effective in January 2021. Although it is known what the terms of this withdrawal were, it is still possible that greater restrictions on imports and exports between the European Union countries and the United Kingdom and increased regulatory complexities are forthcoming. These changes may adversely affect our ability to market our future products in the United Kingdom which could have an adverse effect on our business, financial condition, and results of operations. In addition, following Russia' s military invasion of Ukraine in February 2022, NATO deployed additional military forces to Eastern Europe, and the United States, European Union, and other nations announced various sanctions against Russia. The invasion of Ukraine and the retaliatory measures that have been taken, and could be taken in future, by the U. S., NATO, and other countries have created global security concerns that could result in a regional conflict and otherwise have a lasting impact on regional and global economies, any or all of which could adversely affect our business. **Separately, proposals to implement new tariffs or other trade restrictions in the U. S. could impact the products we import into the U. S. and also result in retaliatory measures in international markets where we sell our products. Although we cannot predict whether and in what form such measures will be adopted or implemented, these proposals for tariffs or other trade restrictions could increase our cost of goods sold and negatively impact our business and operating results. Supply chain disruptions and delays as a result of any new tariff policies or trade restrictions could also negatively impact our cost of materials and production processes.** From time to time, we may consider opportunities to acquire or invest in other companies, products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or otherwise advance our business strategies. Potential and completed acquisitions and investments involve numerous risks, including the following: · we may be unable to successfully integrate the acquired business (es) into our business; · we may be unable to realize the anticipated benefits of the acquisition; · the acquisition may not strengthen our competitive position; and · our future results may suffer if we do not effectively manage our expanded operations. ~~We~~ **15We** do not know if we will be able to identify future acquisitions or investments we deem suitable, whether we will be able to successfully complete any such acquisitions or investments on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition. ~~15Our~~ **Our** intended products may never gain significant acceptance in the research or clinical marketplace and therefore may never generate substantial revenue or profits. Physicians, hospitals, clinical laboratories, researchers or others in the healthcare industry may not use our future products unless they determine that they are an effective and cost- efficient means of detecting and diagnosing cancer. If our research and studies do not satisfy providers, payors and others as to the reliability and effectiveness, we may experience reluctance or refusal on the part of the physician to use our future products. In addition, we will need to expend a significant amount of resources on marketing and educational efforts to create awareness of our future products and to encourage their acceptance and adoption. If the market for our future products does not develop sufficiently or the products are not accepted, our revenue potential will be harmed. Our current business strategy focuses on discovering, developing and commercializing diagnostic products. The success of our business will depend on our ability to fully develop and commercialize the diagnostic products in our current development pipeline as well as continue the discovery and development of other diagnostics products. Prior to commercializing the Nu. Q ® tests and other diagnostic products, we will be required to undertake time- consuming and costly development

activities with uncertain outcomes, including conducting clinical studies and obtaining regulatory clearance or approval in the United States, Asia and in Europe. Delays in obtaining approvals and clearances could have material adverse effects on us and our ability to fully carry out our plan of operations. We have limited experience in taking products through these processes and there are considerable risks involved in these activities. The science and methods that we are employing are innovative and complex, and it is possible that our development programs will ultimately not yield products suitable for commercialization or government approval. Products that appear promising in early development may fail to be validated in subsequent studies, and even if we achieve positive results, we may still fail to obtain the necessary regulatory clearances or approvals. Few research and development projects result in commercial products, and perceived viability in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product, or we may be required to expend considerable resources obtaining additional clinical and nonclinical data, which would adversely impact the timing for generating potential revenue from those products. Further, our ability to develop and launch diagnostic tests is dependent on our receipt of substantial additional funding. If our discovery and development programs yield fewer commercial products than we expect, we may be unable to execute our business plan, and our business, financial condition and results of operations may be adversely affected. We are in the process of developing a suite of diagnostic tests as well as additional products. The successful development and commercialization of our intended products is critical to our future success. Our ability to successfully develop, manufacture, market, and sell our future products is subject to a number of risks, many of which are outside our control. There can be no assurance that we will be able to develop and manufacture products in commercial quantities at acceptable costs, successfully market any products, or generate revenues from the sale of any products. Failure to achieve any of the foregoing would have a material adverse effect on our business, financial condition, and results of operations. We must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. We may be required to demonstrate through large, long-term outcome trials that our product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication (s) would preclude the successful development of those candidates for such indication (s), in which event our business, prospects, results of operations and financial condition may be adversely affected.

~~16~~ Access to human and animal sample types, such as blood is necessary for our research and product development. Acquiring samples from individuals / animals with clinical diagnoses or associated clinical outcomes through purchase or clinical studies is necessary. Lack of available samples can delay development timelines and increase costs of development. Generally, the agreements under which we gain access to human and animal samples are non-exclusive. Other companies may compete with us for access. If we are not able to negotiate access to clinical samples with research institutions, hospitals, clinical partners, pharmaceutical companies, or companies developing therapeutics and / or diagnostics on a timely basis, or at all, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future products will be limited or delayed. Equally, we may not be able to conduct or complete clinical studies in a timely manner if we are unable to enroll sufficient numbers of patients in such studies, which could consequently have an adverse effect on our research and development and product commercialization efforts. As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. For example, we currently rely on Diagnostic Oncology CRO, LLC (“DXOCRO”) to support development and clinical validation studies for our Nu. Q ® product portfolio in the United States, including by conducting large-scale finding studies across multiple sites in the U. S. using our Nu. Q ® NETs test to determine clinical utility in sepsis, which we hope to leverage in support of our U. S. commercialization strategy. However, if we are not able to maintain or reach mutually acceptable agreements with DXOCRO or other third parties on a timely basis, these third parties do not successfully carry out their commitments or regulatory obligations or meet expected deadlines, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to agreed-upon clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. We are focused on developing our pipeline for current and future products. It is likely that our efforts will result in significant growth in the number of our consultants, advisors, and employees, in addition to the scope of our operations. For example, in connection with the anticipated commercialization of our products, we may add personnel to certain areas of our business including laboratory operations, quality assurance, and compliance. Further, as we build our commercialization efforts and expand research and development activities for new products, the scope and complexity of our operations is increasing significantly. As a result of our growth, our operating expenses and capital requirements have also increased, and we expect that they will continue to increase. Our ability to manage our growth effectively requires us to expend funds to implement and improve our managerial, operational and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plan or disrupt our operations. We have limited experience with sales and marketing and any failure to build and manage a sales and marketing team effectively, or to successfully engage and maintain third party providers for such services, could have a material adverse effect on our business. As an organization we

have limited experience with direct sales however we are building a team of experienced individuals in terms of market intelligence, product management and account management in addition to building relationships with market- leading established distributors as commercial partners. For example, **Heska Antech** has commenced ~~pre-order~~ sales of our Nu. Q ® Vet Cancer Test for screening of cancer in canines to veterinarians worldwide at the point of care pursuant to our exclusive global supply and licensing agreement. We have also engaged IDEXX to make our Nu. Q ® Vet Cancer Test available to reference laboratories in the United States. Although we are investing in direct marketing to support these commercial launches, we may rely on third party resources such as **Heska Antech**'s global network of veterinarians and IDEXX's reference laboratory network to successfully market this test and generate revenue. Any failure to build and manage a sales and marketing team effectively, or to successfully engage and maintain third- party providers for such services, could have a material adverse effect on our business.

17Our products will require several dynamic and evolving sales models tailored to different worldwide markets, users and products. Our clinical sales strategy is initially focused on the clinical IVD market with the CE marking of our first product in Europe, the Nu. Q ® NETs test, in May 2022. With this CE marking of our first product in Europe we intend to enter the European markets and, following the completion of any necessary regulatory clearances, certain Asian markets. Even if we receive a CE mark for a certain product, we must still seek regulatory clearance in other jurisdictions. A failure to obtain these regulatory clearances in other jurisdictions could negatively affect our business. Pending completion of our review of the regulatory environment in the United States we may decide to enter the United States market through a Clinical Laboratory Improvement Amendments ("CLIA"), certified laboratory located in the United States. We remain firmly committed to pursuing FDA approval as our primary objective. FDA approval can consist of PMA or 510 (k) clearance depending on the test complexity and risk posed to patients. We intend to pursue the most appropriate approval pathway for each individual product developed. We intend to progressively grow to large volumes of tests sold to centralized laboratories and eventually reach the mass diagnostics testing market. The exact nature of the ideal sales strategy will evolve as we continue to develop our intended products and seek entry into the IVD markets. There are significant risks involved in building and managing our sales and marketing organization, as well as identifying and negotiating deals with the right sales and distribution partners, including risks related to our ability to:

- identify appropriate partners;
- negotiate beneficial partnership and distribution agreements;
- hire qualified individuals as needed;
- generate sufficient leads within our targeted market for our sales force;
- provide adequate training for effective sales and marketing;
- protect intellectual property rights;
- retain and motivate our direct sales and marketing professionals; and
- effectively oversee geographically dispersed sales and marketing teams.

Our failure to adequately address these risks could have a material adverse effect on our ability to increase sales and use of our future products, which would cause our revenues to be lower than expected and harm our results of operations. Further, we are required to comply with numerous other federal, state, and local laws relating to matters such as safe working conditions, industrial safety, and labor laws. We may incur significant costs to comply with such laws and regulations in the future, and lack of compliance could have material adverse effects on our operations. We believe that we have structured our business operations to comply with applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise, which could have a material adverse impact on our business. We rely on third parties to manufacture and supply our intended products. The manufacture of our intended diagnostic products requires specialized equipment and utilizes complicated production processes that would be difficult, time- consuming and costly to duplicate. If the operations of third- party manufacturers are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill our future sales orders. Any prolonged disruption in the operations of third- party manufacturers could have a significant negative impact on our ability to sell our future products, could harm our reputation and could cause us to seek other third- party manufacturing contracts, thereby increasing our anticipated development and commercialization costs. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards required by the FDA and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop products or receive approval of any products in a timely manner.

18We depend on third- party distributors to market and sell our products, which will subject us to a number of risks. We depend, and expect to continue to depend, on third- party distributors to market, sell, and service our products in our intended markets. For example, **Heska Antech** has commenced pre- order sales of our Nu. Q ® Vet Cancer Test for screening of cancer in canines to veterinarians at the point of care and we engaged IDEXX to make our Nu. Q ® Vet Cancer Test available to reference laboratories in the United States. Further, we have engaged with others including DNatech, Portugal, and, through our agreement with **Heska Antech**, with Scil Lab Europe, to launch the Nu. Q ® Vet Cancer Test to customers in Europe. In November 2023, we launched the Nu. Q ® Vet Cancer Test in the UK and Ireland through our distributor, the Veterinary Pathology Group, and in the UK through Nationwide Laboratories. **Our test is also available in Japan through Fujifilm Vet Systems Co. Ltd, a leading provider of veterinary testing services in Japan**. We are subject to a number of risks associated with reliance upon these parties and other third- party distributors including the following:

- lack of day- to- day control over the activities of third- party distributors;
- third- party distributors may not commit the necessary resources to market and sell our products to our level of expectations;
- third- party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us; and
- disagreements with our distributors could result in costly and time- consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar.

If we fail to establish and maintain satisfactory relationships with our third- party distributors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which could harm our results of operations and financial condition. The operations of our future third- party manufacturers will likely be dependent upon third- party suppliers. A supply interruption or an increase in demand beyond a supplier's capabilities could harm the ability of our future manufacturers to manufacture our intended products until new sources of supply are identified and qualified. Reliance on

these suppliers could subject us to a number of risks that could harm our business, including: · interruption of supply resulting from modifications to or discontinuation of a supplier's operations; · delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component; · a lack of long-term supply arrangements for key components with our suppliers; · inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms; · difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner; · production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications; · delay in delivery due to suppliers prioritizing other customer orders over ours; · damage to our brand reputation caused by defective components produced by the suppliers; and · fluctuation in delivery by the suppliers due to changes in demand from us or their other customers. We have implemented certain risk mitigation strategies including the diversification of suppliers by region and the internalization of certain production processes. However, any interruption in the supply of components of our future products or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our future customers, which would have an adverse effect on our business. The products we develop could lead to product liability claims based on allegations that one or more of our products contained a design or manufacturing defect which resulted in the failure to detect the disease for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future.

We are subject to regulation by the FDA in the United States, the CE in Europe, the CFDA in China, and other regulatory bodies in other countries where we intend to sell our future products. Before we are able to place our intended products in the clinical IVD markets in the United States, China and Europe, we will be required to obtain clearance or approval of our future products from the FDA and the CFDA with respect to the United States and China, respectively, and receive a CE mark with respect to Europe. In Europe, since May 2022, IVD medical devices are regulated by the new EU IVDR. The most challenging changes under the EU IVDR as compared to the previous Directive are those regarding the classification of products, which brings almost all IVDs under the direct review and control of Notified Bodies, and the performance evaluation of IVDs, which requires extensive clinical and analytical performance studies in addition to a demonstration of scientific validity. These changes and other additional requirements to obtain a CE Mark could result in delays and further expense, in terms of staff costs to us compared to the process under the previous Directive. Additionally, even if we receive the required government clearance or approval of our intended products, we are still subject to continuing regulation and oversight. Under the FDA, diagnostics are considered medical devices and are subject to ongoing controls and regulations, including inspections, compliance with established manufacturing practices, device-tracking, record-keeping, advertising, labeling, packaging, and compliance with other standards. The process of complying with such regulations with respect to current and new products can be costly and time-consuming. Failure to comply with these regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, delays by the FDA or other regulators in granting clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators, any of which could have a material adverse effect on our business, financial condition, and results of operations. Furthermore, any FDA regulations governing our future products are subject to change at any time, which may cause delays and have material adverse effects on our operations. In Europe, IVD companies are currently able to self-certify that they meet the appropriate regulatory requirements (which are subject to change with the EU MDR and the EU IVDR noted above) but are subject to inspection for enforcement. European national agencies, such as customs authorities and / or the Departments of Health, Industry and Labor, conduct market surveillance to ensure the applicable requirements have been met for products marketed within the European Union. Reductions or changes in reimbursement policies could limit our ability to sell our products. Market acceptance and sales of our products will depend, in part, on reimbursement policies and may be affected by healthcare reform measures. Government authorities and third-party payers, such as private health insurers and health maintenance organizations, decide which products they will pay for and establish reimbursement levels for those products. To manage healthcare costs, many governments and third-party payers in the United States increasingly scrutinize the pricing of new products and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. We cannot be sure that reimbursement will be available for our products and, if reimbursement is available, the scope of such reimbursement. Reimbursement may impact the demand for, or the price of, our products. If reimbursement is not available or is available only at limited amounts, we may not be able to successfully commercialize our future products. There are a number of U. S. and international laws protecting the privacy and security of personal information. These laws include the U. S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and related regulations, U. S. state laws (such as the California Consumer Privacy Act ("CCPA") and the California Privacy Rights Act ("CPRA")), Canada's Personal Information and Electronic Documents Act ("PIPEDA") or the applicable provincial alternatives, the EU's General Data Protection Regulation ("GDPR"), EU member states directives, or similar applicable laws. These laws place limits on how we may collect, use, share and store medical information and other personal information, and they impose obligations to protect that information against unauthorized access, use, loss, and disclosure. If we, or any of our service providers who have access to the personal data for which we are responsible, are found to be in violation of the privacy or security requirements of HIPAA, PIPEDA, GDPR, or applicable foreign, U. S. state and Canadian provincial laws, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results. In addition, entities operating in the healthcare industry have increasingly become targets for hackers. Although we utilize a variety of measures to secure the data

that we control, even compliant entities can experience security breaches or have inadvertent failures despite employing reasonable practices and safeguards. 20 We may also face new risks relating to data privacy and security as the United States, individual U. S. states or Canadian provinces, E. U. member states, and other international jurisdictions adopt or implement new data privacy and security laws and regulations as we continue to commercialize our products worldwide. For example, amendments to privacy and security laws (such as the CCPA and the CPRA) may impose additional requirements on us and increase our regulatory and litigation risk. As we continue to expand, our business will need to adapt to meet these and other similar legal requirements. Our success depends, in large part, on our ability to protect proprietary methods, discoveries and technologies that we develop under the patents and intellectual property laws of the United States, Europe and other countries, so that we can seek to prevent others from unlawfully using our inventions and proprietary information. Our patent portfolio includes 50-52 patent families (plus two-three in- licensed families) and a total 79-75 patents granted related to our diagnostic tests (including veterinary applications), with 12-13 patents granted in the United States, 19-20 patents granted in Europe and a further 48-42 patents granted worldwide. Additionally, we have 132-128 patent applications pending, worldwide. If we are not able to protect our proprietary technology and information, our competitors may use our inventions to develop competing products. We cannot assure you that any of the pending patent applications will result in patents being issued. In addition, due to technological changes that may affect our products or judicial interpretation of the scope of our patents, our products might not, now or in the future, be adequately covered by our patents. Our ability to commercialize our products depends on our ability to develop, manufacture, market and sell our products without infringing the proprietary rights of third parties. Third parties may allege that our products or our methods or discoveries infringe their intellectual property rights. Numerous United States and foreign patents and pending patent applications, which are owned by third parties, exist in fields that relate to our products and our underlying methodologies, discoveries and technologies. A third party may sue us for infringing its patent rights. Our ability to successfully commercialize our products depends on our ability to protect our proprietary technology and information. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of third- party proprietary rights. In addition, a third party may claim that we have improperly obtained or used its confidential or proprietary information. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation could divert our management' s attention from other aspects of our business. 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. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations. Additionally, we cannot be certain of the level of protection, if any that will be provided by our patents if they are challenged in court, where our competitors may raise defenses such as invalidity, unenforceability or possession of a valid license. If we are found to infringe upon intellectual property rights of third parties, we might be forced to pay damages, potentially including triple damages. In addition to any damages, we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non- exclusive and, therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some or all of our products, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. 21 In addition to patented technology, we rely upon trade secret protection to protect our interests in proprietary know- how and for processes for which patents are difficult or impossible to obtain or enforce. We may not be able to protect our trade secrets adequately. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors and outside scientific advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. We rely, in part, on non- disclosure and confidentiality agreements with our employees, consultants and other parties to protect our trade secrets and other proprietary technology. These agreements may be breached, and we may not have adequate remedies for any breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential information into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us, which could adversely affect our competitive advantage. The market price of our common stock is likely to be highly volatile and the trading volume may fluctuate and cause significant price variation to occur. We cannot assure you that the market prices of our common stock will not fluctuate or decline significantly in the future. Some of the factors that could negatively affect the prices of our shares or result in fluctuations in those prices or in trading volume of our common stock could include the following, many of which will be beyond our control: · competition; · comments by securities analysts regarding our business or prospects; · additions or departures of key personnel; · our ability to execute our business plan; · issuance of common stock or other securities; · operating results that fall below expectations; · loss of any strategic relationship; · industry developments; · economic and other external factors; and · period- to- period fluctuations in our financial results. In addition, the securities markets have from time- to- time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price and trading volume of our common stock. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined in Exchange Act Rule 13a- 15 (f), internal control over financial reporting is a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: · pertain to the maintenance of records that in reasonable detail accurately and fairly

reflect our transactions and dispositions of assets; · provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and / or directors; and · provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements. ²²We have determined that we have material weaknesses in our internal control over financial reporting as of December 31, ~~2023~~ **2024**. See Part II, Item 9A of this Report for a complete discussion of these material weaknesses in our internal control over financial reporting and remediation efforts. Although we have taken and continue to take steps to address these material weaknesses, the existence of a material weakness is an indication that there is more than a remote likelihood that a material misstatement of our financial statements will not be prevented or detected in the current or any future period. There can be no assurance that we will be able to fully implement our plans and controls, as further described in Item 9A, to address these material weaknesses, or that the plans and controls, if implemented, will be successful in fully remediating these material weaknesses. In addition, we may in the future identify further material weaknesses in our internal control over financial reporting that we have not discovered to date. If we fail to successfully remediate the identified material weaknesses, or we identify further material weaknesses in our internal controls, the market's confidence in our financial statements could decline and the market price of our common stock could be adversely impacted. Additionally, for so long as we remain as a smaller reporting company, under current rules our accounting firm will not be required to provide an opinion regarding our internal controls over financial reporting. Our independent registered public accountants have expressed substantial doubt about our ability to continue as a going concern. This opinion could materially limit our ability to raise additional funds by issuing new debt or equity securities or otherwise. If we fail to raise sufficient capital when needed, we will not be able to complete our proposed business plan. As a result, we may have to liquidate our business and investors may lose their investments. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish our plan of operations described herein, obtain financing and eventually attain profitable operations. Investors should consider our independent registered public accountant's comments when deciding whether to invest in the Company. Our common stock is listed on the NYSE American. The continued listing of our common stock on the NYSE American is subject to our continued compliance with certain listing requirements, including requirements related to corporate governance, our financial condition and operating results, the trading price of our common stock, number of stockholders and our market capitalization. If we fall out of compliance with the NYSE American's listing standards and fail to regain compliance within the applicable cure periods, our common stock may be delisted from the NYSE American. The delisting of our common stock could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital on terms acceptable to us, or at all, reduce the amount of analyst coverage of our securities, result in the loss of confidence by investors and employees, and could lead to fewer business development opportunities, any of which could adversely affect our business. Our Second Amended and Restated Certificate of Incorporation contains a provision limiting the liability of our officers and directors for their acts or failures to act, except for acts involving intentional misconduct, fraud or a knowing violation of law. This limitation on liability may reduce the likelihood of derivative litigation against our officers and directors and may discourage or deter our stockholders from suing our officers and directors based upon breaches of their duties to our Company. Our corporate governance documents, certain corporate laws applicable to us, and share ownership by executive officers and directors, could make a takeover attempt, which may be beneficial to our stockholders, more difficult. Our board of directors has the power, under our charter documents to: · issue additional shares of common stock without having to obtain stockholder approval for such action; · fill vacant directorships except for vacancies created by the removal of a director; · amend our bylaws without stockholder approval subject to certain exceptions; and · require compliance with an advance notice procedure with regard to business to be brought by a stockholder before an annual or special meeting of stockholders and with regard to the nomination by stockholders of candidates for election as directors. Further, our executive officers and directors beneficially own an amount of our outstanding shares of common stock such that if they were collectively to oppose a third party's acquisition proposal for, or a change in control of, the Company, such officers and directors may have sufficient voting power to be able to influence whether such an acquisition or change in control takes place, even if other stockholders would support such a sale or change of control. These provisions and circumstances may discourage potential acquisition proposals and could delay or prevent a change of control, including under circumstances in which our stockholders might otherwise receive a premium over the market price of our common stock. ²³~~We~~ **We** have never declared or paid cash dividends on our common stock. We do not intend to declare dividends for the foreseeable future, as we anticipate that we will reinvest any future earnings in the development and growth of our business. Therefore, investors will not receive any funds unless they sell their common stock, and stockholders may be unable to sell their shares on favorable terms or at all. We cannot assure you of a positive return on investment or that you will not lose the entire amount of your investment in our common stock. Our Second Amended and Restated Certificate of Incorporation authorizes the issuance of ~~100,175~~ **100,175**, 000, 000 shares of common stock, par value \$ 0. 001 per share. The future issuance of all or part of our remaining authorized common stock may result in substantial dilution in the percentage of our common stock held by our then existing stockholders. We may value any common stock issued in the future on an arbitrary basis. The issuance of common stock for future services or acquisitions or other corporate actions may have the effect of diluting the percentage ownership of our stockholders and, depending upon the prices at which such shares are sold or issued, on their investment in our common stock and, therefore, could have an adverse effect on any trading market for our common stock. ²³~~Sales~~ **Sales** of a substantial number of shares of our common stock in the public market or the perception that large sales of our shares could occur, could cause the market price of our common stock to decline or limit our future ability to raise capital through an offering of equity securities. The trading market for our common stock could be affected by whether and to what extent equity research analysts publish research or reports about us and our business. If one or more equity analysts cover us and publish research reports about

our common stock, the price of our stock could decline rapidly if one or more securities analysts downgrade our stock or if those analysts' issue or offer unfavorable commentary or cease publishing reports about us. If any of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our common stock price or trading volume to decline and our common stock to be less liquid. Our common stock is listed on..... of which could adversely affect our business. We are a smaller reporting company and a non-accelerated filer and we cannot be certain if the reduced disclosure requirements applicable to our filing status, as well as the exemption from the requirement to provide an auditor's attestation report regarding the effectiveness of our internal controls, will make our common stock less attractive to investors. We are a "smaller reporting company," meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$ 250 million measured as of the last business day of our most recently completed second fiscal quarter. "Smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. We are also a "non-accelerated filer," based on our eligibility as a "smaller reporting company" as well as having annual revenues of less than \$ 100 million in the most recent fiscal year for which audited financial statements are available. As a "non-accelerated filer," we are exempt from the provisions of Section 404 (b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" and as a "non-accelerated filer" may make it harder for investors to analyze our results of operations and financial prospects and may make our common stock a less attractive investment. 24