Risk Factors Comparison 2024-03-01 to 2023-02-27 Form: 10-K

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Violations of the Anti- Kickback Statute are punishable by the imposition of criminal fines, civil money penalties, treble damages, and / or exclusion from participation in federal health care programs. Many states have also enacted similar anti- kickback laws. The Anti- Kickback Statute and similar state laws and regulations are expansive. If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on our business, results of operations, financial condition, and our stock price. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, which could have a materially adverse effect on our business, results of operations and financial condition. We will consult counsel concerning the potential application of these and other laws to our business and our sales, marketing and other activities and will make good faith efforts to comply with them. However, given the broad reach of federal and state anti- kickback laws and the increasing attention given by law enforcement authorities, we are unable to predict whether any of our activities will be challenged or deemed to violate these laws. We are also subject to the physician self- referral laws, commonly referred to as the Stark law, which is a strict liability statute that generally prohibits physicians from referring Medicare patients to providers of " designated health services, " including clinical laboratories, with whom the physician or the physician' s immediate family member has an ownership interest or compensation arrangement, unless an applicable exception applies. Moreover, many states have adopted or are considering adopting similar laws, some of which extend beyond the scope of the Stark law to prohibit the payment or receipt of remuneration for the prohibited referral of patients for designated healthcare services and physician self- referrals, regardless of the source of the payment for the patient' s care. If it is determined that certain of our practices or operations violate the Stark law or similar statutes, we could become subject to civil and criminal penalties, including exclusion from the Medicare programs and loss of government reimbursement. The imposition of any such penalties could harm our business. 25Another development affecting the health care industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act' s " whistleblower " or " qui tam " provisions. The False Claims Act, as amended by the Fraud Enforcement and Recovery Act of 2009 and the Patient Protection and Affordable Care Act of 2010 (" Affordable Care Act "), imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. We submit claims for services performed at our laboratories. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third- party payor and not merely a federal health care program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improper use of Medicare numbers when detailing the provider of services, and allegations as to misrepresentations with respect to the services rendered. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly adversely affect our financial performance. Further, the beneficiary inducement prohibition of the federal Civil Monetary Penalty Law prohibits any entity from offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the entity knows or should know is likely to influence the beneficiary' s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services, including waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. On December 7, 2016, the OIG released amendments to the CMP. Some of the amendments may impact our business, such as allowing certain remuneration to financially needy individuals. Entities found in violation may be liable for civil monetary penalties of up to $ 10, 000 for each wrongful act. Although we believe that our sales and marketing practices are in material compliance with all applicable federal and state laws and regulations, relevant regulatory authorities may disagree and violation of these laws, or, our exclusion from such programs as Medicaid and other governmental programs as a result of a violation of such laws, could have a material adverse effect on our business, results of operations, financial condition and cash flows. Open Payments Program With the launch of Rayaldee, part of our business is now subject to the federal Physician Payments Sunshine Act under the Affordable Care Act, and its implementing regulations, which is implemented though the physicians Open Payments Program (the " Open Payments Program "). The Open Payments Program requires manufacturers of drugs, devices, biological and medical supplies covered by Medicare, Medicaid or the Children' s Health Insurance Program, to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals. Manufacturers must also report, on an annual basis, certain ownership

and investment interests held by physicians and their immediate family members and payments or other " transfers of value " made to such physician owners. A failure to report each payment, other transfer of value, or ownership / investment interest in a timely, accurate, and complete manner may result in civil monetary penalties of up to $ 150, 000 annually. Further, the " knowing " failure to report each payment, other transfer of value, or ownership / investment interest may result in a one million dollar annual penalty. Several other states and a number of countries worldwide have adopted or are considering the adoption of similar transparency laws. Any failure by us to implement proper procedures to track and report on a timely basis transfers of value to physicians and teaching hospitals could result in substantial penalties. Foreign Corrupt Practices Act We are also subject to the U. S. Foreign Corrupt Practices Act (" FCPA "), which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls. Our international activities create the risk of unauthorized payments or offers of payments by our employees, consultants, sales agents or distributors, even though they may not always be subject to our control. We discourage these practices by our employees and agents. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Any failure by us to adopt appropriate compliance procedures and ensure that our employees and agents comply with the FCPA and applicable laws and regulations in foreign jurisdictions could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions. 26MANUFACTURING AND QUALITY Our current pharmaceutical manufacturing facilities are located in Waterford, Ireland, Guadalajara, Mexico, Nesher, Israel, and Banyoles, Spain. In addition to such facilities, we have entered into agreements with various third parties for the formulation and manufacture of our pharmaceutical clinical supplies. These suppliers and their manufacturing facilities must comply with FDA regulations, current good laboratory practices and current good manufacturing practices (" cGMPs "). We plan to continue to outsource the manufacturing and formulation of our clinical supplies. The FDA and similar regulatory bodies may inspect our facilities and the facilities of those who manufacture on our behalf worldwide. If the FDA or similar regulatory bodies inspecting our facilities or the facilities of our suppliers find regulatory violations in manufacturing and quality control practices or procedures they may require us to cease partial or complete manufacturing operations until the violations are corrected. They may also impose restrictions on distribution of specific products until the violations are corrected. We are committed to providing high quality products to our customers, and we plan to meet this commitment by working diligently to continue implementing updated and improved quality systems and concepts throughout our organization. SALES & MARKETING Our diagnostics business includes BioReference' s significant sales and marketing team in the U. S. to drive growth and leverage new products. We have a highly specialized, field based sales and marketing team in the United States dedicated to the launch and commercialization of Rayaldee. We also have limited sales and marketing personnel in Ireland, Chile, Spain, Mexico and Israel. HUMAN CAPITAL RESOURCES Employees and Labor Relations As of December 31, 2023, we had 3, 930 full- time employees worldwide. With the exception of an immaterial number of employees of OPKO Spain, none of our employees are represented by a collective bargaining agreement. Overall, we consider our employee relations to be good. Health and Safety As a company in the healthcare industry, employee safety is a key focus of our leadership, communications, and training. We are required to comply with the College of American Pathologists and CLIA laboratory safety requirements in addition to OSHA regulations. With a clear leader in our EHS Manager, direction, standards of practice, training and auditing are consolidated and then disseminated to our managers, supervisors and all employees. We continually align our health and safety goals with those prescribed by applicable regulatory agencies and balance these goals with the needs of our employees. For example, during the COVID- 19 pandemic, we transitioned non-essential workers from the office to working from home, worked to ensure proper personal protective equipment using guidance provided by the CDC and OSHA where applicable, and we optimized our essential worker stations in our laboratories and other key process areas to provide for appropriate sanitation, social distancing and other appropriate measures to address the risks of the pandemic. Competitive Pay and Benefits We are committed to fair pay and we offer competitive medical benefits to all of our employees. Our U. S. health benefits package is above the competitive range for similar companies in our comparative industries and is one of the key tools we use for recruitment. 27Inclusion and Diversity We recognize the importance of and value diversity and inclusion in our workplace. As such, we have celebrated our diversity through employee and social media announcements in conjunction with company newsletters and employee events. We welcome discussions about our differences, embracing them and learning from them to move forward as a stronger, more productive organization. These differences are not limited to ethnicity or religion, but also in the way we process information and communicate with our colleagues. We are in a unique position where our workforce is already quite diverse and according to feedback from employee surveys, there is great pride and respect shared among our teams. In addition, one of our strategic business goals is to recognize and serve diverse communities. Through BioReference, we work closely with clients in these communities by offering excellent customer service and patient care. Talent Development We recognize it is important that our employees are able to develop and grow their careers. We have a Head of Learning and Training whose responsibility is to enhance employee training and development as well as to ensure compliance while working in a collaborative environment. In addition, we have changed recruitment strategies to source from more diverse channels, which we anticipate will lead to more candidate hiring options, enhance our recruitment platform and eventually strengthen employee retention. Code of Ethics We have

adopted a Code of Business Conduct and Ethics. We require all employees, including our principal executive officer, principal financial officer, principal accounting officer and other senior officers and our employee directors, to read and to adhere to the Code of Business Conduct and Ethics in discharging their work- related responsibilities. Employees are required to report any conduct that they believe in good faith to be an actual or apparent violation of the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at http: / / www. OPKO. com. Any amendment to, or waivers of, the Code of Business Conduct and Ethics will be disclosed on our website promptly following the date of such amendment or waiver. Available Information We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. Information that we file with the Securities and Exchange Commission is available at the SEC' s web- site at www. sec. gov. We also make available free of charge on or through our web site, at www. opko. com, our Annual Reports on Form 10- K, Quarterly Reports on Form 10- Q, Current Reports on Form 8- K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with the SEC. The information on our website is not, and shall not be deemed to be, a part hereof or incorporated into this or any of our other filings with the SEC. ITEM 1A. RISK FACTORS. You should carefully consider the risks described below, as well as other information contained in this report, including the ~~consolidated~~ **Consolidated** ~~financial~~ **Financial** ~~statements~~ **Statements** and the notes thereto and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The occurrence of any of the events discussed below could significantly and adversely affect our business, prospects, results of operations, financial condition, and cash flows. RISKS RELATED TO OUR BUSINESS We have had a history of operating losses and may not be able to achieve profitability in the near future. BioReference' s COVID- 19 testing volume positively impacted our profitability during 2020- 2021. Prior to 2020, we had incurred losses since our inception, and after achieving profitability for the years ended December 31, 2020 and 2021, we ~~incurrent~~ **incurred** a net loss for the ~~year~~ **years** ended December 31, 2022 **and 2023** . ~~We may~~ **In response to the global COVID- 19 pandemic, BioReference conducted a substantial amount of COVID- 19 testing that positively impacted our revenues 2020- 2021. Simultaneously, however, the volume of its core testing business decreased as a result of COVID- 10. During 2022- 2023, testing needs for COVID- 19 decleined as a result of declining infection rates and the normalization of living with COVID- 10 following the increase in accessibility to COVID- 19 vaccines and antiviral treatments. As COVID- 19 testing volumes decreased, we experienced a return to our core business testing, but growth in BioReference' s core business, however, has been gradual and has** not **offset the** ~~continue to generate~~ substantial **decline in** revenue from COVID- 19 testing **. Our pharmaceutical business** ~~as~~ **has** ~~vaccine use is adopted and infection rates decline, unless such decline is offset by significant revenue generation from our other income streams. We have~~ historically generated only limited revenue from operations and we may not generate substantial revenue from the sale of proprietary pharmaceutical products or certain of our diagnostic products for some time, if at all. Other than NGENLA (Somatrogon), which has been approved in **many territories including** the **U. S.,** EU, Japan, Canada and Australia, Rayaldee is our only **other proprietary** pharmaceutical product that has been approved for marketing in the U. S. or elsewhere. We continue to incur substantial research and development and general and administrative expenses related to our operations including our pre- clinical development activities and clinical trials. We may continue to incur losses from our operations in the future and these losses could increase as we continue our research activities and conduct development of, and seek regulatory approvals and clearances for, our product candidates, particularly if we are unable to generate or sustain profits and cash flow from sales of Rayaldee, NGENLA, or our operations at BioReference. If we are unable to generate or sustain profits and cash flow from our operations, our product candidates fail in clinical trials or do not gain regulatory approval or clearance, or if our approved products and product candidates do not achieve market acceptance, we may not achieve profitability. In particular, if we are unable to successfully commercialize Rayaldee or NGENLA, we may never generate substantial revenues from Rayaldee or NGENLA. **28We** ~~If we are unable to obtain FDA approval for Somatrogon (hGH- CTP) in the U. S., we will not be able to commercialize Somatrogon (hGH- CTP) in the U. S. and will therefore not generate revenues from NGENLA in the U. S. In addition, if we are required by the FDA to perform studies in addition to those we currently anticipate, our expenses will increase beyond current expectations and the timing of any potential product approval may be delayed. We~~ may require additional funding, which may not be available to us on acceptable terms, or at all. As of December 31, ~~2022~~ **2023** , we had cash and cash equivalents of $ ~~153~~ **95** . ~~2~~ **9** million. Prior to 2020, we had not generated sustained positive cash flows sufficient to offset our operating and research and development expenses and our primary sources of cash has been from the public and private placement of stock, the issuance of convertible notes and credit facilities available to us. While we have generated significant cash from operations as a result of testing related to the COVID- 19 pandemic, demand for our COVID- 19 related testing ~~has~~ waned ~~,~~ **during 2022** and **2023,** ~~we are unable to predict whether pricing~~ and ~~reimbursement policies for~~ **revenues from other sources have not offset the substantial decline in revenue from COVID- 19** testing ~~will sustain, or whether restrictions will be placed on elective procedures or if stay at home orders will be reinstated and accordingly, the sustainability of the cash flow is uncertain~~ . If we are unable to generate a sufficient amount of product and service revenue to finance our cash requirements for research, development and operations, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, or strategic collaborations. Our ability to obtain additional capital may depend on prevailing economic conditions and financial, business and other factors beyond our control, as well as our ability to comply with credit facilities and other loan requirements. The amended and restated credit agreement, dated August 30, 2021 (as amended, the " Credit Agreement ") with JPMorgan Chase Bank, N. A. (" CB ") governing our revolving credit facility with CB contains, and other agreements that govern our indebtedness may contain restrictive and financial covenants that impose restrictions on us and certain of our subsidiaries, including covenants that require us to maintain specified financial ratios. We have obtained waivers and / or amended our revolving credit facility with CB from time to time in the past to avoid a default under certain covenants, and our ability to comply with these financial covenants may be adversely affected in the future. Failure to comply with specified

financial covenants and other requirements could result in an event of default under our Credit Agreement and / or other lenders, which, if not cured or waived, could restrict us from utilizing the facility or accelerate any repayment obligations we may have under the facility and which could have a material adverse effect on our financial condition. Disruptions in the U. S. and global financial markets may also adversely impact the availability and cost of credit, as well as our ability to raise money in the capital markets. Economic conditions have been, and continue to be, volatile. Continued instability in these market conditions may limit our ability to replace, in a timely manner, maturing liabilities and access the capital necessary to fund and grow our business. There can be no assurance that additional capital will be available to us on acceptable terms, or at all, which could adversely impact our business, results of operations, liquidity, capital resources and financial condition. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or cease operations altogether. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants and other onerous terms. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our products and product candidates or grant licenses on terms that may not be favorable to us ~~. Our business has been, and may continue to be, affected by the coronavirus disease 2019 (COVID- 19) outbreak. The outbreak of the coronavirus disease 2019 (COVID- 19) evolved into a global pandemic, significantly affecting the U. S. and most countries around the world. In 2022, testing needs for COVID- 19 declined as a result of declining infection rates and the normalization of living with COVID- 19 following the increase in accessibility to COVID- 19 vaccines and antiviral treatments. The extent to which this coronavirus continues to impact our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the virus, including variants of the virus, and the actions to contain the spread of or to detect, prevent, or treat COVID- 19, among others. As a result of the demand for COVID- 19 testing, the Company' s overall testing volume increased significantly in 2020 and 2021, which positively impacted its operations in such years. Simultaneously, however, demand for tests that comprise the Company' s core testing business has declined. As the demand for COVID- 19 PCR testing declined in 2022, we have seen a gradual increase in the demand for services of our core testing business. The demand and duration of the need for COVID- 19 testing are uncertain, however, and the Company could experience significant volatility in its results of operations if the demand for testing increases again and the demand for the services provided by the Company' s core testing business decreases. We may also experience supply chain disruptions, including shortages, delays and price increases in testing equipment and supplies as a result of global disruptions in healthcare markets, which could materially adversely impact our business. It is also possible that the Company will experience an adverse impact on cash collections as a result of the COVID- 19 pandemic. COVID- 19 could also disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. The regulatory framework governing laboratories, diagnostic and pharmaceutical companies may be affected as governmental authorities divert resources to respond to the COVID- 19 outbreak, which may have an unanticipated and unforeseen impact on our operations. It is possible that the timing of regulatory submissions and approvals for our productswill be adversely impacted or delayed. With respect to our ongoing and planned clinical trials, restrictions and efforts to avoid further spread of COVID- 19 may present challenges to the conduct of these trials consistent with normally applicable approaches and good clinical practice standards, and although regulators including the FDA have offered guidance applicable during the COVID- 19 pandemic allowing for flexibility of standards in certain areas and alternate methods of meeting trial oversight obligations (for example, via remote monitoring), the potential impact of these challenges cannot be fully predicted at this time~~ . Our research and development activities may not result in commercially viable products. Many of our product candidates are in the early stages of development and are prone to the risks of failure inherent in drug, diagnostic, and medical device product development. These risks further include the possibility that such products would: • be found to be ineffective, unreliable, or otherwise inadequate or otherwise fail to receive regulatory approval; • be difficult or impossible to manufacture on a commercial scale; • be uneconomical to market or otherwise not be effectively marketed; • fail to be successfully commercialized if adequate reimbursement from government health administration authorities, private health insurers, and other organizations for the costs of these products is unavailable; • be impossible to commercialize because they infringe on the proprietary rights of others or compete with products marketed by others that are superior; or • fail to be commercialized prior to the successful marketing of similar products by competitors. The results of pre- clinical trials and previous clinical trials for our products may not be predictive of future results, and our current and planned clinical trials may not satisfy the requirements of the FDA or other non- U. S. regulatory authorities. Positive results from pre- clinical studies and early clinical trial experience should not be relied upon as evidence that later- stage or large- scale clinical trials will succeed. Likewise, there can be no assurance that the results of studies conducted by collaborators or other third parties will be viewed favorably or are indicative of our own future study results. We may be required to demonstrate with substantial evidence through well- controlled clinical trials that our product candidates are either (i) with respect to drugs or Class III devices, safe and effective for use in a diverse population for their intended uses or (ii) with respect to Class I or Class II devices, are substantially equivalent in terms of safety and effectiveness to devices that are already marketed under section 510 (k) of the Food, Drug and Cosmetic Act. Success in early clinical trials does not mean that future clinical trials will be successful because product candidates in later- stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other non- U. S. regulatory authorities despite having progressed through initial clinical trials. Further, our drug candidates may not be approved or cleared even if they achieve their primary endpoints in phase 3 clinical trials or registration trials. In addition, our diagnostic test candidates may not be approved or cleared, as the case may be, even though clinical or other data are, in our view, adequate to support an approval or clearance. The FDA or other non- regulatory authorities may disagree with our trial design and our

interpretation of data from pre- clinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval or clearance of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA and other non- U. S. regulatory authorities' approval. Any of these regulatory authorities may also approve or clear a product candidate for fewer or more limited indications or uses than we request or may grant approval or clearance contingent on the performance of costly post- marketing clinical trials. The FDA or other non- U. S. regulatory authorities may not approve the labeling claims necessary or desirable for the successful commercialization of our product candidates. ~~The~~ **29The** results of our clinical trials may show that our product candidates may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other non- U. S. regulatory authorities. We rely on licensing agreements with ~~Vifor~~ **VFMCRP**, Nicoya, and international partners for the international development and marketing of Rayaldee. Failure to maintain these license agreements could prevent us from successfully developing and commercializing Rayaldee worldwide. In May 2016, EirGen, our wholly- owned subsidiary, partnered with VFMCRP through a Development and License Agreement for the development and marketing of Rayaldee in Europe, Canada, Mexico, Australia, South Korea and certain other international markets. The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the product in human patients, provided that initially the license is for the use of the product for the treatment or prevention of secondary hyperparathyroidism related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency / deficiency. Effective May 5, 2020, we entered into the VFMCRP Amendment, pursuant to which the parties agreed to exclude Mexico, South Korea, the Middle East and all of the countries of Africa from the VFMCRP Territory. In May 2021, we further amended the VFMCRP Agreement for VFMCRP to assume all the rights to Rayaldee in Japan that had been previously granted to ~~JT~~ **Japan Tobacco**. In addition, the parties agreed to certain amendments to the milestone structure and to reduce minimum royalties payable. As revised, the Company is eligible to receive up to $ ~~17~~ **15** million in regulatory milestones and $ ~~210~~ **200** million in milestone payments tied to launch, pricing and sales of Rayaldee, and tiered, double- digit royalties. The success of the Development and License Agreement with VFMCRP is dependent in part on, among other things, the skills, experience and efforts of VFMCRP' s employees responsible for the project, VFMCRP' s commitment to the arrangement, and the financial condition of VFMCRP, all of which are beyond our control. In the event that VFMCRP, for any reason, including but not limited to early termination of the agreement, fails to devote sufficient resources to successfully develop and market Rayaldee internationally, our ability to earn milestone payments or receive royalty payments would be adversely affected, which would have a material adverse effect on our financial condition and prospects ~~. In October 2017, we entered into a Development and License Agreement (the " JT Agreement ") with JT under which JT was granted the exclusive rights for the development and commercialization of Rayaldee in Japan. The JT Agreement was terminated in May 2021~~. On June 18, 2021, EirGen and Nicoya entered into the Nicoya Agreement granting Nicoya the exclusive rights for the development and commercialization of the Nicoya Product in the Nicoya Territory. The license grant to Nicoya covers the therapeutic and preventative use of the Nicoya Product for SHPT in non- dialysis and hemodialysis chronic kidney disease patients. EirGen received an initial upfront payment of $ 5 million and was eligible to receive an additional $ 5 million upon the first to occur of (A) a predetermined milestone and (B) the first anniversary of the effective date (the " First Milestone "). However, the parties amended the Nicoya Agreement to provide that Nicoya pay $ 2. 5 million plus accrued interest by October 31, 2022 in partial satisfaction of the First Milestone, and $ 2. 5 million upon the earlier of (i) submission of the investigational new drug application by Nicoya or its affiliated party, and (ii) February 15, **2023. EirGen received the additional $ 2. 5 million upon Nicoya' s submission of an investigation new drug (IND) application to the center for drug evaluation of China in March** 2023. EirGen is also eligible to receive up to an additional aggregate amount of $ 115 million upon the achievement of certain development, regulatory and sales- based milestones by Nicoya for the Nicoya Product in the Nicoya Territory. EirGen will also receive tiered, double digit royalty payments at rates in the low double digits on net product sales within the Nicoya Territory and in the Nicoya Field. Nicoya will, at its sole cost and expense, be responsible for performing all development activities necessary to obtain all regulatory approvals for the Nicoya Product in the Nicoya Territory and for all commercial activities pertaining to the Nicoya Product in the Nicoya Territory. The success of the Nicoya Agreement is dependent in part on, Nicoya' s commitment to the product and our collaboration, as well as the experience of its employees, all of which are beyond our control. Our exclusive worldwide agreement with Pfizer is important to our business. If we do not successfully develop Somatrogon (hGH- CTP) and / or Pfizer does not successfully commercialize Somatrogon (hGH- CTP), our business could be adversely affected. In December 2014, we entered into a development and commercialization agreement with Pfizer relating to our long- acting hGH- CTP for the treatment of GHD in adults and children (the " Original Pfizer Agreement "). Under the **Restated** Pfizer Agreement, we are eligible to receive up to $ 275 million upon the achievement of certain regulatory milestones. Upon the launch of Somatrogon (hGH- CTP) for pediatric GHD, we are eligible to receive a regional, tiered gross profit share based upon sales of both Somatrogon (hGH- CTP) and Pfizer' s Genotropin ® (somatropin). We are responsible for the development program and are obligated to pay for the development up to an agreed cap, which has been exceeded. In May 2020, we entered into an Amended and Restated Development and Commercialization License Agreement (the " Restated Pfizer Agreement ") with Pfizer, effective January 1, 2020, pursuant to which the parties agreed, among other things, to share all costs for Manufacturing Activities, as defined in the Restated Pfizer Agreement, for developing a licensed product for the three indications included in the Restated Pfizer Agreement. The Restated Pfizer Agreement did not change the milestone payments, royalties and profit share provisions under the Original Pfizer Agreement. ~~While~~ hGH- CTP has been approved in the **U. S.,** EU, Japan, Canada and Australia under the name NGENLA ~~; Pfizer received a Complete Response Letter from the FDA in January 2022 in response to the BLA we and Pfizer submitted in 2020~~. We ~~and Pfizer have evaluated the FDA' s comments and will work with the agency to determine an appropriate path forward. In the event that the parties~~ are ~~able to obtain regulatory approvals to market a product covered by the Restated Pfizer Agreement, we will be~~ substantially dependent on Pfizer for the successful commercialization of such product. The success of

the collaboration arrangement with Pfizer is dependent in part on, among other things, the skills, experience and efforts of Pfizer' s employees responsible for the project and Pfizer' s commitment to the arrangement. The Restated Pfizer Agreement is terminable for any reason by Pfizer upon ninety days written notice to OPKO. In the event that Pfizer terminates the **Restated Pfizer** Agreement or fails to devote sufficient resources to continue to successfully develop and commercialize any product resulting from the collaboration arrangement, our ability to earn milestone payments or receive royalty or profit sharing payments would be adversely affected, which would have a material adverse effect on our financial condition and prospects and the trading prices of our securities. Our business is substantially dependent on our ability to achieve regulatory approval for the marketing of Somatrogon (hGH- CTP) in pediatric and adult patients and the commercial success of this product. On October 21, 2019, we and Pfizer announced that the global phase 3 trial evaluating Somatrogon (hGH- CTP) dosed once- weekly in pre- pubertal children with GHD met its primary endpoint of non- inferiority to daily Genotropin ® (somatropin) for injection, as measured by annual height velocity at 12 months. In addition, change in height standard deviation scores at six and 12 months, key secondary endpoints, were higher in the hGH- CTP dosed once- weekly cohort in comparison to the Genotropin ® (somatropin) dosed once- daily cohort. hGH- CTP was generally well tolerated in this study and comparable to Genotropin ® (somatropin) dosed once- daily with respect to the types, numbers and severity of the adverse events observed between the treatment arms. Although the primary endpoint and key secondary endpoints were met and the safety profile for hGH- CTP was consistent with that observed with those treated with Genotropin ® (somatropin), further testing and analysis, other clinical trials or patient use may undermine those determinations or unexpected side effects may arise. We previously announced topline data from an earlier phase 3, double blind, placebo controlled study of hGH- CTP in adults with GHD. Although there was no statistically significant difference between hGH- CTP and placebo on the primary endpoint of change in trunk fat mass from baseline to 26 weeks, after unblinding the study, we identified an exceptional value of trunk fat mass reduction in the placebo group that may have affected the primary outcome. We completed post- hoc sensitivity analyses for the adult study to evaluate the influence of outliers on the primary endpoint results using multiple statistical approaches. Analyses that excluded outliers showed a statistically significant difference between hGH- CTP and placebo on the change in trunk fat mass. Additional analyses that did not exclude outliers showed mixed results. There can be no assurance that the FDA or regulatory agencies in other countries will consider the sensitivity analysis or consider the product for approval for adults with GHD. ~~In January~~ **30In June** ~~2021~~ **2023** , ~~we and Pfizer announced that~~ the FDA **approved NGENLA (Somatrogon (** ~~had accepted for filing the BLA submission for the pediatric indication which was submitted in October 2020. In January 2022, Pfizer received a Complete Response Letter with respect to the pediatric indication. Pfizer and the Company have evaluated the best path forward for~~ hGH- CTP ~~in~~ **)) for** the ~~U~~ **treatment of pediatric GHD in the United States** . **However,** ~~S. but~~ there can be no ~~assurances~~ **assurance** that **NGENLA (Somatrogon (** ~~we will receive an approval for~~ hGH- CTP **))** for the treatment of pediatric GHD **will** ~~by the FDA. There can~~ be ~~no assurance~~ **commercially successful in the United States or** that we will obtain marketing approval for ~~either~~ the ~~pediatric or~~ adult indication. Before ~~they~~ **it** can be marketed, ~~our products in development~~ **Somatrogon (hGH- CTP) for the adult indication** must be approved by the FDA or similar foreign governmental agencies. The process for obtaining FDA marketing approval is both time- consuming and costly, with no certainty of a successful outcome. If we are unable to ~~achieve~~ **successfully commercialize NGENLA (Somatrogon (hGH- CTP)) to treat pediatric GHD and / or receive** regulatory approval for hGH- CTP to treat ~~pediatric patients or~~ adults with GHD, our business ~~will~~ **could** be significantly adversely impacted ~~, which could have a materially adverse effect on our business, financial condition and results of operations~~ . **NGENLA has been** ~~Japan' s Ministry of Health, Labour and Welfare~~ approved **in over 50 territories** ~~NGENLA (Somatrogon) for the long- term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone. In October 2021, Health Canada approved NGENLA for the long- term treatment of pediatric patients who have GHD, and Australia' s Therapeutic Goods Administration (TGA) approved NGENLA~~ for the long- term treatment of pediatric patients with growth disturbance. NGENLA may **nevertheless** fail to be successfully commercialized in these territories which would adversely impact our anticipated milestone payments under the Restated Pfizer Agreement and negatively affect our business, financial condition and results of operations ~~. Protein therapeutics have the potential to cause an immune or antibody response in patients. Antibodies may be transient or persistent and can have no effect or can neutralize the therapeutic effect of the protein. Antibodies that neutralize the activity of a therapeutic protein are known as neutralizing antibodies. As previously reported, low titers of anti- hGH- CTP non- neutralizing antibodies were noted over a four year period in 17 subjects, or approximately 35 % of the subjects, in our phase 2 open label extension study in children with GHD. The low titer non- neutralizing antibodies did not affect growth parameters or IGF- 1 levels in the patients. Immunogenicity testing and analysis for our phase 3 study is ongoing, and we expect that the full results of the study will be submitted for presentation at a future scientific meeting. The FDA reviews information on immune responses observed during clinical studies and the implications on safety and efficacy and could request additional studies or analyses of hGH- CTP or could decline to approve hGH- CTP for the indications we seek. Any of these occurrences could have a material adverse impact on our business, results of operation and financial condition. Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with NGENLA may develop antibodies to Somatrogon (hGH- CTP). Antibodies may be transient or persistant and can have no effect or can neutralize the therapeutic effect of the protein. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to Somatrogon (hGH- CTP) in the studies described below with the incidence of antibodies in other studies or to other products may be misleading~~ . Our business is dependent on our ability to develop, launch and generate revenue from our diagnostic products. Our business is dependent on our ability to successfully commercialize our diagnostic products. We are committing significant resources to the development and commercialization of these products, and there is no

guarantee that we will be able to successfully commercialize these tests. We have limited experience in developing, manufacturing, selling, marketing and distributing innovative diagnostic tests. If we are not able to successfully develop, market or sell diagnostic tests we develop for any reason, including the failure to obtain any required regulatory approvals, or obtain favorable reimbursement, we will not generate any meaningful revenue from the sale of such tests. Our business is substantially dependent on our ability to generate profits and cash flow from our laboratory operations. We have made a significant investment in our laboratory operations through the acquisition of BioReference. We compete in the clinical laboratory market primarily on the basis of the quality of testing, reporting and information systems, reputation in the medical community, the pricing of services and ability to employ qualified personnel. Our failure to successfully compete on any of these factors could result in the loss of clients and a reduction in our revenues and profits. To offset efforts by payors to reduce the cost and utilization of clinical laboratory services, we will need to obtain and retain new clients and business partners and grow the laboratory operations. In response to the global **COVID- 19** pandemic, BioReference conducted a substantial amount of COVID- 19 testing that positively impacted our revenues in previous years. Simultaneously, however, the volume of its core testing business decreased as a result of COVID- 19. ~~In~~ **During** 2022 **- 2023** , testing needs for COVID- 19 declined as a result of declining infection rates and the normalization of living with COVID- 19 following the increase in accessibility to COVID- 19 vaccines and antiviral treatments. As COVID- 19 testing volumes ~~decrease~~ **decreased** , we **experienced** ~~have seen~~ a return to our core business testing ~~.~~ **but** ~~Growth~~ **growth** in ~~our~~ **BioReference' s** core business, however, has been gradual **and has not offset the subtantial decline in revenue from COVID- 19 testing. We have engaged in significant cost reduction efforts, including reducing our workforce, in an effort to make the diagnostic business profitable and align our core business testing needs with the size of our operations** . If we are unable to return to and surpass adequate growth in our core business testing or client base, it could have a material adverse impact on our ability to generate profits and cash flow from the laboratory operations in the future. ~~Discontinuation~~ **31Discontinuation** or recalls of existing testing products, failure to develop, or acquire, licenses for new or improved testing technologies or our clients using new technologies to perform their own tests could adversely affect our business. From time to time, manufacturers discontinue or recall reagents, test kits or instruments used by us to perform laboratory testing. Such discontinuations or recalls could adversely affect our costs, testing volume and revenue. The clinical laboratory industry is subject to changing technology and new product introductions. Our success in maintaining a leadership position in genomic and other advanced testing technologies will depend, in part, on our ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. We may not be able to negotiate acceptable licensing arrangements and it cannot be certain that such arrangements will yield commercially successful diagnostic tests. If we are unable to license these testing methods at competitive rates, our research and development costs may increase as a result. In addition, if we are unable to license or develop new or improved technologies to expand our esoteric testing operations, our testing methods may become outdated when compared with our competition and testing volume and revenue may be materially and adversely affected. Currently, most clinical laboratory testing is categorized as " high " or " moderate " complexity, and thereby is subject to extensive and costly regulation under CLIA. The cost of compliance with CLIA makes it impractical for most physicians to operate clinical laboratories in their offices, and other laws limit the ability of physicians to have ownership in a laboratory and to refer tests to such a laboratory. Manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point- of- care laboratory equipment to physicians and by selling test kits approved for home or physician office use to both physicians and patients. Diagnostic tests approved for home use are automatically deemed to be " waived " tests under CLIA and may be performed in physician office laboratories as well as by patients in their homes with minimal regulatory oversight. Other tests meeting certain FDA criteria also may be classified as " waived " for CLIA purposes. The FDA has regulatory responsibility over instruments, test kits, reagents and other devices used by clinical laboratories and has taken responsibility from the Centers for Disease Control for classifying the complexity of tests for CLIA purposes. Increased approval of " waived " test kits could lead to increased testing by physicians in their offices or by patients at home, which could affect our market for laboratory testing services and negatively impact our revenues. If our competitors develop and market products that are more effective, safer or less expensive than our products and product candidates, our net revenues, profitability and commercial opportunities will be negatively impacted. If our competitors develop and market products or services that are more effective, safer or less expensive than our current and future products or services, our revenues, profitability and commercial opportunities will be negatively impacted. Numerous companies, including major pharmaceutical companies, specialty pharmaceutical companies and specialized biotechnology companies, are engaged in the development, manufacture and marketing of pharmaceutical products competitive with those that we intend to commercialize ourselves and through our partners. Competitors to our diagnostics business include major diagnostic companies, reference laboratories, molecular diagnostic firms, universities and research institutions. Most of these companies have substantially greater financial and other resources, larger research and development staffs and more extensive marketing and manufacturing organizations than ours. This enables them, among other things, to make greater research and development investments and efficiently utilize their research and development costs, as well as their marketing and promotion costs, over a broader revenue base. This also provides our competitors with a competitive advantage in connection with the highly competitive product acquisition and product in- licensing process. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities. We cannot predict with accuracy the timing or impact of the introduction of potentially competitive products or their possible effect on our sales. In addition to product development, testing, approval, and promotion, other competitive factors in the pharmaceutical and diagnostics industry include industry consolidation, product quality and price, product technology, reputation, customer service, and access to technical information. The clinical laboratory business is intensely competitive both in terms of price and service. Pricing of laboratory testing services is often one of the most significant factors used by health care providers and third- party payors in selecting a laboratory. As a result of the clinical laboratory

industry undergoing significant consolidation, larger clinical laboratory providers are able to increase cost efficiencies afforded by large- scale automated testing. This consolidation results in greater price competition. We may be unable to increase cost efficiencies sufficiently, if at all, and as a result, our net earnings and cash flows could be negatively impacted by such price competition. Additionally, we may also face changes in contracting with third party payors, fee schedules, competitive bidding for laboratory services or other actions or pressures reducing payment schedules as a result of increased or additional competition. If our competitors market products that are more effective, safer, easier to use or less expensive than our current products and product candidates, or that reach the market sooner than our products and product candidates, we may not achieve commercial success. In addition, the biopharmaceutical, diagnostic, medical device, and laboratory industries are characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete or less competitive. ~~Our~~ **32Our** product development activities could be delayed or stopped. We do not know whether our current or planned pre- clinical and clinical studies will be completed on schedule, or at all. Furthermore, we cannot guarantee that our planned pre- clinical and clinical studies will begin on time or at all. The commencement of our planned clinical trials could be substantially delayed or prevented by several factors, including: • a limited number of, and competition for, suitable patients with the particular types of disease required for enrollment in our clinical trials or that otherwise meet the protocol' s inclusion criteria and do not meet any of the exclusion criteria; • a limited number of, and competition for, suitable serum or other samples from patients with particular types of disease required for our validation studies; • a limited number of, and competition for, suitable sites to conduct our clinical trials; • delay or failure to obtain FDA or other non- U. S. regulatory authorities' approval or agreement to commence a clinical trial; • delay or failure to obtain sufficient supplies of the product candidate for our clinical trials; • requirements to provide the drugs, diagnostic tests, or medical devices required in our clinical trial protocols or clinical trials at no cost or cost, which may require significant expenditures that we are unable or unwilling to make; • delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; • delay or failure to obtain institutional review board (" IRB ") approval to conduct or renew a clinical trial at a prospective site; and • insufficient liquidity to fund our preclinical and clinical studies. The completion of our clinical trials could also be substantially delayed or prevented by several factors, including: • slower than expected rates of patient recruitment and enrollment; • failure of patients to complete the clinical trial; • unforeseen safety issues; • lack of efficacy evidenced during clinical trials; • termination of our clinical trials by one or more clinical trial sites; • inability or unwillingness of patients or medical investigators to follow our clinical trial protocols; • inability to monitor patients adequately during or after treatment; and • insufficient liquidity to fund ongoing studies. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB for any given site, or us. Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re- examination, which may impact the costs, timing, or successful completion of a clinical trial. Any failure or significant delay in commencing or completing clinical trials for our product candidates could materially harm our results of operations and financial condition, as well as the commercial prospects for our product candidates. ~~Our~~ **33Our** inability to meet regulatory quality standards applicable to our manufacturing and quality processes and to address quality control issues in a timely manner could delay the production and sale of our products or result in recalls of products. Manufacturing or design defects, unanticipated use of our products, or inadequate disclosure of risks relating to the use of our products could lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or required by governmental authorities) and could result, in certain cases, in the removal of a product from the market. Any recall could result in significant costs as well as negative publicity that could reduce demand for our products. Personal injuries relating to the use of our products can also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals. We are committed to providing high quality products to our customers, and we plan to meet this commitment by working diligently to continue implementing updated and improved quality systems and concepts throughout our organization. We cannot assure you that we will not have quality control issues in the future, which may result in warning letters and citations from the FDA. If we receive any warning letters from the FDA in the future, there can be no assurances regarding the length of time or cost it will take us to resolve such quality issues to our satisfaction and to the satisfaction of the FDA. If our remedial actions are not satisfactory to the FDA, we may have to devote additional financial and human resources to our efforts, and the FDA may take further regulatory actions against us including, but not limited to, assessing civil monetary penalties or imposing a consent decree on us, which could result in further regulatory constraints, including the governance of our quality system by a third party. Our inability to resolve these issues or the taking of further regulatory action by the FDA may weaken our competitive position and have a material adverse effect on our business, results of operations and financial condition. We manufacture pharmaceutical products in Ireland, Mexico, Spain, and Israel ~~. We also prepare necessary test reagents and assemble and package the cassettes for our point- of- care diagnostic system at our facility in Woburn, Massachusetts~~ . Any quality control issues at our facilities may weaken our competitive position and have a material adverse effect on our business results of operations and financial condition. As a medical device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with its Quality System Regulation (" QSR ") requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. In addition, most international jurisdictions have adopted regulatory approval and periodic renewal requirements for medical devices, and we must comply with these requirements in order to market our products in these jurisdictions. In the European

Community, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Further, some emerging markets rely on the FDA' s Certificate for Foreign Government (" CFG ") in lieu of their own regulatory approval requirements. Our failure, or our manufacturers' failure to meet QSR, ISO, or any other regulatory requirements or industry standards could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls or other consequences, which could, in turn, have a material adverse effect on our business, results of operations, and our financial condition. Failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services could adversely affect the results of our operations and adversely impact our reputation. The provision of clinical testing services, including anatomic pathology services, and related services, and the design, manufacture and marketing of diagnostic products involve certain inherent risks. The services that we provide and the products that we design, manufacture and market are intended to provide information for healthcare providers in providing patient care. Therefore, users of our services and products may have a greater sensitivity to errors than the users of services or products that are intended for other purposes. Similarly, negligence in performing our services can lead to injury or other adverse events. We may be sued under physician liability or other liability law for acts or omissions by our pathologists, laboratory personnel and other employees. We are subject to the attendant risk of substantial damages awards and risk to our reputation. Even after we receive regulatory approval or clearance to market our product candidates, the market may not be receptive to our products. Our products may not gain market acceptance among physicians, patients, health care payors and / or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including: • timing of market introduction of competitive products; • safety and efficacy of our product compared to other products; • prevalence and severity of any side effects; **34** • potential advantages or disadvantages over alternative treatments; • strength of marketing and distribution support; • price of our products, both in absolute terms and relative to alternative treatments; • availability of coverage and reimbursement from government and other third- party payors; • potential product liability claims; • limitations or warnings contained in a product' s regulatory authority- approved labeling; and • changes in the standard of care for the targeted indications for any of our products or product candidates, which could reduce the marketing impact of any claims that we could make following applicable regulatory authority approval. In addition, our efforts to educate the medical community and health care payors on the benefits of our products and product candidates may require significant resources and may never be successful. If our products do not gain market acceptance, it would have a material adverse effect on our business, results of operations, and financial condition. If our products are not covered and eligible for reimbursement from government and third party payors, we may not be able to generate significant revenue or achieve or sustain profitability. The coverage and reimbursement status of newly approved or cleared drugs, diagnostic and laboratory tests is uncertain, and failure of our pharmaceutical products, diagnostic tests or laboratory tests to be adequately covered by insurance and eligible for adequate reimbursement could limit our ability to market any future product candidates we may develop and decrease our ability to generate revenue from any of our existing and future product candidates that may be approved or cleared. The commercial success of our existing and future products in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations, and other third- party payors, as well as our ability to obtain in network status with such payors. The government and other third-party payors are increasingly attempting to contain health care costs by limiting both insurance coverage and the level of reimbursement for new drugs and diagnostic tests and restricting in network status of laboratory providers. As a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our products are less safe, less effective, or less cost- effective than existing or later- introduced products. These payors may also conclude that the overall cost of the procedure using one of our devices exceeds the overall cost of the competing procedure using another type of device, and third- party payors may not approve our products for insurance coverage and adequate reimbursement or approve our laboratory for in network status. The failure to obtain adequate coverage or any reimbursement for our products, or health care cost containment initiatives that limit or restrict reimbursement for our products, may reduce any future product revenue. Even though a drug (not administered by a physician) may be approved by the FDA, this does not mean that a Prescription Drug Plan (" PDP "), a private insurer operating under Medicare Part D, will list that drug on its formulary or will set a reimbursement level. PDPs are not required to make every FDA- approved drug available on their formularies. If our drug products are not listed on sufficient number of PDP formularies or if the PDPs' levels of reimbursement are inadequate, our business, results of operations and financial condition could be materially adversely affected. Private health plans, such as managed care plans and pharmacy benefit management programs may also not include our products on formularies, and may use other techniques that restrict access to our products or set a lower reimbursement rate than anticipated. A significant portion of our revenues come from government subsidized healthcare programs such as Medicaid and Medicare. Our failure to comply with applicable Medicare, Medicaid and other governmental payor rules could result in our inability to participate in a governmental payor program, our returning funds already paid to us, civil monetary penalties, criminal penalties and / or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payor program, a substantial portion of our consolidated revenues would be lost, which would adversely affect our results of operations and financial condition. In addition, if a federal government shutdown were to occur for a prolonged period of time, federal government payment obligations, including its obligations under Medicaid and Medicare, may be delayed. Similarly, if state government shutdowns were to occur, state payment obligations may be delayed. If the federal or state governments fail to make payments under these programs on a timely basis, our business could suffer, and our financial position, results of operations or cash flows may be materially affected. ~~As~~ **35As** we evolve from a company primarily involved in development to a company also involved in commercialization of our pharmaceutical and diagnostic products, as well as our laboratory testing services, we may encounter difficulties in managing our growth and expanding our operations successfully. As we advance our product

candidates and expand our business, we will need to expand our development, regulatory and commercial infrastructure. As our operations expand, we expect that we will need to manage additional relationships with various third parties, collaborators and suppliers. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to: manage our development efforts and operations effectively; manage our clinical trials effectively; hire, train and integrate additional management, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems; implement and manage an effective marketing strategy; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure. Our success is dependent to a significant degree upon the involvement, efforts and reputation of our Chairman and Chief Executive Officer, Phillip Frost, M. D. Our success is dependent to a significant degree upon the efforts of our Chairman and CEO, Phillip Frost, M. D., who is essential to our business. The departure of our CEO for whatever reason or the inability of our CEO to continue to serve in his present capacity could have a material adverse effect upon our business, financial condition and results of operations. Our CEO has a highly regarded reputation in the pharmaceutical and medical industry and attracts business opportunities and assists both in negotiations with acquisition targets, investment targets and potential joint venture partners. Our CEO has also provided financing to us, both in terms of a credit agreement and equity investments. If we lost his services or if his reputation was damaged for whatever reason, including, but not limited to, as a result of the allegations underlying various past SEC and shareholder lawsuits against us and Dr. Frost, our relationships with acquisition and investment targets, joint ventures, customers and investors, as well as our ability to obtain additional funding on acceptable terms, or at all, may suffer and could cause a material adverse impact on our operations, financial condition and the value of our Common Stock. If we fail to attract and retain key management and scientific personnel, we may be unable to successfully operate our business and develop or commercialize our products and product candidates. We will need to expand and effectively manage our managerial, operational, sales, financial, development, and other resources in order to successfully operate our business and pursue our research, development, and commercialization efforts for our products and product candidates. Our success depends on our continued ability to attract, retain, and motivate highly qualified management and pre- clinical and clinical personnel. The loss of the services or support of any of our senior management could delay or prevent the development and commercialization of our products and product candidates. Business combinations may disrupt our business, distract our management, may not proceed as planned, and may also increase the risk of potential third party claims and litigation. One aspect of our business strategy calls for acquisitions of businesses and assets that complement or expand our current business and potential disposition of assets and businesses that may no longer help us meet our objectives, which may present greater risks for us than those faced by peer companies that do not consider acquisitions or dispositions as a part of their business strategy. We may not be able to identify attractive acquisition opportunities or, when we decide to sell assets or a business, we may encounter difficulty in finding buyers or alternative exit strategies on acceptable terms in a timely manner, or at all. Even if we do identify attractive opportunities, we or the buyer may not be able to complete the acquisition due to financing or other market constraints. If we acquire an additional business, we could have difficulty integrating its operations, systems, management and other personnel and technology with our own. There may also be unasserted claims or assessments that we failed or were unable to discover or identify in the course of performing due diligence investigations of target businesses, resulting in a loss of value. Dispositions may increase our exposure to third parties claims or litigation that may require expenditure of additional resources or negatively affect the successful outcome of the disposition. Dispositions may also involve continued financial involvement in the divested business, such as through guarantees, indemnities or other financial obligations. Under these arrangements, performance by the divested businesses or other conditions outside of our control could affect our future financial results. Moreover, seeking acquisition and divestiture opportunities and evaluating and completing them require significant investment of time and resources, may disrupt the Company' s business and distract management' s attention from day- to- day business operations. ~~We~~ **36We** may fail to realize the anticipated benefits of the sale ~~of~~ **to** GeneDx. Pursuant to the GeneDx Merger Agreement, on April 29, 2022, GeneDx Holdings Corp. (formerly, Sema4), acquired GeneDx from us for an upfront payment of $ 150 million in cash, together with 80. 0 million ~~Closing Shares~~ **shares of GeneDx Holdings Common Stock** , subject to a customary purchase price adjustment mechanism. ~~Additionally, subject~~ **Subject** to GeneDx achieving certain revenue targets for the fiscal years ending December 31, 2022 and 2023, we are eligible to receive an earnout payment in cash or stock ~~,~~ **(** at GeneDx Holdings ~~'~~ **'** discretion ~~, (the " Milestone Consideration ")~~ equal to a maximum of 30. 9 million shares of GeneDx Holdings ~~' Class A common~~ **Common** ~~stock~~ **Stock** if paid in stock. Based on the closing price of GeneDx Holdings Common Stock on ~~the closing date~~ **April 29, 2022** , the total upfront consideration was approximately $ 322 million, and the total aggregate consideration, including the potential **GeneDx** Milestone Consideration, was approximately $ 447 million. ~~If~~ **We received 23. 1 million shares of Class A Common Stock as a result of** GeneDx ~~does~~ **satisfactorily achieving revenue targets as of December 31, 2022. As of the date of this Annual Report on Form 10- K however, we do** not ~~successfully~~ **anticipate that GeneDx will satisfy the revenue targets as of December 31, 2023 to** achieve ~~its growth objectives for 2023, some of the anticipated benefits of the sale may not be realized fully, as we may then~~ **the remaining GeneDx** ~~not be entitled to receive the full~~ Milestone Consideration **, so we may not receive some of the anticipated benefit of the disposition of GeneDx. In addition, as of December 31, 2023, the aggregate value of our investments in GeneDx Holdings based on the quoted market price of their respective shares of common stock and the number of shares held by us was $ 9. 8 million, which is significantly below the value of our investment in GeneDx Holdings as of the closing date of the GeneDx Transaction. There can be no guarantee that the price of GeneDx Holdings Common Stock will return to its value as of the closing date of the GeneDx Transaction. Fluctuations in the price of GeneDx Holdings Common Stock are subject to market fluctuations and other factors outside our control, which are not directly linked to the financial and operational performance of the Company, but the fluctuations in the value of this investment may adversely impact the Company' s financial condition and results of operations** . If the FDA or other applicable regulatory authorities approve generic products that compete with any of our

products or product candidates, the sale of our products or product candidates may be adversely affected. Once an NDA is approved, the product covered thereby becomes a " listed drug " which, in turn can be relied upon by potential competitors in support of an approval of an abbreviated new drug application, or ANDA, or 505 (b) (2) application. U. S. laws and other applicable policies provide incentives to manufacturers to create modified, non- infringing versions of a drug to facilitate the approval of an ANDA or other application for a generic substitute. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient (s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product or product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product or product candidate. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our products or product candidates would materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments that we have made in our products and product candidates. We rely on third parties to manufacture and supply our pharmaceutical and diagnostic products and product candidates. If our manufacturing partners are unable to produce our products in the amounts that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities we require. We expect to continue to depend on third- party contract manufacturers for the foreseeable future. Our products and product candidates require precise, high quality manufacturing. Any of our contract manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and other non- U. S. regulatory authorities to ensure strict compliance with QSR regulations for devices or cGMPs for drugs, and other applicable government regulations and corresponding standards relating to matters such as testing, quality control, and documentation procedures. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with QSR or cGMPs, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns, or other problems that could seriously harm our business. Any performance failure on the part of our contract manufacturers could delay clinical development or regulatory approval or clearance of our product candidates or commercialization of our products and product candidates, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third party for manufacturing may adversely affect our future profit margins. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer before it can begin manufacturing our products or product candidates. Such approval would result in additional non- clinical testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all. Independent clinical investigators and contract research organizations that we engage to conduct our clinical trials may not be diligent, careful or timely. We depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations are independent contractors and we will not be able to control, other than by contract, the amount of resources, including time, that they devote to products that we develop. If independent investigators fail to devote sufficient resources to the development of product candidates or clinical trials, or if their performance is substandard, it will delay the marketing approval or clearance and commercialization of any products that we develop. Further, the FDA requires that we comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research organizations fail to comply with good clinical practice, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. ~~Failure~~ **37Failure** of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations and good clinical practice procedures could adversely affect the clinical development of our product candidates and harm our business, results of operations, and financial condition ~~. If the validity of an informed consent from a subject was to be challenged, it may negatively impact our product development efforts. We take steps to ensure that all clinical data and genetic and other biological samples are collected from subjects who provide informed consent for the data and samples as required by applicable laws and we work to ensure that the subjects from whom our data and samples are collected do not retain any proprietary or commercial rights to the data or samples or any discoveries derived from them. However, because we may collect data and samples from countries that are governed by a number of different regulatory regimes, there are many complex legal questions relating to the adequacy of informed consent that we must continually address. The adequacy of any given subject' s informed consent may be challenged in the future, and any given informed consent may prove unlawful or otherwise inadequate for our purposes. Any findings against us, or our clinical collaborators, could obligate us to stop using some of our clinical samples, which in turn may hinder our product development efforts. Such a result would also likely involve legal challenges that may consume our management and financial resources~~ . Failure to timely or accurately bill and collect for our services could have a material adverse effect on our revenues and our business. Billing for laboratory testing services is extremely complicated and is subject to extensive and non- uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payors, such as patients, insurance companies, Medicare, Medicaid, physicians, hospitals and employer groups. Changes in laws and regulations and payor practices increase the complexity and cost of our billing process. Additionally, in the U. S., third- party payors generally require billing codes on claims for reimbursement that describe the services provided. For laboratory services, the American Medical Association establishes most of the billing codes using a data code set called Current Procedural Terminology, or CPT, codes and the World Health

Organization establishes diagnostic codes using a data set called International Statistical Classification of Diseases, or ICD- 10, codes. Each third- party payor generally develops payment amounts and coverage policies for their beneficiaries or members that ties to the CPT code established for the laboratory test and the ICD- 10 code selected by the ordering or performing physician. Therefore, coverage and reimbursement may differ by payor even if the same billing code is reported for claims filing purposes. For laboratory tests without a specific billing code, payors often review claims on a claim- by- claim basis and there are increased uncertainties as to coverage and eligibility for reimbursement. In addition to the items described above, third- party payors, including government programs, may decide to deny payment or recoup payments for testing that they contend was improperly billed or not medically necessary, against their coverage determinations, or for which they believe they have otherwise overpaid (including as a result of their own error), and we may be required to refund payments already received. Our revenues may be subject to retroactive adjustment as a result of these factors among others, including without limitation, differing interpretations of billing and coding guidance and changes by government agencies and payors in interpretations, requirements, and " conditions of participation " in various programs. We have in the ordinary course of business been the subject of recoupments by payors and have from time to time identified and reimbursed payors for overpayments. Incorrect or incomplete documentation and billing information, as well as the other items described above, among other factors, could result in non- payment for services rendered or having to pay back amounts incorrectly billed and collected. Further, the failure to timely or correctly bill could lead to various penalties, including: (1) exclusion from participation in the CMS and other government programs; (2) asset forfeitures; (3) civil and criminal fines and penalties; and (4) the loss of various licenses, certificates and authorizations necessary to operate our business, any of which could have a material adverse effect on our results of operations or cash flows. The information technology systems that we rely on may be subject to unauthorized tampering, cyberattack or other data security incidents that could impact our billing processes or disrupt our operations In addition to our internal information technology systems, we rely on the IT systems of certain third parties to whom we outsource certain of our services or functions, or with whom we store confidential information, including patient data. These IT systems are subject to potential cyberattacks or other security breaches. If such attacks are successful, they could disrupt our operations and result in unauthorized persons gaining access to confidential or proprietary information. A breach or security incident affecting these third parties could harm our business, results of operations and reputation, and subject us to liability, governmental investigation, significant damage to our reputation or otherwise adversely affect our business. ~~Although~~ **38Although** the Company has security measures implemented, cyber- attacks and threats against us and our third- party providers continue to evolve and are often not recognized until such attacks are launched against a potential target. A successful cybersecurity attack or other data security incident could result in the misappropriation and / or loss of confidential or personal information, create system interruptions, or deploy malicious software that attacks our systems. The unauthorized dissemination of sensitive personal information or proprietary or confidential information due to a breach of these IT systems could expose us or other third- parties to regulatory fines or penalties, litigation and potential liability, or otherwise harm our business. Any mitigation or remediation efforts that we undertake may require expenditures of significant resources and the diversion of the attention of management. In addition, we have taken, and continue to take, precautionary measures to reduce the risk of, and detect and respond to, future cyber threats, and prevent or minimize vulnerabilities in our IT systems. We have also taken, and will continue to take, measures to assess the cybersecurity protections implemented by our third- party providers. There can be no assurances that our precautionary measures or measures used by our third- party providers will prevent, contain or successfully defend against cyber or information security threats that could have a significant impact on our business, results of operations and reputation and subject us to liability. Healthcare plans have taken steps to control the utilization and reimbursement of healthcare services, including clinical test services. We also face efforts by non- governmental third- party payors, including healthcare plans, to reduce utilization and reimbursement for clinical testing services. The healthcare industry has experienced a trend of consolidation among healthcare insurance plans, resulting in fewer but larger insurance plans with significant bargaining power to negotiate fee arrangements with healthcare providers, including clinical testing providers. These healthcare plans and independent physician associations, may demand that clinical testing providers accept discounted fee structures or assume all or a portion of the financial risk associated with providing testing services to their members through capped payment arrangements. In addition, some healthcare plans limit the laboratory network to only a single national or regional laboratory to obtain improved fee- for- service pricing. There is also an increasing number of patients enrolling in consumer driven products and high deductible plans that involve greater patient cost- sharing. The increased consolidation among healthcare plans also has increased the potential adverse impact of ceasing to be a contracted provider with any such insurer. We expect continuing efforts to limit the number of participating laboratories in payor networks, reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services. These efforts, including future changes in third- party payor rules, practices and policies, or failing to become a contracted provider or ceasing to be a contracted provider to a healthcare plan, may have a material adverse effect on our business. If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed. Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop or license under the patent and other intellectual property laws of the U. S. and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize our products and product candidates. Because certain U. S. patent applications are confidential, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. For this and other reasons, we or our third- party collaborators may be unable to secure desired patent rights, thereby losing desired exclusivity. If licenses are not available to us on acceptable terms, we may not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability, or infringement of the third- party patent or otherwise circumvent the third- party patent. Our strategy depends on our ability to rapidly identify and seek

patent protection for our discoveries. In addition, we will rely on third- party collaborators to file patent applications relating to proprietary technology that we develop jointly during certain collaborations. The process of obtaining patent protection is expensive and time- consuming. If our present or future collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business will be adversely affected. Unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not guarantee that it is valid or enforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, unenforceable, or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology, pharmaceutical, and medical device companies. Any challenge to, finding of unenforceability or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management, and could have a material adverse effect on our business, results of operations and financial condition. ~~We~~ **39We** cannot assure you that any patents that have issued, that may issue, or that may be licensed to us will be enforceable or valid, or will not expire prior to the commercialization of our products and product candidates, thus allowing others to more effectively compete with us. Therefore, any patents that we own or license may not adequately protect our products and product candidates or our future products, which could have a material adverse effect on our business, results of operations, and financial condition. We cannot be assured that our filings for patent term extensions or supplementary protection certificates to potentially extend a patent term of a patent covering an approved drug or biological product will be granted in any particular jurisdiction in which the Company or its licensee obtains approval for a drug or biological product. If we are unable to protect the confidentiality of our proprietary information and know- how, the value of our technology and products could be adversely affected. In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know- how, and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality agreements with our employees, consultants, and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual' s relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants, or contractors use technology or know- how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition, and results of operations. We will rely heavily on licenses from third parties. Failure to comply with the provisions of these licenses could result in the loss of our rights under the license agreements. Many of the patents and patent applications in our patent portfolio are not owned by us, but are licensed from third parties. Such license agreements give us rights for the commercial exploitation of the patents resulting from the respective patent applications, subject to certain provisions of the license agreements. Failure to comply with these provisions could result in the loss of our rights under these license agreements. Our inability to rely on these patents and patent applications, which are the basis of our technology, would have a material adverse effect on our business, results of operations and financial condition. We license patent rights to certain of our technology from third- party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed. We have obtained and may in the future obtain licenses from third party owners that are necessary or useful for our business. We cannot guarantee that no third parties will step forward and assert inventorship or ownership in our in- licensed patents. In some cases, we may rely on the assurances of our licensors that all ownership rights have been secured and that all necessary agreements are intact or forthcoming. Our success will depend in part on our ability or the ability of our licensors to obtain, maintain, and enforce patent protection for our licensed intellectual property and, in particular, those patents to which we have secured exclusive rights in our field. We or our licensors may not successfully prosecute the patent applications which are licensed to us. Even if patents issue in respect of these patent applications, we or our licensors may fail to maintain these patents or may determine not to pursue litigation against other companies that are infringing these patents. Without protection for the intellectual property we have licensed, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business, results of operations and financial condition. ~~Our~~ **40Our** commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to develop, manufacture, use, sell, offer for sale or import products, or impair our competitive position. In addition, other entities may have or obtain patents or proprietary rights that cover our current research and preclinical studies. The U. S. case law pertaining to statutory exemptions to patent infringement for those who are using third party patented technology in the process of pursuing FDA regulatory approval changes over time. Lawsuits involving such exemptions are very fact intensive and it is currently unclear under U. S. case law whether preclinical studies would always qualify for such an exemption, and whether such exemptions would apply to research tools. To the extent that our current research and preclinical studies may be covered by the patent rights of others, the risk of suit may continue after such patents expire because the statute of limitations for patent infringement runs for six years. To the extent that a third party develops and patents technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available or may not be available on commercially reasonable terms, if at all. If licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we challenge the validity, enforceability or infringement of the third- party patent, or circumvent the third- party patent,

which would be costly and would require significant time and attention of our management. Third parties may have or obtain by license or assignment valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition, and results of operations. If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts. Third parties may sue us for infringing their patent rights. 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 proprietary rights of others. In addition, a third- party may claim that we have improperly obtained or used its confidential or proprietary information. Furthermore, in connection with our third- party license agreements, we may have agreed to indemnify the licensor for costs incurred in connection with litigation relating to intellectual property rights. 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 would divert our management' s efforts. 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. Our involvement in patent litigation and other proceedings could have a material adverse effect on our business, results of operations, and financial condition. If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. 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 of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. We have faced, and may in the future face, intellectual property infringement claims that could be time- consuming and costly to defend, and could result in our loss of significant rights and the assessment of treble damages. We may from time to time receive notices of claims of infringement and misappropriation or misuse of other parties' proprietary rights. Some of these additional claims may also lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third- party trade secrets, infringement by us of third- party patents and trademarks or the validity of our patents, will not be asserted or prosecuted against us. We may also initiate claims to defend our intellectual property or to seek relief on allegations that we use, sell, or offer to sell technology that incorporates third party intellectual property. Intellectual property litigation, regardless of outcome, is expensive and time- consuming, could divert management' s attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third party' s patent) to the party claiming infringement, develop non- infringing technology, stop selling our tests or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non- infringing technologies or license the proprietary rights on a timely basis could harm our business. It is possible that in the patent laws related to the field of genomic- based products and diagnostics and patents covering such products changes to permit the patenting of genes and / or gene based products and / or related diagnostic methods. In such a case, we might be required to pay royalties, damages and costs to firms who own the rights to these patents, or we might be restricted from using any of the inventions claimed in those patents. We may become subject to product liability claims for our diagnostic tests, clinical trials, pharmaceutical products and medical device products. Our success depends on the market' s confidence that we can provide reliable, high- quality pharmaceuticals, medical devices, and diagnostics tests. Our reputation and the public image of our products or technologies may be impaired if our products fail to perform as expected or our products are perceived as difficult to use. Our products are complex and may develop or contain undetected defects or errors. Furthermore, if a product or future product candidate harms people, or is alleged to be harmful, we may be subject to costly and damaging product liability claims brought against us by clinical trial participants, consumers, health care providers, corporate partners or others. We have product liability insurance covering commercial sales of current products and our ongoing clinical trials. Any defects or errors could lead to the filing of product liability claims, which could be costly and time- consuming to defend and result in substantial damages. If we experience a sustained material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could materially harm our business. We cannot assure you that our product liability insurance would protect our assets from the financial impact of defending a product liability claim. A product liability claim could have a serious adverse effect on our business, financial condition and results of operations. ~~Adverse~~ **41Adverse** results in material litigation matters or governmental inquiries could have a material adverse effect upon our business and financial condition. We may from time to time become subject in the ordinary course of business to material legal action related to, among other things, intellectual property disputes, professional liability, contractual and employee- related matters, as well as inquiries from governmental agencies and Medicare or Medicaid carriers requesting comment and information on allegations of billing irregularities and other matters that are brought to their attention through billing audits, third parties or other sources. The health care industry is subject to substantial federal and state government regulation and audit. From time to time, we may receive inquiries, document requests, Civil Investigative Demands (" CIDs ") or subpoenas from the Department of Justice, the Office of Inspector General and Office for Civil Rights (" OCR ") of the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, various payors and fiscal intermediaries, and other state and federal regulators regarding investigations, audits and reviews. We are currently responding

to CIDs, subpoenas or document requests for various matters relating to our laboratory operations. Some pending or threatened proceedings against us may involve potentially substantial amounts as well as the possibility of civil, criminal, or administrative fines, penalties, or other sanctions, which could be material. Settlements of suits involving the types of issues that we routinely confront may require monetary payments as well as corporate integrity agreements. For example, to resolve a investigation and related civil action concerning alleged fee- for- service claims for payment to Medicare, Medicaid, and the TRICARE Program, the Company and BioReference entered into (i) a settlement agreement (the " Settlement Agreement "), effective July 14, 2022, with the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services (" OIG- HHS "), and the Defense Health Agency, acting on behalf of the TRICARE Program, the Commonwealth of Massachusetts, the State of Connecticut, and the relator identified therein (" Relator "), and (ii) a Corporate Integrity Agreement, effective July 14, 2022 (the " CIA "), with the OIG- HHS. Under the Settlement Agreement, the Company and BioReference admitted only to having made payments to certain physicians and physicians' groups for office space rentals for amounts that exceeded fair market value, and that it did not report or return any such overpayments to the Federal Health Care Programs (the " Covered Conduct "). The Covered Conduct had commenced prior to the Company' s acquisition of BioReference in 2015. With the exception of the Covered Conduct, the Company and BioReference expressly denied the allegations of the Relator as set forth in her civil action, and the Company agreed to pay a total of $ 10, 000, 000 plus accrued interest from September 24, 2021 at a rate of 1. 5 % per annum. Under the CIA, which has a term of 5 years, BioReference is required to, among other things: (i) maintain a Compliance Officer, a Compliance Committee, board review and oversight of certain federal healthcare compliance matters, compliance programs, and disclosure programs; (ii) provide management certifications and compliance training and education; (iii) establish written compliance policies and procedures to meet federal health care program requirements; (iv) create procedures designed to ensure compliance with the Anti- Kickback Statute and / or Stark Law; (v) engage an independent review organization to conduct a thorough review of BioReference' s systems, policies, processes and procedures related to certain arrangements; (vi) implement a risk assessment and internal review process; (vii) establish a disclosure program for whistleblowers; and (viii) report or disclose certain events and physician payments. The Company' s or BioReference' s failure to comply with its obligations under the CIA could result in monetary penalties and the exclusion from Medicare, Medicaid, and TRICARE. Additionally, qui tam or " whistleblower " actions initiated under the civil False Claims Act may be pending but placed under seal by the court to comply with the False Claims Act' s requirements for filing such suits. The Company generally has cooperated, and intends to continue to cooperate, with appropriate regulatory authorities as and when investigations, audits and inquiries arise. Such legal actions and government investigations could result in substantial monetary damages, negatively impact our ability to obtain additional funding on acceptable terms, or at all, and damage to our reputation with customers, business partners and other third parties, all of which could have a material adverse effect upon our results of operations and financial position. Further, the legal actions and government investigations could damage our reputation with investors and adversely affect the trading prices of our securities **. The ongoing Russia- Ukraine conflict and the recent escalation of the Israel- Hamas conflict may adversely impact our business operations and financial performance. United States and global markets are experiencing volatility and disruption following the geopolitical instability resulting from the ongoing Russia- Ukraine conflict and the recent escalation of the Israel- Hamas conflict. In response to the ongoing Russia- Ukraine conflict, the North Atlantic Treaty Organization (" NATO ") deployed additional military forces to eastern Europe, and the United States, the United Kingdom, the European Union and other countries have announced various sanctions and restrictive actions against Russia, Belarus and related individuals and entities, including the removal of certain financial institutions from the Society for Worldwide Interbank Financial Telecommunication (SWIFT) payment system. Certain countries, including the United States, have also provided and may continue to provide military aid or other assistance to Ukraine and to Israel, increasing geopolitical tensions among a number of nations. The invasion of Ukraine by Russia and the escalation of the Israel- Hamas conflict and the resulting measures that have been taken, and could be taken in the future, by NATO, the United States, the United Kingdom, the European Union, Israel and its neighboring states and other countries have created global security concerns that could have a lasting impact on regional and global economies. Although the length and impact of the ongoing conflicts are highly unpredictable, they could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions and increased cyber attacks against U. S. companies. Additionally, any resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets. These ongoing conflicts and the resulting geopolitical instability can adversely impact our business operations and financial performance** . RISKS RELATED TO REGULATORY COMPLIANCE Our ability to successfully operate our laboratories and develop and commercialize certain of our diagnostic tests and LDTs will depend on our ability to maintain required regulatory licensures and comply with all the CLIA requirements. In order to successfully operate our laboratory business and offer certain of our diagnostic tests and LDTs, we must maintain our CLIA certification and comply with all the CLIA requirements. CLIA is designed to ensure the quality and reliability of clinical laboratories 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. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory' s CLIA certificate, which is necessary to conduct business, as well as significant fines and / or criminal penalties. Laboratories must undergo on- site surveys at least every two years, which may be conducted by the Federal CLIA program or by a private CMS approved accrediting agency such as CAP, among others. Our laboratories are also subject to regulation of laboratory operations under state clinical laboratory laws as will be any new CLIA- certified laboratory that we establish or acquire. State clinical laboratory laws may require that laboratories and / or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, such as California, Florida, Maryland,

New York, Pennsylvania and Rhode Island, require that laboratories obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. If we are unable to obtain and maintain licenses from states where required, we will not be able to process any samples from patients located in those states. Only Washington and New York States are exempt under CLIA, as these states have established laboratory quality standards at least as stringent as CLIA' s. Potential sanctions for violation of these statutes and regulations include significant fines and the suspension or loss of various licenses, certificates and authorizations, which could adversely affect our business and results of operations. ~~If~~ **42If** we fail to comply with CLIA requirements, HHS or state agencies could require us to cease diagnostic testing. Even if it were possible for us to bring our laboratories back into compliance after failure to comply with such requirements, we could incur significant expenses and potentially lose revenues in doing so. Moreover, new interpretations of current regulations or future changes in regulations under CLIA may make it difficult or impossible for us to comply with the CLIA classification, which would significantly harm our business and materially adversely affect our financial condition. The regulatory approval process is expensive, time consuming and uncertain and may prevent us or our collaboration partners from obtaining approvals for the commercialization of some or all of our product candidates. The research, testing, manufacturing, labeling, approval, selling, marketing, and distribution of drug products, diagnostic products, or medical devices are subject to extensive regulation by the FDA and other non- U. S. regulatory authorities, which regulations differ from country to country. In general, we are not permitted to market our product candidates in the U. S. until we receive approval of a BLA, an approval of an NDA, a clearance letter under the premarket notification process, or 510 (k) process, or an approval of a PMA from the FDA. To date, we have only submitted one NDA which was approved in June 2016, and one BLA which was approved for filing in January 2021. We have received FDA approval for our 4Kscore test for use in men age 45 and older who have not had a prior prostate biopsy or are biopsy negative and have an age- specific abnormal total PSA and / or abnormal digital rectal exam, but we have not received marketing approval or clearance **from FDA** for any of our other diagnostic product candidates that we currently plan to market ~~. In response to the BLA we submitted for Somatrogon (hGH- CTP) Pfizer received a Complete Response Letter, to which we and Pfizer are responding~~ . Obtaining approval of a NDA or PMA can be a lengthy, expensive, and uncertain process. With respect to medical devices, while the FDA reviews and clears a premarket notification in as little as three months, there is no guarantee that our products will qualify for this more expeditious regulatory process, which is reserved for Class I and II devices, nor is there any assurance that even if a device is reviewed under the 510 (k) process that the FDA will review it expeditiously or determine that the device is substantially equivalent to a lawfully marketed non- PMA device. If the FDA fails to make this finding, then we cannot market the device. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product. Furthermore, we are not permitted to make changes to a device approved through the PMA or 510 (k) which affects the safety or efficacy of the device without first submitting a supplement application to the PMA and obtaining FDA approval or cleared premarket notification for that supplement. In some cases, the FDA may require clinical trials to support a supplement application. In addition, failure to comply with FDA, non- U. S. regulatory authorities, or other applicable U. S. and non- U. S. regulatory requirements may, either before or after product approval or clearance, if any, subject our company to administrative or judicially imposed sanctions, including, but not limited to the following: ▪ restrictions on the products, manufacturers, or manufacturing process; ▪ adverse inspectional observations (Form 483), warning letters, or non- warning letters incorporating inspectional observations; ▪ civil and criminal penalties; ▪ injunctions; ▪ suspension or withdrawal of regulatory approvals or clearances; ▪ product seizures, detentions, or import bans; ▪ voluntary or mandatory product recalls and publicity requirements; ▪ total or partial suspension of production; ▪ imposition of restrictions on operations, including costly new manufacturing requirements; and ▪ refusal to approve or clear pending NDAs or supplements to approved NDAs, applications or pre- market notifications. Regulatory approval of an NDA or NDA supplement, BLA, PMA, PMA supplement or clearance pursuant to a pre- market notification is not guaranteed, and the approval or clearance process, as the case may be, is expensive and may, especially in the case of an NDA or PMA application, take several years. The FDA also has substantial discretion in the drug and medical device approval and clearance process. Failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre- clinical studies and clinical trials. The number of pre- clinical studies and clinical trials that will be required for FDA approval or clearance varies depending on the drug or medical device candidate, the disease or condition that the drug or medical device candidate is designed to address, and the regulations applicable to any particular drug or medical device candidate. The FDA can delay, limit or deny approval or clearance of a drug or medical device candidate for many reasons, including: ▪ a drug candidate may not be deemed safe or effective; ▪ a medical device candidate may not be deemed to be substantially equivalent to a lawfully marketed non- PMA device, in the case of a premarket notification; ▪ the FDA may not find the data from pre- clinical studies and clinical trials sufficient; ▪ the FDA may not approve our or our third- party manufacturer' s processes or facilities; or ▪ the FDA may change its approval or clearance policies or adopt new regulations. Beyond these risks, there is also a possibility that our licensees or collaborators could decide to discontinue a study at any time for commercial, scientific or other reasons. ~~The~~ **43The** terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products and product candidates, which could materially impair our ability to generate anticipated revenues. We, our approved or cleared products, and the manufacturers of our products are subject to continual review. Our approved or cleared products may only be promoted for their indicated uses. Marketing, labeling, packaging, adverse event reporting, storage, advertising, and promotion for our approved products will be subject to extensive regulatory requirements. We train our marketing and sales force against promoting our products for uses outside of the cleared or approved indications for use, known as " off- label uses. " If the FDA determines that our promotional materials or training constitute promotion of unsupported claims or an off- label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities

might take action if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and / or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. We and the manufacturers of our products are also required to comply with current Good Manufacturing Practices (" cGMP ") regulations or the FDA' s QSR regulations, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Moreover, device manufacturers are required to report adverse events by filing Medical Device Reports with the FDA, which reports are publicly available. Further, regulatory agencies must approve manufacturing facilities before they can be used to manufacture our products, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non- U. S. regulatory authorities, or if previously unknown problems with our products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions. Furthermore, any limitation on indicated uses for a product or product candidate or our ability to manufacture and promote a product or product candidate could significantly and adversely affect our business, results of operations, and financial condition. In addition, the FDA and other non- U. S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay marketing approval or clearance of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our products or product candidates and we may not achieve or sustain profitability, which would materially impair our ability to generate anticipated revenues. If we fail to comply with complex and rapidly evolving laws and regulations, we could suffer penalties, be required to pay substantial damages or make significant changes to our operations. We are subject to numerous federal and state regulations, including, but not limited to: • federal and state laws applicable to billing and claims payment; • federal and state laboratory anti- mark- up laws; • federal and state anti-kickback laws; • physician self- referral law; • federal and state false claims laws; • federal self- referral and financial inducement prohibition laws, commonly known as the Stark Law, and the state equivalents; • federal and state laws governing laboratory licensing and testing, including CLIA; • federal and state laws governing the development, use and distribution of LDTs; • HIPAA, along with the revisions to HIPAA as a result of the amendments from the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH Act "), and analogous state laws and non- US laws, including the General Data Protection Regulation; • federal, state and foreign regulation of privacy, security, electronic transactions and identity theft; • federal, state and local laws governing the handling, transportation and disposal of medical and hazardous waste; • Occupational Safety and Health Administration rules and regulations; • changes to laws, regulations and rules as a result of the implementation and / or repeal of part or all of 2010 Health Care Reform Legislation; and • changes to other federal, state and local laws, regulations and rules, including tax laws. ~~If~~ **44If** we fail to comply with existing or future applicable laws and regulations, we could suffer civil or criminal penalties, including the loss of our licenses to operate our laboratories and our ability to participate in federal and state healthcare programs. Different interpretations and enforcement policies of existing statutes and regulations applicable to our business could subject our current practices to allegations of impropriety or illegality, or could require us to make significant changes to our operations. Under the False Claims Act (" FCA "), whistleblower or qui tam provisions allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically and we may be subject to such suits. Violations of the FCA could result in enormous economic liability and could have a material impact on us. As a result of political, economic, and regulatory influences, the healthcare delivery industry in the U. S. is under intense scrutiny and subject to fundamental changes. We cannot predict which reform proposals will be adopted, when they may be adopted, or what impact they may have on us. The costs associated with complying with federal and state regulations could be significant and the failure to comply with any such legal requirements could have a material adverse effect on our financial condition, results of operations, and liquidity. Failure to maintain the security of patient- related information or compliance with security requirements could damage our reputation with customers, cause us to incur substantial additional costs and become subject to litigation. Pursuant to HIPAA, including the HITECH amendments thereunder, and certain similar state laws, we must comply with comprehensive privacy and security standards with respect to the use and disclosure of protected health information. If we do not comply with existing or new laws and regulations related to protecting privacy and security of personal or health information, we could be subject to monetary fines, civil penalties, or criminal sanctions. We may also be required to comply with the data privacy and security laws of other countries in which we operate or from which we receive data transfers, including the General Data Protection Regulation (" GDPR "), which affects our European operations and possibly our laboratory and clinical development operations. The GDPR, which is wide- ranging in scope, governs the collection and use of personal data in the European Union and imposes operational requirements for companies that receive or process personal data of residents of the European Union that are different than those currently in place in the European Union. We have implemented policies and procedures required to comply with the new EU regulations but may be subject for penalties if we are found to be non- compliant. We have had data and security breaches in the ordinary course and such breaches may continue to happen from time to time despite our best efforts to prevent such breaches and safeguard private information. Some of these other data and security breaches have been reported to OCR and we have received requests for information from OCR in connection with certain of these matters, or we are awaiting discussion, investigation or action by OCR. Any action by OCR may require us to pay fines or take remedial actions that may be expensive and require the attention of management, any of which may have a material adverse effect on us and our results of operations. We have and will continue to receive certain personal and financial information about our clients and their patients. In addition, we depend upon the secure transmission of confidential information over public networks. While we take reasonable and prudent steps to protect this protected information, a compromise in our security systems that results in client or patient personal

information being obtained by unauthorized persons or our failure to comply with security requirements for financial transactions could adversely affect our reputation with our clients and result in litigation against us or the imposition of penalties, all of which may adversely impact our results of operations, financial condition and liquidity. Failure to comply with environmental, health and safety laws and regulations, including the Federal Occupational Safety and Health Administration Act, the Needlestick Safety and Prevention Act and the Comprehensive Medical Waste Management Act, could result in fines and penalties and loss of licensure, and have a material adverse effect upon our business. We are subject to licensing and regulation under federal, state and local laws and regulations relating to the protection of the environment and human health and safety, including laws and regulations relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and radioactive materials, as well as regulations relating to the safety and health of laboratory employees. The Federal Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including clinical laboratories, whose workers may be exposed to blood- borne pathogens such as HIV and the hepatitis B virus. These requirements are designed to minimize exposure to, and transmission of, blood- borne pathogens. In addition, the Needlestick Safety and Prevention Act requires, among other things, that we include in our safety programs the evaluation and use of engineering controls such as safety needles if found to be effective at reducing the risk of needlestick injuries in the workplace. Waste management is subject to federal and state regulations governing the transportation and disposal of medical waste including bodily fluids. In New Jersey, we are subject to the Comprehensive Medical Waste Management Act, which requires us to register as a generator of special medical waste. All of our medical waste is disposed of by a licensed interstate hauler. These records are audited by the State of New Jersey on a yearly basis. We are also subject to the Federal Hazardous Materials Transportation Law, and the Hazardous Materials Regulations. The federal government has classified hazardous medical waste as hazardous materials for the purpose of these regulations. ~~Failure~~ **45Failure** to comply with such federal, state and local laws and regulations could subject us to denial of the right to conduct business, fines, criminal penalties and / or other enforcement actions, any of which could have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements us, which may be costly. Our failure or the failure of third- party payors or physicians to comply with ICD- 10- CM Code Set, and our failure to comply with other emerging electronic transaction standards could adversely impact our business. We continue our assessment of information systems, applications and processes for compliance with ICD- 10- CM Code Set requirements. Clinical laboratories are typically required to submit health care claims with diagnosis codes to third party payors. The diagnosis codes must be obtained from the ordering physician for clinical laboratory testing and from the interpreting pathologist for anatomic pathology services. Our failure or the failure of third party payors or physicians to comply with these requirements could have an adverse impact on reimbursement, delay sales and cash collections. Also, the failure of our IT systems to keep pace with technological advances may significantly reduce our revenues or increase our expenses. Public and private initiatives to create healthcare information technology (" HCIT ") standards and to mandate standardized clinical coding systems for the electronic exchange of clinical information, including test orders and test results, could require costly modifications to our existing HCIT systems. If we fail to adopt or delay in implementing HCIT standards, we could lose customers and business opportunities. Failure to comply with complex federal and state laws and regulations related to submission of claims for clinical laboratory services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs. We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for clinical laboratory services, including those that relate to coverage of our services under Medicare, Medicaid and other governmental health care programs, the amounts that may be billed for our services and to whom claims for services may be submitted. These rules may also affect us in light of the practice management products that we market, to the extent that these products are considered to affect the manner in which our customers submit their own claims for services. Submission of our claims is particularly complex because we provide both anatomic pathology services and clinical laboratory tests, which generally are paid using different reimbursement principles. The clinical laboratory tests are often paid under a clinical laboratory fee schedule, and the anatomic pathology services are often paid under a physician fee schedule. Our failure to comply with applicable laws and regulations could result in our inability to receive payment for our services or result in attempts by third- party payors, such as Medicare and Medicaid, to recover payments from us that have already been made. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including substantial civil money penalties for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare and Medicaid. Government authorities may also assert that violations of laws and regulations related to submission or causing the submission of claims violate the FCA or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. Under the FCA, whistleblower or qui tam provisions allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically and we may be subject to such suits. Violations of the FCA could result in enormous economic liability. The FCA provides that all damages are trebled, and each false claim submitted is subject to a penalty of up to $ 21, 916. For example, we could be subject to FCA liability if it was determined that the services we provided were not medically necessary and not reimbursable, particularly if it were asserted that we contributed to the physician' s referrals of unnecessary services to us. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by an entity for services that we performed if we were found to have knowingly participated in the arrangement that resulted in submission of the improper claims. Changes in regulation and policies, including increasing downward pressure on health care reimbursement, may adversely affect reimbursement for diagnostic services and could have a material adverse impact on our business. Reimbursement levels for health care services are subject to continuous and often unexpected changes in policies, and we face a variety of efforts by government payors to reduce utilization and reimbursement for diagnostic testing services. Changes in governmental reimbursement may result from

statutory and regulatory changes, retroactive rate adjustments, administrative rulings, competitive bidding initiatives, and other policy changes. The U. S. Congress has considered, at least yearly in conjunction with budgetary legislation, changes to one or both of the Medicare fee schedules under which we receive reimbursement, which include the physician fee schedule for anatomical pathology services, and the clinical laboratory fee schedule for our clinical laboratory services. For example, currently there is no copayment or coinsurance required for clinical laboratory services, although there is for our services that are paid under the physician fee schedule. However, Congress has periodically considered imposing a 20 percent coinsurance on laboratory services. If enacted, this would require us to attempt to collect this amount from patients, although in many cases the costs of collection would exceed the amount actually received. ~~The~~ **46The** Center for Medicare and Medicaid Services (“ CMS ”) pays laboratories on the basis of a fee schedule that is reviewed and re- calculated on an annual basis. CMS may change the fee schedule upward or downward on billing codes that we submit for reimbursement on a regular basis. Our revenue and business may be adversely affected if the reimbursement rates associated with such codes are reduced. Even when reimbursement rates are not reduced, policy changes add to our costs by increasing the complexity and volume of administrative requirements. Medicaid reimbursement, which varies by state, is also subject to administrative and billing requirements and budget pressures. In recent years, state budget pressures have caused states to consider several policy changes that may impact our financial condition and results of operations, such as delaying payments, reducing reimbursement, restricting coverage eligibility and service coverage, and imposing taxes on our services. Third party payors are increasingly challenging established prices, and new products that are more expensive than existing treatments may have difficulty finding ready acceptance unless there is a clear therapeutic benefit. On April 1, 2014, the PAMA was enacted into law. Under PAMA, Medicare payment for clinical diagnostic laboratory tests is established by calculating a weighted mean of private payor rates. Effective January 1, 2018, clinical laboratory fee schedule rates are based on weighted median private payor rates as required by PAMA. Even though the permitted annual decrease are capped through 2023, the cap does not apply to new tests or new advanced diagnostic tests. We cannot assure you that any of our products will be considered cost effective, or that reimbursement will be available or sufficient to allow us to sell them competitively and profitably. The federal government is faced with significant economic decisions in the coming years. Some solutions being offered in the government could substantially change the way laboratory testing is reimbursed by government entities. We cannot be certain what or how any such government changes may affect our business. Medicare legislation and future legislative or regulatory reform of the health care system may affect our ability to sell our products profitably. In the U. S., there have been a number of legislative and regulatory initiatives, at both the federal and state government levels, to change the healthcare system in ways that, if approved, could affect our ability to sell our products and provide our laboratory services profitably. As such, we cannot assure you that reimbursement payments under governmental and private third party payor programs will remain at levels comparable to present levels or will be sufficient to cover the costs allocable to patients eligible for reimbursement under these programs. Any changes that lower reimbursement rates under Medicare, Medicaid or private payor programs could negatively affect our business. Most significantly, on March 23, 2010, President Obama signed into law both the Affordable Care Act and the reconciliation law known as Health Care and Education Affordability Reconciliation Act (the “ Reconciliation Act ”) and, combined we refer to both Acts as the “ 2010 Health Care Reform Legislation. ” The constitutionality of the 2010 Health Care Reform Legislation was confirmed on June 28, 2012 by the Supreme Court of the U. S. It is uncertain whether any efforts to amend the Affordable Care Act will be successful or enacted into law, and if enacted, what the impact might be on our business. It is also uncertain how the current administration intends to alter 2010 Health Care Reform Legislation, if at all including whether regulatory changes to the implementation of the 2010 Health Care Reform Legislation will restrict patient access to affordable insurance or other third- party payor sources and impact their access to novel, biosimilar and complex generic products. In addition, litigation may prevent some or all of the legislation from taking effect. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation. To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the U. S. Health and Human Services Department Office of Inspector General (the “ OIG ”), have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program. In addition, certain states, such as New York, require that certain health care providers have a compliance program that generally adheres to the standards set forth in a model compliance program. Also, under the 2010 Health Care Reform Legislation, the U. S. Department of Health and Human Services, or HHS, requires suppliers, such as us, to adopt, as a condition of Medicare participation, compliance programs that meet a core set of requirements. While we have adopted U. S. healthcare compliance and ethics programs that generally incorporate the OIG’ s recommendations and train our employees in such compliance, having such a program can be no assurance that we will avoid any compliance issues. ~~RISKS~~ **47RISKS** RELATED TO INTERNATIONAL OPERATIONS Failure to obtain regulatory approval outside the U. S. will prevent us from marketing our products and product candidates abroad. We intend to market certain of our products and product candidates in non- U. S. markets. In order to market our products and product candidates in the European Union and many other non- U. S. jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non- U. S. regulatory authorities, the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval or clearance. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non- U. S. regulatory authority does not ensure approval by other regulatory authorities in other countries or by the FDA. The non- U. S. regulatory approval process may include all of the risks associated with obtaining FDA approval or clearance. We may not obtain non- U. S. regulatory approvals on a timely basis, if at all. We may not be able to file for non- U. S. regulatory approvals and may not receive necessary approvals to commercialize our products and product candidates in any market, which would have a material adverse effect on our business, results of operations and financial condition. Non- U. S. governments often impose strict price controls, which may adversely

affect our future profitability. We intend to seek approval to market certain of our products and product candidates in both the U. S. and in non - U. S. jurisdictions. If we obtain approval in one or more non- U. S. jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug or medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product and product candidates to other available products. If reimbursement of our products and product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to generate revenues and achieve or sustain profitability, which would have a material adverse effect on our business, results of operations and financial condition. Potential political, economic and military instability in the State of Israel, where we have office, laboratory and manufacturing operations, may adversely affect our results of operations. We maintain office, laboratory and manufacturing facilities in the State of Israel. Political, economic and military conditions in Israel may directly affect our ability to conduct business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its neighbors. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could affect adversely our operations. Ongoing and revived hostilities or other Israeli political or economic factors could harm our operations and product development and cause our revenues to decrease. Due to the international scope of our business activities, our results of operations may be significantly affected by currency fluctuations. We derive a significant portion of our consolidated net revenues from international sales, subjecting us to risks relating to fluctuations in currency exchange rates. Currency variations can adversely affect margins on sales of our products in countries outside of the U. S. and margins on sales of products that include components obtained from suppliers located outside of the U. S. Through our subsidiaries, we operate in a wide variety of jurisdictions. Certain countries in which we operate or may operate have experienced geopolitical instability, economic problems and other uncertainties from time to time. To the extent that world events or economic conditions negatively affect our future sales to customers in these and other regions of the world, or the collectability of receivables, our future results of operations, liquidity and financial condition may be adversely affected. We may manage exposures arising in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. Certain firmly committed transactions are hedged with foreign exchange forward contracts whereby exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. However, our subsidiaries receive their income and pay their expenses primarily in their local currencies. To the extent that transactions of these subsidiaries are settled in their local currencies, a devaluation of those currencies versus the U. S. dollar could reduce the contribution from these subsidiaries to our consolidated results of operations as reported in U. S. dollars. For financial reporting purposes, such depreciation will negatively affect our reported results of operations since earnings denominated in foreign currencies would be converted to U. S. dollars at a decreased value. While we have employed economic cash flow and fair value hedges to minimize the risks associated with these exchange rate fluctuations, the hedging activities may be ineffective or may not offset more than a portion of the adverse financial impact resulting from currency variations. Accordingly, we cannot assure you that fluctuations in the values of the currencies of countries in which we operate will not materially adversely affect our future results of operations. ~~We~~ **48We** may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business. We are subject to the FCPA and other laws that prohibit U. S. companies or their agents and employees from providing anything of value to a foreign official or political party for the purposes of influencing any act or decision of these individuals in their official capacity to help obtain or retain business, direct business to any person or corporate entity or obtain any unfair advantage. We have operations and agreements with third parties and we generate sales internationally. Our international activities create the risk of unauthorized and illegal payments or offers of payments by our employees, consultants, sales agents or distributors, even though they may not always be subject to our control. We discourage these practices by our employees and agents. However, our existing safeguards and any future improvements may prove to be less than effective, and our employees, consultants, sales agents or distributors may engage in conduct for which we might be held responsible. Any failure by us to adopt appropriate compliance procedures and ensure that our employees and agents comply with the FCPA and applicable laws and regulations in foreign jurisdictions could result in substantial penalties or restrictions on our ability to conduct business in certain foreign jurisdictions. Violations of the FCPA may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, operating results and financial condition. In addition, the U. S. government may seek to hold our Company liable for successor liability FCPA violations committed by companies in which we invest or that we acquire. We are subject to risks associated with doing business globally. Our operations, both within and outside the U. S., are subject to risks inherent in conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks differ in some respects from those associated with our U. S. business and our exposure to such risks may increase if our international business continues to grow. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government tenders that are held annually in many cases, nationalization, increasingly complex labor environments, expropriation and other governmental actions, changes in taxation, including legislative changes in U. S. and international taxation of income earned outside of the U. S., importation limitations, export control restrictions, violations of U. S. or local laws, including the FCPA, dependence on a few government entities as customers, pricing restrictions, economic destabilization, political and economic instability and disruption or destruction in a significant geographic region- due to the location of manufacturing facilities, distribution facilities or customers- regardless of cause, including war, terrorism, riot, civil insurrection or social unrest, or natural or man- made disasters, including famine, flood, fire, earthquake, storm or disease. Our

international business is subject to both U. S. and foreign laws and regulations, including, without limitation, regulations relating to import- export controls, technology transfer restrictions, repatriation of earnings, data privacy and protection, investment, exchange rates and controls, the FCPA and other anti- corruption laws, the anti- boycott provisions of the U. S. Export Administration Act, labor and employment, works councils and other labor groups, taxes, environment, security restrictions, intellectual property, changes in taxation, including legislative changes in U. S. and international taxation of income earned outside of the U. S., handling of regulated substances, and other commercial activities. Failure by us, our employees, affiliates, partners or others with whom we work to comply with these laws and regulations could result in administrative, civil or criminal liabilities. New regulations and requirements, or changes to existing ones in the various countries in which we operate can significantly increase our costs and risks of doing business internationally. Failure to comply with the laws and regulations that affect our global operations, could have an adverse effect on our business, financial condition or results of operations. Changes in regulations, political leadership and environment, or security risks may dramatically affect our ability to conduct or continue to conduct business in international markets. Our international business may also be impacted by changes in foreign national policies and priorities, which may be influenced by changes in the environment, geopolitical uncertainties, government budgets, and economic and political factors more generally, any of which could impact funding for programs or delay purchasing decisions or customer payments. The occurrence and impact of these factors is difficult to predict, but one or more of them could have a material adverse effect on our financial position, results of operations and / or cash flows. ~~RISKS~~ **49RISKS** RELATED TO ACQUISITIONS AND INVESTMENTS We have a large amount of goodwill and other intangible assets on our balance sheet that are subject to periodic impairment evaluations. We have a large amount of goodwill and other intangible assets and we are required to perform an annual, or in certain situations a more frequent, assessment for possible impairment for accounting purposes. At December 31, ~~2022~~ **2023**, we have goodwill and other intangible assets of $ ~~1~~ **0**. ~~6~~ **8** billion. Goodwill is tested at least annually for impairment or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors include our share price, our financial performance compared to budgets, long- term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test previously performed. ~~Sales~~ **Based on the current financial performance** of **our diagnostics segment and our Ireland reporting unit, which includes Eirgen and** Rayaldee ~~and our operations at EirGen~~, **if future results** are ~~currently underperforming expectations~~ **not consistent with our estimates** and ~~if~~ **assumptions, then** we ~~do not achieve our planned operating results, we~~ may be ~~required~~ **exposed** to ~~incur a non- cash~~ impairment ~~charge~~ **charges , which could be material. At December 31, 2023, the combined goodwill of our diagnotics segment and our Ireland reporting unit was $ 367. 3 million**. There can be no assurance that future reviews of our goodwill and other intangible assets will not result in impairment charges. Any impairment charges in the future will adversely affect our results of operations. A significant write down of goodwill and / or other intangible assets would have a material adverse effect on our reported results of operations and net worth and the trading price of our securities ~~. We submitted the initial BLA with the FDA for approval of Somatrogon (hGH- CTP) in the U. S. and Pfizer received a Complete Response Letter in January 2022. Pfizer and OPKO have evaluated the FDA' s comments and will work with the agency to determine the best path forward for Somatrogon (hGH- CTP) in the United States. If we are unable to successfully commercialize Somatrogon (hGH- CTP) in the U. S., or changes in projections and assumptions negatively impact our forecast of net cash flows, we may be exposed to a material impairment charge related to the IPR & D for Somatrogon~~. RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK The trading prices of our securities may fluctuate significantly. The trading prices of our Common Stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as: • the announcement of new products or product enhancements by us or our competitors; • results of our clinical trials and other development efforts; • developments concerning intellectual property rights and regulatory approvals; • variations in our and our competitors' results of operations; • changes in earnings estimates or recommendations by securities analysts, if our Common Stock is covered by analysts; • developments in the biotechnology, pharmaceutical, diagnostic and medical device industry; • the announcement and / or commencement and / or settlement of lawsuits or similar claims against us or any of our officers, directors and affiliates; • the results of product liability or intellectual property lawsuits; • future issuances of our Common Stock or other securities, including debt; • purchases and sales of our Common Stock by our officers, directors or affiliates; • the addition or departure of key personnel; • announcements by us or our competitors of acquisitions, investments or strategic alliances; and • general market conditions and other factors, including factors unrelated to our operating performance. Further, the securities market in general, and the market for biotechnology, pharmaceutical, diagnostic and medical device companies in particular, has experienced extreme price and volume fluctuations in recent years. Continued market fluctuations could result in extreme volatility in the trading prices of our Common Stock, which could cause a decline in the value of our securities. ~~Directors~~ **50Directors**, executive officers, principal stockholders and affiliated entities own a substantial amount of our capital stock, and they may make decisions that you do not consider to be in the best interests of our stockholders. As of ~~February 15~~ **January 31**, ~~2023~~ **2024**, our directors, executive officers, principal stockholders and affiliated entities beneficially owned, in the aggregate, approximately ~~47~~ **52**. 4 % of our outstanding voting securities. Phillip Frost, M. D., our Chairman and CEO, is deemed to beneficially own, in the aggregate, approximately ~~31~~ **34**. 6 % of our Common Stock as of ~~February 15~~ **January 31**, ~~2023~~ **2024**. As a result, Dr. Frost, acting with other members of management, would have the ability to significantly impact the election of our Board of Directors, the adoption or amendment of provisions in our Certificate of Incorporation, the approval of mergers and other significant corporate transactions and the outcome of issues requiring approval by our stockholders. This concentration of ownership may also have the effect of delaying or preventing a change in control of our company that may be favored by other stockholders. This could prevent transactions in which holders of our securities might otherwise recover a premium for their securities over current market prices. A significant short position in

our stock could have a substantial impact on the trading price of our stock. Historically, there has been a significant " short " position in our Common Stock. As of January 31, ~~2023~~ **2024**, investors held a short position of approximately ~~36~~ **97**, ~~250~~ **072**, ~~059~~ **172** million shares of our Common Stock which represented approximately ~~4~~ **13**. ~~7~~ **9** % of our outstanding Common Stock. The anticipated downward pressure on our stock price due to actual or anticipated sales of our stock by some institutions or individuals who engage in short sales of our Common Stock could cause our stock price to decline. Such stock price decrease could encourage further short- sales that could place additional downward pressure on our stock price. This could lead to further increases in the already large short position in our Common Stock and cause volatility in our stock price. The volatility of our stock may cause the value of a stockholder' s investment to decline rapidly. Additionally, if our stock price declines, it may be more difficult for us to raise capital and may have other adverse effects on our business. Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes- Oxley Act, including with respect to companies we acquire, could have a material adverse effect on our business and operating results. In addition, current and potential stockholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of our Common Stock. Section 404 of the Sarbanes- Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm on the effectiveness of internal control over financial reporting as of year- end. We are required to report, among other things, control deficiencies that constitute material weaknesses or changes in internal control that, or that are reasonably likely to, materially affect internal control over financial reporting. A " material weakness " is a significant deficiency or combination of significant deficiencies that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. We have identified and remediated control deficiencies in the past, and we cannot assure you that we will at all times in the future be able to report that our internal controls are effective. In addition, material weaknesses in the design and operation of the internal control over financial reporting of companies that we acquire could have a material adverse effect on our business and operating results. If we cannot provide reliable financial reports or prevent fraud, our results of operation could be harmed. Our failure to maintain the effective internal control over financial reporting could cause the cost related to remediation to increase and could cause our stock price to decline. In addition, we may not be able to accurately report our financial results, may be subject to regulatory sanction, and investors may lose confidence in our financial statements. Compliance with changing regulations concerning corporate governance and public disclosure may result in additional expenses. There have been changing laws, regulations, and standards relating to corporate governance and public disclosure, including the Sarbanes- Oxley Act of 2002, the Dodd- Frank Act, regulations promulgated by the Securities and Exchange Commission and rules promulgated by the Nasdaq Global Select Market and the other national securities exchanges. These new or changed laws, regulations, and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations, and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue- generating activities to compliance activities. Our board members, Chief Executive Officer, Chief Financial Officer, and Principal Accounting Officer could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified board members and executive officers, which could harm our business. If our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies, we could be subject to liability under applicable laws or our reputation may be harmed, which could materially adversely affect our business, results of operations and financial condition.