

Risk Factors Comparison 2024-03-29 to 2023-03-29 Form: 10-K

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The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from our expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below and in other sections of this Annual Report and in our subsequent filings with the SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial, may also affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks. The following information should be read in conjunction with Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and related notes included in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report. Risks Related to Our Business Generally extremely expensive to remediate, may prompt federal or state investigation, fines, civil and / or criminal sanctions and significant reputational damage. Monetary damages imposed on us could be significant and not covered by our liability insurance. Techniques used by bad actors to obtain unauthorized access, disable or degrade service, or sabotage systems evolve frequently and may not immediately produce signs of intrusion, and we may be unable to anticipate these techniques or to implement adequate preventative measures. In addition, a security breach could require that we expend substantial additional resources related to the security of our information systems and providing required breach notifications, diverting resources from other projects and disrupting our businesses. If we experience a data security breach, ~~it could result in increased costs or loss of revenue~~, our reputation could be damaged ~~;~~, and we could be subject to additional litigation, regulatory risks and ~~other~~ business losses. ~~A security breach or privacy violation that leads to unauthorized disclosure or loss of unauthorized use or modification of, or that prevents access to or otherwise impacts the confidentiality, security, or integrity of, sensitive, confidential, or proprietary information we or our third-party service providers maintain or otherwise process, could require us to comply with breach notification laws, and cause us to incur significant costs for remediation, fines, penalties, notification to individuals, media and governmental authorities, implementation of measures intended to repair or replace systems or technology, and to prevent future occurrences, potential increases in insurance premiums, and forensic security audits or investigations.~~ Our failure, or the failure by our third-party providers on our platform, to comply with applicable laws or regulations or any other obligations relating to privacy, data protection, or information security, or any compromise of security that **results in unauthorized access to, or use or release of personally identifiable information or other data relating to our customers, or other individuals, or the perception that any of the foregoing types of failure or compromise have occurred, could damage our reputation, discourage new and existing customers from using our platform, or result in fines, investigations, or proceedings by governmental agencies and private claims and litigation, any of which could adversely affect our business, financial condition, and results of operations. Even if not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition, and results of operations.** Our success ~~Our failure to manage our growth successfully could harm our growth and operating results. Since the our sale of our the~~ Cold-EEZE™ business in March 2017, we have ~~been~~ actively **exploring explored and pursued** new product technologies, applications, product line extensions and other new product and business opportunities. In October 2020, we purchased our first CLIA licensed laboratory in Old Bridge, New Jersey, where we ~~offer~~ **offered** a variety of important medical tests, including, among others, COVID-19 diagnostic testing and Influenza A and B. In December 2020, we expanded our diagnostic services to a second location in Garden City, New York. In August 2021, we acquired Nebula, a privately-owned personal genomics company. We ~~have transitioned~~ **are in the process of integrating** Nebula’s whole genome sequencing services ~~with into~~ **the area where** clinical diagnostic services ~~already were~~ offered at our CLIA-certified molecular testing laboratories. In March 2022, we formed ProPhase Biopharma, Inc. for the licensing, development and commercialization of novel drugs, dietary supplements, and compounds. We may in the future consider and pursue investments and acquisitions in other sectors and industries. We have and will continue to incur significant expenses as we grow our new businesses. In order for us to be profitable, we must generate sufficient revenue to cover our expenses. There can be no assurance that our different business lines will succeed or that we will be successful in initiating or acquiring any new lines of business in the future, or that any such new business lines will achieve profitability. ~~As of December 31, 2022, we had working capital of approximately \$40.7 million, which we believe is a sufficient level of working capital to support our businesses for at least the next twelve months.~~ Our businesses are subject to significant competitive pressures. ~~Our principal competition for our lab diagnostic services are commercial laboratories, such as Quest Diagnostics Incorporated and Laboratory Corporation of America Holdings, both of which have significant infrastructures and resources to support their diagnostic processing services. In addition, we compete with large, multispecialty group medical clinics and health systems. Academic medical university-based clinics may also provide in-house clinical laboratories offering COVID-19 and other RPP Molecular tests. Additionally, we compete against regional clinical laboratories providing diagnostic services, including Interpace BioSciences, Inc. If we are unable to compete effectively, our earnings may be significantly negatively impacted.~~ The number of companies entering the personal genomics market has increased in recent years. We face competition from other companies attempting to capitalize on the same, or similar, opportunities as we are, including those with existing diagnostic, laboratory services and other companies entering the personal genetics market with new offerings such as direct access and / or consumer self-pay tests and genetic interpretation services. Some of our current and potential competitors have longer operating histories and greater financial, technical, marketing and other resources than we do. These factors may allow our competitors to respond

more quickly or efficiently than we can to new or emerging technologies. These competitors may engage in more extensive research and development efforts, undertake more far-reaching marketing campaigns and adopt more aggressive pricing policies, which may allow them to build larger customer bases than we will be able to achieve. Our competitors may develop products or services that are similar to our products and services or that achieve greater market acceptance than our products and services. This could attract customers away from our services and reduce our market share. The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include major multi-national pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, and universities and other research institutions. Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staffs, established manufacturing capabilities and facilities, and experienced marketing organizations with well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies that have greater resources. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated on our competitors. Competition may increase further as a result of advances in the commercial applicability of genome editing or other new technologies and greater availability of capital for investment in these industries. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment for participation in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our development programs. Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, have broader acceptance and higher rates of reimbursement by third-party payors, or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, new technologies developed by our competitors may render our product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitor products. The key competitive factors affecting the success of our product candidates are likely to be their efficacy, safety, and availability of reimbursement. We compete with other contract manufacturers of OTC drug and dietary supplement products. These suppliers range widely in size. We compete primarily on the basis of price, quality and service. Management believes that our manufacturing capacity and abilities offer a significant advantage over many of our competitors in the full-service contract development and manufacturing industry. We have over 20 years of manufacturing experience and industry know how in large scale batch production of OTC lozenge products. To the extent that any of our competitors are able to offer better prices, quality and / or services, however, we could lose customers and our sales and margins may decline. The OTC healthcare products and dietary supplements industries are highly competitive. Many of the participants in these industries have substantially greater capital resources, technical staffs, facilities, marketing resources, product development, and distribution experience than we do. We believe that our ability to continue to compete in these industries will depend on a number of factors, including product quality and price, availability, speed to market, consumer marketing, reliability, credit terms, brand name recognition, delivery time and post-sale service and support. However, our failure to appropriately and timely respond to consumer preferences and demand for new products could significantly harm our business, financial condition and results of operations. Furthermore, unfavorable publicity or consumer perception of products we develop and commercialize could have a material adverse effect on our business and operations.

Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, including a pandemic, epidemic or infectious disease outbreak, the conflict in Ukraine or Gaza Strip, and bank failures affecting the financial services industry, could adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties that we rely upon for our business operations. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including but not limited to a pandemic, epidemic or infectious disease outbreak such as COVID- 19 pandemic, the conflict in Ukraine or Gaza Strip, and bank failures affecting the financial services industry. Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. A severe or prolonged economic downturn, or additional global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product or product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Disruptions to our supply chain could materially and adversely affect our business, financial condition and results of operations. Disruptions to our supply chain, including our access to testing supplies and personal protective equipment for our diagnostic services business, materials and equipment (such as our saliva collections kits) necessary for our personal genomics business, and raw materials and product components necessary for our manufacturing operations, could have a material impact on our business, financial

condition and results of operations. We do not have long- term contracts with most of our suppliers. Although we maintain relationships with suppliers with the objective of ensuring that we have adequate supply for the delivery of our products and services, increases in demand for such items and services can result in shortages and higher costs. Our suppliers may not be able to meet our delivery schedules. Further, we may experience shortages in certain items as a result of limited availability, increased demand, pandemics (such as the COVID- 19 pandemic), epidemics or other infectious disease outbreaks, weather conditions and natural disasters, global economic conditions, as well as other factors outside of our control. The COVID- 19 pandemic adversely impacted, and it or another pandemic, epidemic or infectious disease outbreak may in the future adversely impact, third parties that are critical to our businesses, including vendors, suppliers, and business partners. While our businesses have not been significantly negatively impacted up to this point by the COVID- 19 pandemic, it is difficult if not impossible to predict whether and how we could be impacted by the COVID- 19 pandemic, or another pandemic, epidemic or infectious disease outbreak, in the future. Increases in the price of testing supplies, equipment and raw materials needed for our businesses and costs associated with doing business could materially and adversely affect our business, financial condition and results of operations. We purchase ~~testing supplies and personal protective equipment for our diagnostic services business, and~~ certain materials and equipment (such as our saliva collections kits) for our personal genomics business ~~and~~. We must also purchase certain key raw materials and product components for our manufacturing operations. If the price of these ~~testing~~ testing supplies, equipment, raw materials, and components were to increase significantly, we may not be able to pass on such increases to customers who use our services or purchase our products, which could have a material adverse impact on our business, financial condition and results of operations. Our freight costs may also increase due to factors such as limited carrier availability, increased fuel costs, increased compliance costs associated with new or changing government regulations, pandemics (such as the COVID- 19 pandemic), epidemics or other infectious disease outbreaks, or inflation. Higher prices for natural gas, propane, electricity and fuel may also increase our production and delivery costs. The prices charged for our products may not reflect changes in our packaging material, freight, tariff and energy costs at the time they occur, or at all. The adulteration of key testing materials and raw materials needed for our businesses could materially and adversely affect our business, financial condition and results of operations. We are reliant upon the supply of ~~diagnostic and~~ diagnostic and genomics testing materials and raw materials that meet our specifications and the specifications of third parties for whom we manufacture. If any ~~diagnostic or~~ diagnostic or genomics testing material or raw material is adulterated and does not meet our specifications or third parties' specifications, it could significantly impact our ability to perform ~~diagnostic or~~ diagnostic or genomic services or manufacture products and could materially and adversely impact our business, financial condition and results of operations. We may be subject to product liability claims. As a direct marketer and manufacturer of products designed for human consumption, we are subject to product liability claims if the use of our products or the products that we manufacture for third parties are alleged to have resulted in injury or to include inadequate instructions for use or inadequate warnings concerning possible side effects and interactions with other substances. Our current products and the products that we currently manufacture for third parties are not subject to pre- market regulatory approval in the United States and could contain contaminated substances. While we currently maintain product liability insurance, a successful claim brought against us related to our branded products or products that we manufacture for third parties in excess of, or outside of, our existing insurance coverage, could result in increased costs and could adversely affect our reputation with customers, which could in turn materially adversely affect our business, financial condition and results of operations. We may require additional capital to support our growing ~~diagnostic services business,~~ diagnostic services business, personal genomics business, product development and commercialization programs, and biopharmaceutical business, but additional funding may not be available to us on acceptable terms, or at all. The amount of capital that may be needed to support our various businesses will depend on many factors which may include, but are not limited to (i) the revenue we generate from our ~~diagnostic services,~~ diagnostic services, personal genomics products and services, drug and dietary supplement lines, and contract manufacturing services; (ii) the expenses we incur in growing these businesses and services; (iii) the cost involved in applying for and obtaining FDA, international regulatory or other technical approvals, if required; and (iv) whether we elect to establish partnering or other strategic arrangements for the development, sales, manufacturing and marketing of our products and services. Income from our various businesses may not generate all the funds we need to support the growth of these businesses. To the extent that we do not generate sufficient cash from operations, we may, in the short and long- term, seek to raise capital through the issuance of equity securities or through other financing sources. To the extent that we seek to raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may include financial and other covenants that could restrict our use of the proceeds from such financing or impose other business and financial restrictions on us. In addition, we may consider alternative approaches such as licensing, joint venture, or partnership arrangements to provide long- term capital. Additional funding may not be available to us on acceptable terms, or at all. Adverse credit market conditions may significantly affect our access to capital, cost of capital and ability to meet liquidity needs. Disruptions, uncertainty or volatility in the credit markets could adversely impact the availability and cost of credit to us in the future. For example, the credit and financial markets may be adversely affected by the war in Ukraine and measures taken in response thereto. If the credit markets are not favorable, we may be forced to delay raising capital or pay unattractive interest rates, which could increase our interest expense, decrease our profitability and significantly reduce our financial flexibility. Longer- term disruptions in the capital and credit markets as a result of uncertainty, changing or increased regulation, reduced alternatives or failures of significant financial institutions could adversely affect our access to liquidity needed for our business. Any disruption could require us to take measures to conserve cash until the markets stabilize or until alternative credit arrangements or other funding for our business needs can be arranged. Such measures could include deferring capital expenditures or other discretionary uses of cash. Overall, our results of operations, financial condition and cash flows could be materially adversely affected by disruptions in the credit markets. System failures could adversely affect our results of operations and financial condition. Like many companies, our business is highly dependent upon our information technology

infrastructure (websites, accounting and manufacturing applications, and product and customer information databases) to manage effectively and efficiently our operations, including order entry, customer billing, accurate tracking of purchases and volume incentives and managing accounting, finance and manufacturing operations. The occurrence of a natural disaster, security breach or other unanticipated problem could result in interruptions in our day- to- day operations that could adversely affect our business. A long- term failure or impairment of any of our information systems could have a material adverse effect on our results of operations and financial condition. We **may** will face legal, reputational, and..... that the privacy of personal information is not satisfactorily protected or does not meet regulatory..... information and / or personal data may be extremely expensive to remediate, may prompt..... and results of operations. Our success **successful without our** is dependent on key personnel. Our success depends, in part, upon the continued service of key personnel, such as Mr. Ted Karkus, Chairman and Chief Executive Officer, and certain managers and strategists within the Company. The loss of the services of any one of them could have a material adverse effect on us. In order to be successful, we must retain and motivate executives and other key employees, including those in managerial, technical, marketing and health product positions. In particular, our product generation efforts depend on hiring and retaining qualified health and science professionals. Competition for skilled employees who can perform the services that we require is intense and hiring, training, motivating, retaining and managing employees with the skills required is time- consuming and expensive. If we are not able to hire sufficient professional staff to support our operations, or to train, motivate, retain and manage the employees we do hire, it could have a material adverse effect on our business operations or financial results. **We may not be successful in executing our growth strategy to identify, discover, develop, in- license or acquire additional product candidates or technologies, and our growth strategy may not deliver the anticipated results or we may refine or otherwise alter our growth strategy. We may seek to acquire businesses or undertake business combinations, collaborations or other strategic transactions which may not be successful or on favorable terms, if at all, and we may not realize the intended benefits of such transactions. We have acquired or in- licensed certain of our existing diagnostic tests, such as BE- Smart Esophageal Pre- Cancer diagnostic screening test, and product candidates, such as Linebacker LB- 1 and LB- 2. As part of our strategy, we plan to continue to identify products, diagnostic tests, product candidates or technologies that we believe are complementary to our existing products, diagnostic tests, and product candidates. We may do this through our internal discovery program, or by acquiring the rights to products, diagnostic tests, product candidates, and technologies through a variety of transaction types, including in- licensing, strategic transactions, mergers or acquisitions. Research programs and business development efforts to identify new products, diagnostic tests, product candidates, and technologies require substantial technical, financial, and human resources. We may focus our efforts and resources on potential products, diagnostic tests, product candidates, technologies or businesses that ultimately prove to be unsuccessful. Our research programs and business development efforts, including businesses or technology acquisitions, collaborations or licensing attempts, may fail to yield additional complementary or successful products, diagnostic tests, and product candidates for clinical development and commercialization or successful business combinations for a number of reasons, including, but not limited to, the following:**

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates or businesses with a high probability of success for development progression;
- we may not be able or willing to assemble sufficient resources or expertise to in- license, acquire or discover additional products, diagnostic tests, and product candidates, acquire businesses or undertake business combinations, collaborations, or other strategic transactions;
- we may not be able to agree to acceptable terms with potential licensors or other partners or with respect to business acquisitions;
- we may incur substantial liabilities as part of an acquisition or merger that may not be offset by the benefits of the acquired assets or the synergies we hope to realize; and
- any product candidates or technologies to which we acquire the rights or that we discover may not allow us to leverage our expertise and our development and commercial infrastructure as currently expected. In addition, we cannot be certain that such discovery of, or transaction related to, targeted products, diagnostic tests product candidates or technologies will be on favorable terms; or that, following any such discovery or transaction, we will be able to realize the intended benefits of it. The consummation or performance of any acquisition, business combination, collaboration or other strategic transaction we may undertake in furtherance of our growth strategy or any refined or otherwise altered strategy, may involve additional risks, such as difficulties in assimilating different workplace cultures, retaining personnel and integrating operations, which may be geographically dispersed, increased costs, exposure to liabilities, incurrence of indebtedness, or use a substantial portion of our available cash for all or a portion of the consideration or cause dilution to our existing stockholders if we issue equity securities for all or a portion of the consideration. If any of these events occurs or we are unable to meet our strategic objectives for any such transaction, we may not be able to achieve the expected benefits from the transaction and our business may be materially harmed. Furthermore, in- licensing and acquisitions of products, diagnostic tests, product candidates, technologies or businesses often require significant payments and expenses and consume additional resources. We will need to continue to devote a substantial amount of time and personnel to research, develop and commercialize any such in- licensed or acquired products, diagnostic tests, product candidate or technologies, or integrate any new business, including extensive nonclinical or clinical testing, or both, and approval by the FDA and applicable foreign regulatory authorities, if any. All such products are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the diagnostic tests, product candidate, or product developed based on in- licensed technology, will not be shown to be effective or sufficiently safe for approval by regulatory authorities. If intellectual property related to products, diagnostic tests, product candidates or technologies we in- license or acquire is not adequate, we may not be able to commercialize the affected products even after expending resources on their development. In addition, we may not be able to economically manufacture or successfully commercialize any product, diagnostic test or product candidate that we

develop based on acquired or in-licensed technology that is granted regulatory approval, and such products may not gain wide acceptance or be competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidates could be expensive and time-consuming. If we cannot effectively manage these aspects of our business strategy, we may ultimately decide to reprioritize our efforts even after having expended resources on a particular prospect, and our business may be materially harmed. If we are unable to identify, discover, develop (in-license or otherwise acquire), and integrate new products, diagnostic tests or product candidates, or their related companies, in accordance with this strategy, our growth strategy or strategic transactions may not deliver the anticipated results, our ability to pursue this component of our growth strategy would be limited, and we may need to refine or otherwise alter this strategy. We cannot be certain that we will be successful in such efforts. We may not be able to successfully develop and commercialize our business units in the MENA region in accordance with our expansion strategy; regulatory requirements vary from country to country, including those in the MENA region; and changes in the value of the relevant currencies used in our operations, including those used in the MENA region, may adversely impact our operations. In June 2023, we announced our intention to develop our business units in the MENA region, in particular, the Gulf Cooperation Council, an alliance of six Arab states in the Persian Gulf region, which includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates. Our entry into new markets may place a significant strain on our resources and increase demands on our executive management, personnel and operational systems, and our human, administrative and financial resources may be inadequate to meet these demands. Conducting and launching operations on an international scale requires close coordination of activities across multiple jurisdictions and time zones and consumes significant management resources. If we fail to coordinate and manage these activities effectively, our business, financial condition or results of operations could be adversely affected. Each jurisdiction in the MENA region that we target for commercialization of our products requires regulatory approvals and compliance with numerous and sometimes varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from country to country in the MENA region and from that required to obtain clearance or approval in the United States. Approval or clearance in the United States does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one regulatory authority in the MENA region does not ensure approval or certification by regulatory authorities in other countries in the MENA region or the United States. Any non- U. S. regulatory approval or certification process may include similar risks associated with obtaining clearance or approval in the United States. In addition, some countries only approve or certify a product for a certain period of time, in which case we will be required to re-approve or re-certify our products in a timely manner prior to the expiration of our prior approval or certification. We may not obtain regulatory approvals that we seek on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive or maintain necessary approvals to commercialize our products in any MENA market. If we fail to receive or maintain necessary approvals or certifications to commercialize our products in any MENA jurisdiction on a timely basis, or at all, or if we fail to have our products re-approved or re-certified, our business, results of operations and financial condition could be materially and adversely affected. Even if we successfully receive regulatory approvals and can commercialize our products, diagnostic tests, and product candidates in one or more of the jurisdictions in the MENA region, international sales entail a variety of risks, including longer payment cycles and difficulties in collecting accounts receivable outside of the United States, currency exchange fluctuations, challenges in staffing and managing foreign operations, tariffs and other trade barriers, unexpected changes in legislative or regulatory requirements of foreign countries into which we sell our products, difficulties in obtaining export licenses or in overcoming other trade barriers, laws and business practices favoring local companies, political instability, including conflicts and tensions involving the Israel- Hamas war, economic instability, difficulties protecting or procuring intellectual property rights, and restrictions resulting in delivery delays and significant taxes or other burdens of complying with a variety of foreign laws. In addition, expansion into the MENA markets may be affected by local economic and market as well as geopolitical conditions of each MENA country. Changes in the value of the relevant currencies in the MENA region may affect the cost of certain items required in our operations. Changes in currency exchange rates may also affect the relative prices at which we are able to sell products in the same market. Our revenue from customers in the MENA region may be negatively impacted as increases in the U. S. dollar relative to such customers' local currency could make our products more expensive, impacting our ability to compete. Our costs of materials from international suppliers may increase if in order to continue doing business with us they raise their prices as the value of the U. S. dollar decreases relative to their local currency. Foreign policies and actions regarding currency valuation could result in actions by the United States and other countries to offset the effects of such fluctuations. The recent global financial downturn has led to a high level of volatility in foreign currency exchange rates and that level of volatility may continue, which could adversely affect our business, financial condition or results of operations.

Risks Related to Our Diagnostics Business There can be no assurance that we will be able to substitute the continue to successfully offer, perform or generate revenues from our lab diagnostic services or tests with new business segments. Our **During years end December 31, 2023 and 2022, the net revenue from diagnostic services was \$ 24** business is subject to substantial risks and uncertainties. **8 million** To address these risks and **\$ 108** uncertainties, we must, among other things, successfully execute our business strategy, respond to competitive developments, and attract and retain qualified personnel. We cannot assure you that we will continue to operate profitably **3 million, respectively, which were 54.9 % and 88.3 % of** or **our net** that our business strategy will be successful in the long-term. Our ability to continue to generate revenues- **revenue** from COVID-19 and other RPP molecular testing, **respectively. By significantly decreasing** and to continue to generate profits from our diagnostic services business, will depend on a variety of factors, including: • the level of demand for COVID-

19 testing in light of widespread and effective vaccination and other successful containment efforts; • the level of demand for other diagnostic testing; • the price we are able to receive for performing our testing services, and the length of time for which that demand persists; • the availability of COVID-19 and other diagnostic testing from other laboratories; • the ability of our laboratories to maintain status as authorized laboratories to perform COVID-19 and other diagnostic testing and related services and to respond to any changes in regulatory requirements; • the potential for supply disruptions and our reliance on certain single source suppliers; • the potential for disruption in the delivery of patient samples to our laboratories; • the capacity of our laboratories to satisfy both COVID-19 testing and other testing demands; • the extent to which we choose to allocate limited laboratory capacity, supplies and other resources to areas of our business other than COVID-19 testing; • the complexity of billing for, and collecting revenue for, our testing services; • our ability to maintain laboratory operations during the COVID-19 pandemic or during another pandemic, epidemic or other infectious disease outbreak and to perform our tests accurately and punctually; • our ability to expand and/or diversify our diagnostic services; and • the ease of use of our ordering and reporting processes. In addition, the process of expanding our diagnostic services business may divert resources and distract management's attention from other areas of our business that may be more profitable or strategic. If we are unable to successfully provide diagnostic services while continuing to operate our existing genomics business, contract manufacturing business and/or dietary supplements business, our results of operations, financial position and reputation may suffer. If demand for COVID-19 testing becomes no longer necessary and we are unable to generate sufficient profits from other RPP Molecular tests, our business could be materially adversely affected. We launched our diagnostic service business in October 2020. Fluctuations in profits from our diagnostic business have occurred and may occur in the future due to a variety of factors, including, among others, the amount and timing of sales of billable tests, the prices we charge for our tests due to changes in product, customer or payor mix, general price degradation for tests or other competitive factors, future pandemics, epidemics or other infectious disease outbreaks, the rate and timing of our billings and collections, the timing and amount of our commitments and other payments, as well as the other risk factors discussed in this Annual Report. Our results have been, and may in the future be, impacted by events that may not recur regularly, in the same amounts or at all in the future. For the year ended December 31, 2022, we saw a significant increase in our net revenues due to our substantial COVID-19 testing volumes during that time, particularly during the first, second and third quarters of 2022. In the fourth quarter of 2022, testing volumes significantly decreased as COVID-19 testing demand slowed. The FDA has approved multiple COVID-19 vaccines for administration to the public. There can be no assurance that demand for our COVID-19 testing services will continue to exist in the future due to the widespread and effective vaccination of a majority of Americans against COVID-19 and successful containment efforts. If there is no demand for our COVID-19 testing services, and we are unable to generate sufficient profits from other RPP Molecular tests, our business could be materially adversely affected. On January 31, 2023, President Biden issued a Statement of Administration Policy indicating that the administration intends for the COVID-19 national emergency and **beyond** public health emergency to end on May 11, **we** 2023. When the public health emergency ends, the FDA will continue to have the authority to issue Emergency Use Authorizations (EUAs) until that authority is formally terminated by the Secretary of HHS through a separate process. Upon termination, our laboratories will no longer **generate the same level of revenues as we did in previous years for this business segment. Unless we are able to increase our revenues from existing or new line of businesses, our overall revenue will be lower** permitted to perform COVID-19 testing under an existing EUA. All subsequent COVID-19 testing would need to occur through our own laboratory developed test or an COVID-19 diagnostic test that **than has they have** been approved or cleared by FDA. Billing and collections processing for **these historical periods and could adversely impact** our business. Our ability to reduce our accounts receivable depends on our collection of payment for the diagnostic tests **we delivered, which we may not be able to do successfully as the process** is complex and time-consuming, and any delay in transmitting and collecting claims could have an adverse effect on our revenue. Billing for our diagnostic tests **is was** complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we **may were required to** bill different parties for our tests. This **includes included** billing customers directly, as in the case of our hospital and other medical institution customers, as well as billing through Medicare, Medicaid, insurance companies and patients, all of which may have different billing requirements. We may face increased risk in our collection **Collection** efforts due to the complexities of **receivables from** these billing requirements, including long collection cycles and lower collection rates, which could adversely affect our business, results of operations and financial condition. Several factors make this billing process complex, including: • contractual restrictions in our customer contracts that may limit our ability to utilize certain third-party billing service providers; • differences between the list price for our tests and the reimbursement rates of payors; • compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid; • disputes among payors as to which party is responsible for payment; • differences in coverage among payors and the effect of patient co-payments or co-insurance; • differences in information and billing requirements among payors; • incorrect or missing billing information; and • the resources required to manage the billing and claims appeals process. We have developed internal systems and procedures to handle these billing and collections functions, but we must continue to make significant efforts and expend substantial resources to further develop our systems and procedures to handle these aspects of our business, which could become increasingly important as we focus on increasing test volumes and establishing coverage and reimbursement policies with third-party payors. **As a and patients is our primary source of cash from our diagnostic testing service and is critical to our result results, of operations. Our primary collection risks relate to uninsured patients and these-- the portion of the bill that is the patient's responsibility, which primarily includes co-payments and deductibles. We faced and continue to face increased risk in our collection efforts due to the complexities of billing complexities requirements, along- long** with the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flow, our ability to achieve or sustain profitability and the consistency and comparability of our results of operations. In addition, if claims for our tests are not submitted to payors on a timely basis, or if we are required to switch to a different provider to handle our processing

and collections— **collection cycles** functions, our revenue and our business could be **lower collection rates, which** adversely affected. **Failure and could continue** to accurately bill **affect our business, results of operations and financial condition.** **Our collection risks also include the potential** for testing services, **default or bankruptcy by the party responsible** or for to comply **payment and other risks associated** with **payment collection generally** applicable laws relating to government health care programs, could have a material adverse effect on our business. **We** Billing for diagnostic services is complex and subject to extensive and non-uniform rules and administrative requirements. Depending on the billing arrangement and applicable law, we bill various payers, such as patients, insurance companies, government groups, Medicare and Medicaid. Effective November 2021, billing for diagnostic services is performed internally by our billing department. Failure to accurately bill for our services could have a material adverse effect on our business. In addition, failure to comply with applicable laws relating to billing government health care programs may result in various consequences, including the return of overpayments, civil and criminal fines and penalties, exclusion from participation in government health care programs and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur additional liabilities from third-party claims, all of which could have a material adverse effect on our business. Certain violations of these laws may also provide the basis for a civil remedy under the federal False Claims Act, including fines and damages of up to three times the amount claimed. The qui tam provisions of the federal False Claims Act and similar provisions in certain state false claims acts allow private individuals to bring lawsuits against health care companies on behalf of the government. Although we believe we are compliant, in all material respects, with applicable laws and regulations, there can be no assurance that a regulatory agency or tribunal would not reach a different conclusion. The federal and state governments have substantial **receivables due to us from certain** leverage in negotiating settlements since the amount of potential damages and fines far exceeds the rates at which services will be reimbursed, and the government has the remedy of excluding a non- **based funding** compliant provider from participation in the Medicare and Medicaid programs. We expect that federal and state governments continue aggressive enforcement efforts against perceived health care fraud. Legislative provisions relating to health care fraud and abuse provide government enforcement personnel with substantial funding, powers, penalties and remedies to pursue suspected cases of fraud and abuse. Our **payor** ability to achieve or sustain profitability depends on our collection of payment for the tests we deliver, which we may not be able to do successfully. Our customer base for our COVID-19 and influenza tests is **were** principally comprised of governmental bodies, municipalities, and large corporations who **pay-paid** us directly or through third-party payors. In March 2020, the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) was enacted, providing for reimbursement to healthcare providers for COVID-19 tests provided to uninsured individuals, subject to continued available funding - Approximately 31.5% and 57.6% of our diagnostic services revenue for the years ended December 31, 2022 and 2021, respectively, was generated from this program for the uninsured. On March 22, 2022, the Health Resources & Services Administrations (“HRSA”) uninsured program stopped accepting claims for COVID-19 testing and treatment due to the lack of sufficient funds. Despite requests from the Acting Director of the Office of Management and Budget and the White House Coordinator for COVID-19 Response for additional emergency funding for the uninsured program, **additional** emergency funding **has were** not been allocated to the HRSA uninsured program. **We continue to perform limited** **The expiration of the federal Public Health Emergency on May 11, 2023 also changed regulatory guidelines around COVID-19** testing for uninsured persons and are incurring **including billing codes and reimbursement** the accompanying costs. Further, healthcare policy changes that influence the way healthcare is financed or other changes in the market that impact payment rates by institutional **of in and out of network laboratories. Approximately 28.0% of** or **our** non-institutional customers could also affect our collection rates. If we are unable to convince customers of the value and benefit provided by our tests, these customers may slow, or stop altogether, their purchases of these tests. Our collection risks also include the potential for default or bankruptcy by the party responsible for payment and other risks associated with payment collection generally. Any inability to maintain our past payment collection levels could cause our revenue and ability to achieve profitability to decline and adversely affect our business, prospects and financial condition. The loss of sales to any one or more of our large diagnostic services **revenue for** customers could have a material adverse effect on our business operations and financial condition. For the year ended December 31, 2022, a significant portion **was generated from the HRSA program for the uninsured. None** of our **diagnostic** revenues **for** came from our diagnostic services business. For the year ended December 31, 2023 **was generated from the HRSA program for the uninsured. At December 31, 2023, insurers had significantly aged balances that we are continuing to work to collect. For the years ended December 31, 2023 and 2022, our three customers accounted accounts receivable were approximately 89.3% and 95.2%, respectively, from diagnostic testing services. We estimate our provisions for doubtful accounts based on 23.5%, 17.9%, and 11.9% of our 2022 revenues, respectively.** The loss of sales to these diagnostic services customers could have a **number** material adverse effect on our business operations and financial condition, unless we are able to increase revenue from other sources. If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our diagnostic service business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition. Our diagnostic service operations are subject to extensive federal, state, local and foreign laws and regulations, all of **factors** which are subject to change. These laws and regulations currently include, among other things: • CLIA, which requires that laboratories obtain certification from the federal government, and state licensure laws; • CMS and FDA laws and regulations; • HHPAA, which imposes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments to HHPAA under HITECH, which strengthen and expand HHPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general and impose requirements for breach notification; • state laws regulating genetic testing and protecting the privacy of genetic test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators; • the federal anti-kickback law, or the Anti-Kickback Statute, which

prohibits knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program; • other federal and state fraud and abuse laws, such as anti-**payer mix, the agings of the receivables, historical collection experience and assessment of probability of future collections. We routinely review accounts receivable balances in conjunction with these factors and other economic conditions that might ultimately affect the collectability of the patient accounts and make adjustments to our allowances as warranted. In addition, in determination of our year- end reserve balance**, prohibitions on self-our management considered the specific facts and circumstances related to each of the individual payors. However, there will inevitably be billings that are rejected by the insurance carriers and associated receivables that will not be collected. While past history is helpful in informing the determination of an appropriate reserve, its utility is somewhat limited by the circumstances underlying a significant portion of these aged balances; specifically, an unprecedented volume of activity related COVID- referral-19 diagnostic testing. Accordingly, the determination of and- an false claims appropriate year- end reserve balance required significant management judgment, and the year- end reserve balance established may not be sufficient due to the changes in the acts facts, which may extend to services reimbursable by any- and circumstances set forth above overtime. We have hired third- party collection providers payor, including private insurers; • the federal Physician Payments Sunshine Act, which requires medical device manufactures to assist us with track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or-our collection efforts. However investment interests held by physicians and their immediate family members; • Section 216 of the federal Protecting Access to Medicare Act of 2014, we cannot ensure which requires applicable laboratories to report private payor data in a timely and accurate manner beginning in 2017 and every three years thereafter (and in some cases annually); • state laws that we impose reporting and other compliance- related requirements; • state billing laws, including regulations on “pass through billing” which may limit our- or ability to submit claims for payment and / or our mark up the cost of services in excess of the price paid for such services, and “direct- bill” laws which may limit our ability to purchase services from a laboratory and bill for the services ordered; • similar foreign laws and regulations that apply to us in the countries in which we operate. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. Our failure to comply could lead to civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratory’s ability to provide or receive payment for our services. Any action taken against us by a governmental entity or private party could, regardless of their outcome, damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private- third- party collection provider payors. U. S. Food and Drug Administration (FDA) regulation of diagnostic products could result in increased costs and the imposition of fines or penalties and could have a material adverse effect upon our business. The FDA has regulatory responsibility for instruments, test kits, reagents and other devices used by clinical laboratories. The FDA enforces laws and regulations that govern the development, testing, manufacturing, performance, labeling, advertising, marketing, distribution and surveillance of diagnostic products, including COVID-19 diagnostics authorized by FDA under an Emergency Use Authorization (EUA), and it regularly inspects and reviews the manufacturing processes and product performance of diagnostic products. Since 2014, there have been ongoing discussions and advocacy between stakeholders, including the clinical laboratory industry, the FDA, and Congress, about potential FDA regulation of LDTs. In March 2017, a draft bill on the regulation of LDTs, entitled “The Diagnostics Accuracy and Innovation Act” (“DAIA”) was released for discussion. In December 2018, the sponsors of DAIA released a new version of the legislation called the “Verifying Accurate, Leading- edge IVCT Development Act” (“VALID Act”). The VALID Act proposes a risk- based approach to regulate LDTs and creates a new in vitro clinical test category, which includes LDTs, and a new regulatory structure under the FDA. Similar versions of the VALID Act have since been introduced. In 2022, the VALID Act was incorporated into the Senate user fee bill but was not included in the year- end Consolidated Appropriations Act of 2022. As proposed, the bill would create a precertification program for lower risk tests not otherwise required to go through premarket review. It would grandfather existing tests but would allow the FDA to subject otherwise grandfathered tests to premarket review under certain conditions. Similarly, the Verified Innovative Testing in American Laboratories (“VITAL”) Act was introduced in December 2020 and re- introduced in May 2021. In contrast with the VALID Act, the VITAL Act would prevent FDA from regulating LDTs and would instead assign regulatory authority over LDTs entirely to CMS. We cannot predict whether either of these or other draft bills governing LDTs will become legislation and cannot quantify the effect of such draft bills on our business. While we cannot predict whether the either VALID Act or the VITAL Act as proposed, or any modified version of either act will be successful in collecting outstanding balances enacted into law, it is expected that some form of the acts will be incorporated into a broader health care legislative package. Our inability The likelihood that Congress will pass legislation and the extent to which such legislation may collect outstanding balances and reduce our accounts receivable could cause our revenue and ability to achieve profitability to decline and adversely affect the FDA’s plans to regulate certain LDTs as medical devices is difficult to predict at this time. Until the VALID Act, VITAL Act, or other legislation is passed reforming the federal government’s regulation of LDTs, it is unknown how the FDA may regulate our tests in the future and what testing and data may be required to support any required clearance or approval. Absent congressional legislation to clarify FDA’s authorities, the FDA may consider administrative action, such as rule making, to clarify requirements for LDTs. FDA regulation of the diagnostic products we use and services we offer could result in increased costs and administrative and legal actions for noncompliance, including warning letters, fines, penalties, product suspensions, product recalls, injunctions and other civil and criminal sanctions, which could have a material adverse effect on our business, prospects and financial condition, results of operation and cash flows. Our diagnostic services business could be harmed by the loss or suspension of a license or imposition of a fine or penalties under, or future changes in, or interpretations of, the law or regulations of the Clinical Laboratory

Improvement Act of 1967, and the Clinical Laboratory Improvement Amendments of 1988 (CLIA), or those of Medicare, Medicaid or other national, state or local agencies in the United States. The performance of laboratory testing is subject to extensive U. S. regulation, and many of these statutes and regulations have not been interpreted by the courts. CLIA extends federal oversight to virtually all physician practices performing clinical laboratory testing and to clinical laboratories operating in the United States by requiring that they be certified by the federal government or, in the case of clinical laboratories, by a federally approved accreditation agency. 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. In addition, we expect to be subject to regulation under state law. State laws may require that laboratories and / or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Applicable statutes and regulations could be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect our business. 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 have a material adverse effect on our business. In addition, compliance with future legislation could impose additional requirements on us, which may be costly. Our products could become subject to regulation as medical devices by the FDA or other regulatory agencies even if we do not elect to seek regulatory clearance or approval to market our products for diagnostic purposes, which would adversely impact our ability to market and sell our products and harm our business. We intend to initially launch the BE Smart test as an LDT offered through our own laboratory but also offered for sale to others for research purposes or for "research use only" (RUO). A product sold for RUO, such as a BE Smart RUO test, is not designed or intended to be used as a clinical diagnostic test or as a medical device. RUO products can be sold to academic research institutions, translational research and medicine centers, cancer centers, clinical research laboratories, contract research organizations, and other research companies and providers. Tests that are labeled, promoted, and sold as RUO are not currently subject to regulation as medical devices by the FDA. However, the FDA could disagree that a test labeled as RUO test is intended for research use only or believe that the sales, marketing and promotional efforts related to a RUO test as being inconsistent with research use only products. On November 25, 2013, the FDA issued Final Guidance "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only." The guidance emphasizes that the FDA will review the totality of the circumstances when it comes to evaluating whether equipment and testing components are properly labeled as RUO. The final guidance states that merely including a labeling statement that the product is for research purposes only will not necessarily render the device exempt from the FDA's clearance, approval, and other regulatory requirements if the circumstances surrounding the distribution, marketing and promotional practices indicate that the manufacturer knows its products are, or intends for its products to be, used for clinical diagnostic purposes. These circumstances may include written or verbal sales and marketing claims or links to articles regarding a product's performance in clinical applications and a manufacturer's provision of technical support for clinical applications. In addition, customers who purchase a RUO-labeled test could, in theory, independently elect to use a RUO-labeled product in their own laboratory developed tests (LDTs) for clinical diagnostic use. The FDA has historically exercised enforcement discretion in not enforcing the medical device regulations against laboratories offering LDTs. However, as manufacturers develop more complex tests and diagnostic software, the FDA has been pushing for increased regulation of LDTs. Further, the VALID Act, which has been introduced in Congress over the last few sessions, if ever enacted, will establish a new risk-based regulatory framework for in vitro clinical tests (IVCTs), which include IVDs, LDTs, collection devices, and instruments used with such tests, and a technology certification program, among other proposals. The adoption of new restrictions on IVDs, LDTs, or RUOs, whether by the FDA or Congress, could adversely affect our ability to commercialize some of our RUO and diagnostic products. Further, we could be required to obtain premarket clearance or approval from the FDA before we can sell some of these products to certain customers. If the FDA determines our products or related applications should be subject to additional regulation as in vitro diagnostic devices based upon customers' use of our products for clinical diagnostic or therapeutic decision-making purposes, our ability to market and sell our products could be impeded and our business, prospects, results of operations and financial condition may be adversely affected. In addition, the FDA could consider our products to be misbranded or adulterated under the FD & C Act and subject to recall and / or other enforcement action. We use potentially hazardous materials, chemicals and patient samples in our business and any disputes relating to improper handling, storage or disposal of these materials could be time consuming and costly. Our lab diagnostic services involve the controlled use of hazardous laboratory materials and chemicals, including small quantities of acid and alcohol, and patient samples. We are subject to U. S. laws and regulations related to the protection of the environment, the health and safety of employees and the handling, transportation and disposal of medical specimens, infectious and hazardous waste. We could be liable for accidental contamination or discharge or any resultant injury from hazardous materials, and conveyance, processing, and storage of and data on patient samples. If we fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. Further, future changes to environmental health and safety laws could cause us to incur additional expense or restrict operations. In the event of a lawsuit or investigation concerning such hazardous materials, we could be held responsible for any injury caused to persons or property by exposure to, or release of, these hazardous materials or patient samples that may contain infectious materials. The cost of this liability could exceed our resources. While we expect to maintain broad form liability insurance coverage for these risks, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. Risks Related to Our Personal Genomics Business Prior to our acquisition of Nebula, we had no specific experience operating a personal genomics business. Our success in this industry will depend, in large part, on our ability to establish our presence in the personal genetics market, provide customers with a high level of service at a competitive price, achieve sufficient sales volume to realize economies of scale, and create innovative new features, products, and services to offer to our customers. Our failure to achieve any of these outcomes could adversely affect our business. Prior to our acquisition of Nebula in 2021, we had no specific

experience operating a personal genomics business. Our success in this industry will depend, in large part, on our ability to establish and maintain our presence in this market, provide customers with a high level of service at competitive prices, achieve sufficient sales volume to realize economies of scale, and create innovative new features, products and services to offer to our customers. If customers do not perceive our personal genomic reports to be reliable and of high quality, if we fail to introduce new and improved products and services, or if we introduce new products or services that are not favorably received by the market, we may not be able to attract or retain customers. The growth and expansion of our genomics business and service offerings will place a continuous strain on our management, operational and financial resources. We will be required to manage multiple relationships with various strategic suppliers, customers and other third parties, including regulatory agencies. To effectively manage our growth, we must continue to implement and improve our operational, financial and management information systems and to expand, train and manage our employee base. In the event of further growth of our operations or in the number of our third- party relationships, our supply, systems, procedures or internal controls may not be adequate to support our operations and our management may not be able to manage any such growth effectively. If our estimates of the total addressable market for personal genomic services and the potential for market growth prove to be inaccurate, our business, financial condition, results of operations and prospects may be negatively affected. Our estimates and forecasts for the personal genomic service market are based on a number of complex assumptions, internal and third- party estimates, and other business data, including assumptions and estimates relating to our ability to leverage our diagnostic testing facilities to generate revenue from personal genomic services. While we believe our assumptions and the data underlying our estimates are reasonable, there are inherent challenges in measuring or forecasting such information. As a result, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors and indicators. Consequently, our estimates of the total addressable market and our forecasts of market growth and future revenue from our products and services may prove to be incorrect. For example, if the annual total addressable market or the potential market growth for our products and services is smaller than we have estimated or if the key business metrics we utilize to forecast revenue are inaccurate, it may impair our sales growth and have an adverse impact on our business, financial condition, results of operations and prospects. Media reports have in the past reported on consumer privacy concerns and the use of genetic information accessed from other genetic databases by law enforcement and governmental agencies. These reports may decrease the overall consumer demand for personal genetic products and services, including ours. Companies offering personal genomic services and products have received a high degree of media coverage in recent years. Unfavorable publicity or consumer perception of our product and service offerings, including consumer privacy concerns related to any of our existing or future collaborations, could adversely affect our reputation, resulting in a negative impact on the size of our customer base, the loyalty of our customers, the percentage of our customers that consent to participate in any future research programs, and our ability to attract new customers. If we lose a significant or sole supplier, our business and operations could be materially adversely affected. Currently, we rely on a **sole two supplier-suppliers** to manufacture our saliva collection kits **and tubes** used by customers who purchase our personal genomics services. Change in the ~~supplier~~ for design of certain of the materials that we rely on, in particular the saliva collection kit, could result in a requirement for additional premarket review from the FDA before making such a change. Any new laboratory or laboratories that are engaged to support our personal genomics business must first be validated in accordance with certain governmental standards before we are able to utilize their services for our U. S. customers. We cannot be certain that we will be able to secure alternative laboratory processing services, materials and equipment, and bring such alternative materials and equipment online and revalidate them without experiencing interruptions in our workflow, or that any alternative materials will meet our quality control and performance requirements of our current contracted laboratories that support our personal genomics business. Any significant disruption in service on our website, mobile applications, or in our computer or logistics systems, whether due to a failure with our information technology systems or that of a third- party vendor, could harm our reputation and may result in a loss of customers. Customers purchase our personal genomics testing services and access Nebula offerings through our website or our mobile applications. Our reputation and ability to attract, retain and serve our customers is dependent upon the reliable performance of our and our partners' websites, mobile applications, network infrastructure and content delivery processes. Interruptions to any of these systems, whether due to system failures, computer viruses or physical or electronic break- ins, could affect the security or availability of our or our partner websites or mobile applications, including our databases, and prevent our customers from accessing and using our services. Our systems and operations are also vulnerable to damage or interruption from fire, flood, power loss, telecommunications failure, terrorist attacks, acts of war, electronic and physical break- ins, earthquake and similar events. In the event of any catastrophic failure involving our or our partner websites, we may be unable to serve our customer web traffic. The occurrence of any of the foregoing risks could result in damage to our systems or could cause them to fail completely, and our insurance may not cover such risks or may be insufficient to compensate us for losses that may occur. Additionally, our business model is dependent on our ability to deliver testing kits to customers and have kits processed and returned to us. This requires coordination between our logistics providers and third- party shipping services. Operational disruptions may be caused by factors outside of our control such as hostilities, political unrest, terrorist attacks, natural disasters, pandemics, epidemics and other infectious disease outbreaks affecting the geographies where our operations and customers are located. We may not be effective at preventing or mitigating the effects of such disruptions, particularly in the case of a catastrophic event which could cause failure to deliver pre- implantation genetic screening (PGS) kits. Any such disruption may result in lost revenues, a loss of customers and reputational damage, which would have an adverse effect on our business, results of operations and financial condition. Our personal genomics business is subject to seasonal fluctuations. Our personal genomics kit sales are impacted by seasonal holiday demand. We expect to generate greater revenues from this business during the first quarter of our fiscal year, due to seasonal holiday demand and the fact that kits that are ordered during the holiday season (which occurs during the fourth quarter of our fiscal year) will generally be recognized as revenue when the

customer sends in their kit to the laboratory to be processed and genetic reports are delivered to the customer, which for holiday purchases we expect will occur in the following fiscal quarter. Purchasing patterns of kit sales may also align with other gift-giving and family-oriented holidays such as Mother's Day and Father's Day. This seasonality could cause our operating results to vary considerably from quarter to quarter. We may also experience an increase in lab processing times and costs associated with shipping orders due to freight surcharges due to peak capacity constraints and additional long-zone shipments necessary to ensure timely delivery for the holiday season. Such delays could lead to an inability to meet advertised estimated lab processing times, resulting in customer dissatisfaction or reputational damage. If too many customers access our website within a short period of time, we may experience system interruptions that make our website unavailable or prevent us from efficiently fulfilling orders, which may reduce the volume of kits sold. Also, third-party delivery and direct ship vendors may be unable to deliver merchandise on a timely basis. **We have integrated, and may continue to integrate in the future, machine learning and AI to help us in relation to production and other areas of our business. Machine learning and AI technology present various operational, compliance and reputational risks and if any such risks were to materialize, our business and results of operations may be adversely affected. We have integrated AI into our production processes and may continue to integrate machine learning and AI. We may continue to integrate machine learning and AI technology into other aspects of our business. Given that machine learning and AI is a new and rapidly developing technology that is in its early stages of business use, it presents a number of operational, compliance and reputational risks. AI algorithms are currently known to sometimes produce unexpected results and behave in unpredictable ways that can generate irrelevant, nonsensical, deficient or incorrect content and results. We expect that there will continue to be new laws or regulations concerning the use of machine learning and AI technology, which might be burdensome for us to comply with and may limit our use of new tools and features based on machine learning and AI technology. Further, the use of machine learning and AI technology involves complexities and may require specialized expertise. We may not be able to attract and retain top talent to support any machine learning and AI technology initiatives and maintain our systems and infrastructure. A disruption or failure in any machine learning and AI systems or infrastructure could result in delays and operational challenges. If any of the operational, compliance or reputational risks were to materialize, our business and results of operations may be adversely affected.** Risks Related to our Contract Manufacturing and Dietary Supplement Business Disruptions at our **PMI** the manufacturing facilities **of, or any loss of manufacturing certifications by, or termination or other problems under manufacturing and supply agreements between customers and, our wholly owned subsidiary, PMI,** could materially and adversely affect our business, financial condition, results of operations and customer relationships. Any significant disruption at our manufacturing facility for any reason, including regulatory requirements, an FDA determination that the facility is not in compliance with the applicable cGMP regulations, the loss of certifications, power interruptions, destruction or damage to the facility or disruptions related to the COVID-19 pandemic or another pandemic, epidemic or infectious disease outbreak, could disrupt our ability to manufacture products for our contract manufacturing customers and any of our own branded products. Any such disruption could have a material adverse effect on our business, financial condition and results of operations. Our PMI manufacturing business is subject to seasonal fluctuations and may fluctuate from cold season to cold season. Because the majority of sales from our PMI manufacturing facility are from cold remedy products, our sales are subject to seasonal fluctuations and influenced by the timing, length and severity of each cold season. Our revenues tend to be higher in the first, third and fourth quarters during the cold season. Generally, a cold season is defined as the period of September to March, when the incidence of the common cold rises as a consequence of the change in weather and other factors. Our contract manufacturing and dietary supplement businesses are subject to extensive governmental regulation. Our contract manufacturing and dietary supplement businesses are subject to laws and regulations that cover: • the formulation, manufacturing, packaging, labeling, distribution, importation, sale and storage of our products; • the health and safety of our products; • trade practice and direct selling laws; and • product claims and advertising. Compliance with these laws and regulations is time consuming and expensive. Moreover, new regulations could be adopted that would severely restrict the products we sell or manufacture or our ability to continue our business. We are unable to predict the nature of any future laws, regulations, interpretations or applications, nor can we predict what effect additional governmental regulations or administrative orders, when and if promulgated, would have on our business in the future. These future changes could, however, require the reformulation or elimination of certain products; imposition of additional record keeping and documentation requirements; imposition of new federal reporting and application requirements; modified methods of importing, manufacturing, storing or distributing certain products; and expanded or different labeling and substantiation requirements for certain products and ingredients. Any or all of these requirements could harm our business. In July 2011, the FDA issued draft guidance governing the notification of new dietary ingredients ("NDIs") and in August 2016, the FDA issued revised draft guidance. Although FDA guidance is not mandatory, it is a strong indication of the FDA's current views, including its position on enforcement. We believe that the draft guidance, if implemented as proposed, could have a material impact on our operations. FDA enforcement of the NDI guidance as written could require us to incur additional expenses, which could be significant, and negatively affect our business in several ways, including, but not limited to, the detention and refusal of admission of imported products, the injunction of manufacturing of any dietary ingredients or dietary supplements until the FDA determines that those ingredients or products are in compliance, and the potential imposition of penalties for non-compliance. Our failure to comply with FTC regulations could result in substantial monetary penalties and could adversely affect our operating results. The FTC exercises jurisdiction over the advertising of dietary supplements and has instituted numerous enforcement actions against OTC drug companies for failure to have adequate substantiation for claims made in advertising or for the use of false or misleading advertising claims. Failure by us to comply with applicable regulations could result in substantial monetary penalties, which could have a material adverse effect on our financial condition or results of operations. Our product development and commercialization efforts may be unsuccessful. There are numerous risks associated with dietary supplement product

development and commercialization. We may be subject to delays and / or be unable to successfully implement our business plan and strategy to develop and commercialize one or more dietary supplements, including Equivir. The successful commercialization and market acceptance of any products we develop will be subject to, among other things, consumer purchasing trends, health and wellness trends, regulatory factors, retail acceptance and overall economic and market conditions. As a consequence, we may suspend or abandon some or all of our proposed new products before they ever become commercially viable. Even if we successfully develop a new product, if we cannot successfully commercialize it in a timely manner, our business and financial condition may be materially adversely affected. If our products do not have the effects intended or cause undesirable side effects, our business may suffer. Although many of the ingredients in our current dietary supplement products are vitamins, minerals, and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. While we believe that all of these products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer who has certain medical conditions. In addition, these products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or on an unforeseen cohort. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations, and prospects could be harmed significantly. **We may fail to expand our growing and manufacturing capability in time to meet market demand for our manufacturing service, and regulatory authorities may refuse to accept our facilities. Any problems in our growing or manufacturing process could have a material adverse effect on our business, results of operations, and financial condition. Our current plan is to build capacity at the manufacturing facilities owned by PMI to meet market demand of large lozenge manufacturing and production. Such build- out requires a successful FDA inspection of the manufacturing facilities. PMI successfully cleared its extensive multi- year FDA inspection in August, 2023. However, due to the complexity of the processes used to manufacture products, we may be unable to continue to pass federal, or state regulatory inspections in a cost- effective manner. The manufacturing of products necessitates compliance with GMPs and other regulatory requirements. Our ability to successfully manufacture products will involve manufacture of finished products and labeling and packaging, which includes product information, tamper proof evidence and anti- counterfeit features, under tightly controlled processes and procedures. In addition, we will have to ensure chemical consistency among the batches, including clinical trial batches and, if approved, marketing batches. Demonstrating such consistency may require typical manufacturing controls as well as clinical data. We will also have to ensure that the batches conform to complex release specifications. The FDA or other foreign regulatory authorities may not accept our facilities if there are issues with our manufacturing facilities or processes. If we are unable to manufacture products in the future in accordance with regulatory specifications, or if there are disruptions in our manufacturing process due to damage, loss or otherwise, or generally, failure to pass regulatory inspections of our manufacturing facilities, we may not be able to expand the manufacturing facilities and meet demand or supply sufficient product to our customers, and this may also harm our ability to compete with other manufacturing facilities on a timely or cost- competitive basis. In addition, if we are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, total or partial suspension of production, and / or enforcement actions, including injunctions and criminal or civil prosecution. Any problems in our manufacturing process or facilities or any possible sanctions could adversely affect our business, the results of operations, and financial condition.** Risks Related to Our Drug Development Operations **We Our product candidates are early- still in our pre- clinical development efforts** and it will be many years before our wholly owned subsidiary, ProPhase BioPharma, Inc. (PPIO), is able to commercialize a product candidate, if ever. **Our We are early in the development of our Equivir G (Rx) product candidate and Linebacker portfolio (LB- 1 and LB- 2) product candidates are still in pre- clinical development.** Our ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, will be a result of the successful development and eventual commercialization of these product candidates, which may never occur. Our product candidates may have adverse side effects or fail to demonstrate safety and efficacy. Additionally, our product candidates may have other characteristics that may make them impractical or prohibitively expensive for large- scale manufacturing. Furthermore, our product candidates may not receive regulatory approval or, if they do, they may not be accepted by the medical community or patients or may not be competitive with other products that become available. We must submit IND applications to the FDA to initiate clinical trials in the United States. The filing of IND applications is subject to additional preclinical research, research- scale and clinical- scale manufacturing, and other factors yet to be identified. In addition, commencing any new clinical trial is subject to review by the FDA based on the acceptability and sufficiency of our chemistry, manufacturing, and controls (“CMC”), and preclinical information provided to support our IND applications. If the FDA or foreign regulatory authorities require us to complete additional preclinical studies or we are required to satisfy other requests for additional data or information, our clinical trials may be delayed. Even after we receive and incorporate guidance from the FDA or foreign regulatory authorities, these regulatory authorities could disagree that we have satisfied all requirements to initiate our clinical trials or they may change their position on the acceptability of our trial design or the clinical endpoints selected. They could impose a clinical hold, which may require us to complete additional preclinical studies or clinical trials. The success of our product candidates will depend on several factors, including the following: • sufficiency of our financial and other resources; • completion of preclinical studies; • clearance of IND applications to initiate clinical trials; • successful enrollment in, and completion of, our clinical trials; • data from our clinical trials and support an acceptable risk- benefit profile of our product candidates for our intended patient population and indications and demonstrate safety and efficacy; • establishment of agreements with **contract manufacturing organizations (“CMOs”)** for

clinical and commercial supplies and scaling up of manufacturing processes and capabilities to support our clinical trials; • successful development of our internal process development and transfer to larger- scale facilities; • receipt of regulatory and marketing approvals from applicable regulatory authorities; • receiving regulatory exclusivity for our product candidates; • establishment, maintenance, enforcement, and defense of patent and trade secret protection and other intellectual property rights; • not infringing, misappropriating, or otherwise violating third- party intellectual property rights; • establishing sales, marketing, and distribution capabilities for commercialization of our product candidates, if and when approved, whether by us or in collaboration with third parties; • maintenance of a continued acceptable safety profile of products post- approval; • acceptance of product candidates, if and when approved, by patients, the medical community, and third- party payors; • effective competition with other therapies and treatment options; • establishment and maintenance of healthcare coverage and adequate reimbursement; and • expanding indications and patient populations for our products post- approval. We may not be successful in our efforts to identify and successfully research and develop additional product candidates and may expend our resources to pursue particular product candidates or indications while failing to capitalize on other product candidates or indications that may be more profitable, or for which there is a greater likelihood of commercial success. Part of our business strategy involves identifying and developing new product candidates. The process by which we identify product candidates may fail to yield successful product candidates for a number of reasons, including: • we may not be able to assemble sufficient resources to identify or acquire additional product candidates; • competitors may develop alternative therapies that render new product candidates obsolete or less attractive; • product candidates we develop or acquire may be covered by third- party intellectual property rights; • new product candidates may, on further study, be shown to have adverse side effects, toxicities, or other characteristics that indicate that they are unlikely to receive marketing approval or achieve market acceptance; • new product candidates may not be safe or effective; • the market for a new product candidate may change so that the continued development of that product candidate is no longer reasonable; and • we may not be able to produce new product candidates in commercial quantities at an acceptable cost, or at all. We are focused initially on Equivir G (Rx) and] our Linebacker portfolio (LB- 1 and LB- 2) product candidates and, as a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. **At anytime, we may choose to divert our attention and financial resources to a certain product candidate within our portfolio at the expense of another if we deem that our resources would be better allocated to pursue such product candidate.** Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to that product candidate. If we experience delays or difficulties enrolling patients in the clinical trials for our product candidates, our ability to advance our product candidates through clinical development and the regulatory process could be delayed or prevented. The timely completion of clinical trials depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may encounter delays in enrolling or be unable to enroll a sufficient number of patients to complete any of our clinical trials and, even if patients are enrolled, they may withdraw from our clinical trials before completion. Any clinical trials for our other product candidates will compete for enrollment of patients with other clinical trials for product candidates that are intended for the same or similar study populations as our product candidates. This competition will reduce the number and types of patients available to us because some patients who might opt to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Additionally, since the number of qualified and experienced clinical investigators for therapeutic areas is limited, some of our clinical trial sites may be also conducting clinical trials for some of our competitors, which may reduce the number of patients who are available for our clinical trials at that clinical trial site. In addition, the enrollment of patients depends on many factors, including: • size of the patient population and process for identifying patients; • design of the clinical trial protocol; • regulatory hold on clinical trial recruitment because of unexpected safety events; • availability of eligible prospective patients who may also be eligible patients for competitive clinical trials; • availability and efficacy of approved alternative treatments for the disease under investigation; • ability to obtain and maintain patient consent; • risk that enrolled patients will drop out before completion of the trial; • eligibility and exclusion criteria for the trial in question; • perceived risks and benefits of our product candidates; • efforts by clinical sites and investigators to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • physicians' ability to monitor patients adequately during and after treatment because of patient healthcare access issues, including those caused by COVID- 19, other pandemics, epidemics or infectious disease outbreaks; • proximity and availability of clinical trial sites for prospective patients; and • interruptions, delays, or staffing shortages resulting from the COVID- 19 pandemic, other pandemics, epidemics or infectious disease outbreaks. Enrollment delays in our clinical trials may result in increased development costs for any product candidates we may develop, which may cause our stock price to decline and limit our ability to obtain additional financing. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit, or terminate ongoing or future clinical trials, and postpone or forgo seeking marketing approval, any of which would have an adverse effect on our business, financial condition, results of operations, and prospects. Clinical trials are expensive, time consuming, and subject to uncertainty. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, if at all. Issues may arise that could suspend or terminate our clinical trials. A failure of one or more of our clinical trials may occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include: • FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials; • delays or failure to obtain regulatory clearance to initiate our clinical trials, as well as delays or failures to obtain any necessary approvals by the clinical sites; • delays, suspension, or termination of our clinical trials by the clinical sites; •

modification of clinical trial protocols; • delays in reaching agreement on acceptable terms with prospective **contract research organizations (“CROs”)** and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites, as well as possible future breaches of such agreements; • failure to manufacture sufficient quantities of our product candidates for use in our clinical trials; • failure by third- party suppliers, CMOs, CROs, and clinical trial sites to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • imposition of a temporary or permanent clinical hold by us, IRBs for the institutions at which such trials are being conducted, or by the FDA or other regulatory authorities for safety or other reasons, such as a result of a new safety finding in a clinical trial on a similar product by one of our competitors, that presents unreasonable risk to clinical trial participants; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • changes in the standard of care on which we developed our clinical development plan, which may require new or additional trials; • the cost of clinical trials of our product candidates being greater than we anticipated; • insufficient funding to continue clinical trials with our product candidates; • the emergence of unforeseen safety issues or undesirable side effects; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of our product candidates; • inability to establish clinical trial endpoints that applicable regulatory authorities consider clinically meaningful, or, if we seek accelerated approval, that applicable regulatory authorities consider likely to predict clinical benefit; • regulators withdrawing their approval of a product or imposing restrictions on its distribution; and If (i) we are required to extend the duration of any clinical trials or to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate; (ii) we are unable to successfully complete preclinical studies or clinical trials of our product candidates or other testing; (iii) the results of these trials, studies, or tests are negative or produce inconclusive results; (iv) there are safety concerns; or (v) we determine that the observed safety or efficacy profile would not be competitive in the marketplace, we may: • abandon the development of one or more product candidates; • incur unplanned costs; • be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all; • obtain marketing approval in some jurisdictions and not in others; • obtain marketing approval with labeling that includes significant use restrictions or safety warnings, including black box warnings; • be subject to additional post- marketing requirements; or • have regulatory agencies remove the product from the market or we voluntarily withdraw the product from the market after obtaining marketing approval. Our preclinical studies or clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates and the development of our product candidates may be delayed or unsuccessful, which could prevent or delay regulatory approval and commercialization. If we encounter safety or efficacy problems in our preclinical studies or clinical trials, our developmental plans could be delayed or prevented. Product candidates in later stages of clinical trials may fail to show the desired safety profiles and efficacy results despite having progressed through initial preclinical studies and clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulatory agencies may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulatory agencies may not interpret our data as favorably as we do, which may delay, limit, or prevent regulatory approval. In addition, the design of a clinical trial can determine whether its results will support approval of our product candidates, and flaws in the design of a clinical trial may not be apparent until the clinical trial is well advanced. We have limited experience designing clinical trials and may be unable to design and execute a clinical trial that will support regulatory approval. From time to time, we may publish initial, interim, or preliminary data from our clinical trials. Initial, interim, or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data at the time of publishing initial, interim, or preliminary data. These data also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, initial, interim, and preliminary data should be viewed with caution until the final data are available. Moreover, initial, interim, and preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as more patient data become available when patients mature on study, patient enrollment continues, or, for final data, as other ongoing or future clinical trials with a product candidate further develop. Past results of clinical trials may not be predictive of future results. Unfavorable differences between initial, interim, or preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to decline significantly. If our product candidates cause serious adverse events or undesirable side effects, including injury and death, or have other properties that could delay or prevent regulatory approval, their commercial potential may be limited or extinguished. Product candidates we develop may be associated with undesirable or unacceptable side effects, unexpected characteristics, or other serious adverse events, including death. Inadequate recognition or management of the potential side effects of our product candidates could result in patient injury or death. If any undesirable or unacceptable side effects, unexpected characteristics, or other serious adverse events occur, our clinical trials could be suspended or terminated, and our business and reputation could suffer substantial harm. There can be no assurance that we will resolve any adverse event related to any of our products to the satisfaction of the FDA or any regulatory agency in a timely manner or at all. If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidates, the FDA or other regulatory authorities could order us to cease further clinical trials of, or deny approval of, our product candidates. Even if we demonstrate that such serious adverse events are not product candidate- related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete our clinical trials. Moreover, if we elect, or are required, to delay, suspend, or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from these

product candidates may be delayed or eliminated. The FDA or other regulatory agencies may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates. Although the FDA has found substantial evidence to support approval outside of the traditional phase 1, phase 2, and phase 3 framework for certain therapies, the general approach for FDA approval of a new drug is for the sponsor to provide dispositive data from at least two adequate and well-controlled clinical trials of the relevant biologic in the applicable patient population. Such clinical trials typically involve hundreds of patients, have significant costs, and take years to complete. We do not have agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a NDA. In addition, the standard of care may change with the approval of new products in the same indications to which our product candidates are directed. This may result in the FDA or other regulatory authorities requesting additional studies to show that our product candidate is comparable or superior to the new products. Our clinical trial results may also not support marketing approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including:

- the FDA or other regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or other regulatory authorities that our product candidates are safe and effective for their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other regulatory authorities for approval, including due to heterogeneity of patient populations;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh the safety risks;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or other regulatory authorities to support the submission of a NDA or a similar filing in a foreign jurisdiction or to support commercial reimbursement;
- the FDA or other authorities will review our manufacturing processes and inspect our CMOs' facilities and may not approve our manufacturing processes or CMOs' facilities; and
- the approval policies or regulations of the FDA or other regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we comply with all FDA requests, we may still fail to obtain regulatory approval. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming, and uncertain, and we may be unable to obtain the regulatory approvals necessary for the commercialization of our product candidates; furthermore, if there are delays in obtaining regulatory approvals, we may not be able to commercialize our products, may lose competitive lead time, and our ability to generate revenues from such products will be materially impaired. The process of obtaining marketing approvals, both in the United States and in other jurisdictions, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. It is impossible to predict if or when any of our product candidates will prove to be safe and effective in humans or if we will receive regulatory approval for such product candidates. The risk of failure through the development process is high. Any product candidates we may develop, and the activities associated with their development and commercialization, including their manufacture, preclinical and clinical development, safety, efficacy, recordkeeping, labeling, storage, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. PBIO has not received approval or authorization to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of its product candidates or any product candidates it may seek to develop in the future will ever obtain marketing approval or commercialization. PBIO has not previously submitted a NDA to the FDA or made a similar submission to any foreign regulatory authority. ANDA must include extensive preclinical and clinical data and supporting information to establish a drug product candidate's safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing, and controls for our product. Any drug product candidates we develop may not be effective; may be only moderately effective; or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The FDA and other regulatory authorities have substantial discretion in the approval process and may refuse to accept our NDA applications and decide that our data are insufficient and require additional preclinical studies or clinical trials. The same may happen with review of our drug product candidates by foreign regulatory authorities. In addition, varying interpretations of the data obtained from preclinical studies and clinical trials could delay, limit, or prevent marketing approval of our drug product candidates. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any drug product candidates we may develop, the commercial prospects for those drug product candidates and our ability to generate revenues will be materially impaired and we may lose competitive lead time as similar products enter the market. If ProPhase Biopharma, Inc. (PBIO) is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue. To achieve commercial success for any approved product for which PBIO retains sales and marketing responsibilities, PBIO must develop and build a sales and marketing team or make arrangements with third parties to perform these services. There are risks involved with both establishing internal sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay product launch. PBIO will have to compete with other supplement, pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. If the commercial launch of a product for which we have recruited a sales force and established marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, which may be costly and our investment will be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, hire, train, and retain adequate numbers of effective sales, marketing, customer service, medical affairs, and other support personnel;
- our inability to equip sales personnel with effective materials, including sales

literature, to help them educate physicians and other healthcare providers regarding our product candidates and their approved indications; • our inability to effectively manage a geographically dispersed sales and marketing team; • the inability of medical affairs personnel to negotiate arrangements for reimbursement and other acceptance by payors; • the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability; and • unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we are unable or decide not to establish internal sales, marketing, and distribution capabilities, we will need to enter into arrangements with third parties to perform sales, marketing, and distribution services. In such cases, our product revenue or the profitability to us from these revenue streams is likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over those third parties and they may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our product candidates, and our business, financial condition, results of operations, and prospects will be materially adversely affected. Our products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, and others in the medical community. The use of Equivir G (Rx) for antiviral applications and / or the Linebacker portfolio (LB- 1 and LB- 2) as potential cancer co- therapies may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. Even with the requisite approvals from the FDA and other regulatory authorities internationally, the commercial success of any product candidates we develop will depend, in significant part, on the acceptance of physicians, patients, and healthcare payors of products as medically necessary, cost-effective, safe, and effective therapies. Additional factors will influence whether our product candidates are accepted in the market, including: • the clinical indications for which our product candidates are approved; • physicians, hospitals, cancer treatment centers, and patients considering our product candidates as safe and effective treatments; • the potential and perceived advantages of our product candidates over alternative treatments; • the prevalence, identification, or severity of any side effects; • product labeling or product insert requirements of the FDA or other regulatory authorities, including limitations or warnings contained in the product labeling; • the timing of market introduction of our product candidates as well as competitive products; • the cost of treatment of our product candidates in relation to alternative treatments; • the availability of coverage and adequate reimbursement by third- party payors and government authorities; • the willingness of patients to pay out- of- pocket for our product candidates in the absence of coverage; • relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and • the effectiveness of our sales and marketing efforts. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers, or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies, or other therapeutic approaches, are introduced that are more favorably received than our products, are more cost effective, or render our products obsolete. The market opportunities for our product candidates may be smaller than we currently believe and limited to those patients who are ineligible for or have failed prior treatment, which may adversely affect our business. Our projections of both the number of patients who have the indications we are targeting, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. New studies may change the estimated incidence or prevalence of these cancers. The number of eligible patients may turn out to be lower than we expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations, and prospects. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. Even if we are able to commercialize our product candidates, such products may be subject to unfavorable pricing regulations, third- party reimbursement practices, or healthcare reform initiatives, which could harm our business. The regulations that govern marketing approvals, pricing, and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some non- U. S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for our product candidates in a particular country, but then be subject to price regulations that delay our commercial launch of such product candidates, possibly for lengthy time periods, and such delays would negatively impact the revenues we are able to generate from the sale of our product candidates in that country. Pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval. Uncertainty exists as to the coverage and reimbursement status of any of our products candidates for which we obtain regulatory approval. Additionally, reimbursement coverage may be more limited than the indications for which our products are approved. The marketability of our products may suffer if government and other third- party payors fail to provide coverage and adequate reimbursement. Furthermore, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more of our product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Moreover, eligibility for reimbursement does not imply that our product candidates will be paid for in all cases or at a rate that will cover our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new

products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of our product candidate and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products, and may be incorporated into existing payments for other services. Net prices for our product candidates may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where our product candidates may be sold at lower prices than in the United States. Third- party payors, whether domestic or foreign, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to healthcare systems that could impact our ability to sell our product candidates, if approved, profitably. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of, and containing or lowering the cost of, healthcare. The implementation of cost containment measures that third- party payors and healthcare providers are instituting and any other healthcare reforms may prevent us from being able to generate, or may reduce, our revenues from the sale of our product candidates, if approved, and our product candidates may not be profitable. Such reforms could have an adverse effect on anticipated revenue from product candidates for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. Even if our product candidates are successful in clinical trials and receive marketing approval, we cannot provide any assurances that we will be able to obtain and maintain third- party payor coverage or adequate reimbursement for our product candidates in whole or in part. Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain approval of and commercialize our product candidates and could adversely affect our business. The Affordable Care Act brought significant changes to the way healthcare is financed by both the government and private insurers, and significantly impacted the U. S. pharmaceutical industry, including expanding the list of covered entities eligible to participate in the 340B drug pricing program and establishing a new Medicare Part D coverage gap discount program. We expect that these and other healthcare reform measures in the future, may result in more rigorous coverage criteria and lower reimbursement, and in addition, exert downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government- funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may hinder us in generating revenue, attaining profitability, or commercializing our products once, and if, marketing approval is obtained. In the **European Union (“EU”)**, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU member states. The requirements may differ across the EU member states. In markets outside the United States and the EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings or other price controls on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU, or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or those third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability. Risks Related to Our Intellectual Property Failure to protect our trademarks and other intellectual property could impact our business. We will rely on trademark laws to protect our proprietary rights in any products we develop and commercialize. Monitoring the unauthorized use of our intellectual property will be difficult. Litigation may be necessary to enforce our intellectual property rights or to determine the validity and scope of the proprietary rights of others. Litigation of this type could result in substantial costs and diversion of resources, may result in counterclaims or other claims against us and could significantly harm our results of operations. In addition, the laws of some foreign countries do not protect our proprietary rights to the same extent as do the laws of the United States. From time to time, we may apply to have certain trademarks registered. There is no guarantee that such trademark registrations will be granted. The unauthorized reproduction of our trademarks could diminish the value of our brand and its market acceptance, competitive advantages or goodwill, which could adversely affect our business. If **we, or** our licensors are unable to maintain effective patents or we are unable to maintain our license rights for our approved products, product candidates or any future product candidates, or if the scope of the patent or license rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets. **We have traditionally in- licensed all patent rights protecting our products and / or our product candidates. Commensurate with our purchase of the Stella Purchased Assets, we became the owner of certain patents, patent applications and their foreign counter- parts.** Our success depends in large part on **our, and** our licensors’ ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries, as well as our license rights, with respect to our proprietary technology, products and product candidates. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we **own, acquire (previously, or in the future), or** in- license may fail to result in issued patents with claims that cover our products or product candidates in the United States or in foreign countries. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that **we, our predecessors (as to patents and patent applications acquired), or** our licensors were the first to file any patent application related to our products or product candidates, or whether **we, or they**, were the first to make the inventions claimed in ~~their~~ **the owned** patents or pending patent applications **that we own, in- license or acquire**. As a result, the issuance, scope, validity, enforceability and commercial value of our **owned, acquired, or** licensed patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to such patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our products or product candidates, third parties may

challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Furthermore, even if they are unchallenged, such patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our products or product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties. Any successful opposition to any patents **owned, acquired, or** licensed to us after patent issuance, or the loss or other impairment of any **owned, acquired, or** ~~license~~ **licensed** rights relating to our products or product candidates, could deprive us of rights necessary for the successful commercialization of any products or product candidates that we may develop. Further, if **we, or** our licensors, encounter delays in regulatory approvals, the period of time during which we could market a product or product candidate under patent protection could be reduced. In addition, **our, or** our licensors' patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our **owned, acquired, or licensed** patents. ~~Our~~ **We, our** licensors may not have sufficient patent terms to effectively protect our products and business. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. As a result, our **owned, acquired, or** licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Even if patents covering our products or product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell our products that have been approved for sale, and to use our proprietary technology without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we will market products and are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and product candidates may be subject to claims of infringement of the intellectual property rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our products or our product candidates. We cannot be sure that we know of each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products or our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents upon which our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any compositions formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Our reliance on third parties requires us to share our trade secrets or confidential proprietary information, which increases the possibility that a competitor will discover them or that our trade secrets confidential proprietary information will be misappropriated or disclosed. Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets or confidential proprietary information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees, and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business. Protecting and enforcing our intellectual property rights could consume monetary funds needed for other company objectives. Protecting and enforcing our intellectual property rights and combating unlicensed copying and use

of our intellectual property can be difficult and expensive. Litigation filed by Company and excessive legal costs could result in insufficient cash available to continue our business objective. Similarly, reductions in the legal protection of our intellectual property. We may not be able to prevent disclosure of confidential and proprietary information We receive confidential and proprietary information from collaborators, prospective licensors and licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims, which can result in significant costs if we are found to have improperly used the confidential or proprietary information of others. Even if we are successful in defending against these claims, litigation could result in substantial costs and diversion of personnel and resources. Risks Related to Governmental Regulation Laws and regulations regarding direct selling may prohibit or restrict our ability to sell our products in some markets or require us to make changes to our business model in some markets. Direct selling companies are subject to laws and regulations by various government agencies. These laws and regulations are generally intended to prevent fraudulent or deceptive practices and to protect consumers. The FTC periodically investigates and brings enforcement actions against direct selling companies based on alleged pyramid selling activity and / or false and misleading claims made by the direct selling company or its independent distributors. Direct selling companies that have been the subject of an FTC enforcement action have generally been required to make significant changes to their business model and pay significant monetary fines. Being the target of an investigation or enforcement action by the FTC could have a material adverse effect on our results of operations and financial condition. We depend on third parties to provide services critical to our businesses and we depend on them to comply with applicable laws and regulations. We depend on third parties to provide services critical to our businesses, including laboratory service providers, raw material and equipment suppliers, ground and air transport of clinical and diagnostic services supplies and specimens, research services (including ancestry report generation), and people, among other services. Third parties that provide services to us are subject to similar risks related to security of customer-related information and compliance with U. S., state, local, or international environmental, health and safety, and privacy and security laws and regulations as we are. Any failure by third parties to comply with applicable laws, or any failure of third parties to provide services more generally, could have a material impact on us, whether because of the loss of the ability to receive services from the third parties, our legal liability for the actions or inactions of third parties, or otherwise. We must comply with complex and overlapping laws protecting the privacy and security of health information and personal data. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. Under the administrative simplification provisions of HIPAA, HHS has issued regulations which establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of PHI used or disclosed by health care providers and other covered entities. The privacy regulations regulate the use and disclosure of PHI by health care providers engaging in certain electronic transactions or "standard transactions." They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered health care provider, including the right to access or amend certain records containing PHI or to request restrictions on the use or disclosure of PHI. The HIPAA security regulations establish administrative, physical, and technical standards for maintaining the integrity and availability of PHI in electronic form. These standards apply to covered health care providers and also to "business associates" or third parties providing services involving the use or disclosure of PHI. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI. As a result, we may be required to comply with both HIPAA privacy regulations and varying state privacy and security laws. Moreover, HITECH, among other things, established certain health information security breach notification requirements. In the event of a breach of unsecured PHI, a covered entity must notify each individual whose PHI is breached, federal regulators and in some cases, must publicize the breach in local or national media. Breaches affecting 500 individuals or more are publicized by federal regulators who publicly identify the breaching entity, the circumstances of the breach and the number of individuals affected. These laws contain significant fines and other penalties for wrongful use or disclosure of PHI. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. Adding to the complexity is that our planned operations are currently evolving, and the requirements of these laws will apply differently depending on such things as whether or not we bill electronically for our services or provide services involving the use or disclosure of PHI and incur compliance obligations as a business associate. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage. We are also required to collect and maintain personal information about our employees as well as receive and transfer certain payment information, to accept payments from our customers, including credit card information. Most states have adopted laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements, and generate additional risks of enforcement for non-compliance. The collection and use of such information may be subject to contractual obligations as well. If the security and information systems that we or our outsourced third-party providers use to store or process such information are compromised or if we, or such third parties, otherwise fail to comply with these laws, regulations, and contractual obligations, we could face litigation and the imposition of penalties that could adversely affect our financial performance. Numerous additional local, municipal, state, federal, and

international laws and regulations address privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data, including the California Online Privacy Protection Act, the Personal Information Protection and Electronic Documents Act, the Telephone Consumer Protection Act of 1991, Section 5 of the Federal Trade Commission Act, and effective as of January 1, 2020, the CCPA. These laws, rules, and regulations evolve frequently, and their scope may continually change, through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another. For example, the CCPA, which went into effect on January 1, 2020, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. The CCPA provides for fines of up to \$ 7, 500 per violation. Aspects of the CCPA and its interpretation and enforcement remain uncertain. The effects of this legislation potentially are far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. The CCPA has been amended on multiple occasions, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CPRA became operative on January 1, 2023 (and applies to consumer data collected on or after January 1, 2022, (the “lookback period”), with enforcement beginning July 1, 2023. While the CCPA will remain operative and enforceable from now until July 1, 2023, we will continue to monitor developments related to the CPRA. The effects of this legislation potentially are far-reaching, however, and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. Additionally, many laws and regulations relating to privacy and the collection, storing, sharing, use, disclosure, and protection of certain types of data are subject to varying degrees of enforcement and new and changing interpretations by courts. **New laws governing the privacy of consumer health data, including information concerning genetic information, individual health conditions, and treatment have also passed in the United States. For example, Washington’s My Health My Data Act which broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for obtaining consumer consent), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states, including California, could adopt similar laws. Additionally, the General Data Protection Regulation (“GDPR”) imposes stringent requirements on the processing of “personal data”, including health and sensitive data, by business who target EU consumers or operate in the EU. The CCPA-GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to certain health data, obtaining consent of other— the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of the personal data, providing notification of data breaches, and taking specific measures when disclosing the personal data to third parties. Penalties for businesses who are not compliant with the GDPR can reach up to 4 % of global revenues. Additionally, post-Brexit, the UK has adopted its version of the GDPR (UK GDPR) alongside amendments to its Data Protection Act 2018, creating a separate regulatory environment that may impact global economic conditions and market operations.** ~~changes~~ **Changes** in laws or regulations relating to privacy, data protection, breach notifications, and information security, particularly any new or modified laws or regulations, or changes to the interpretation or enforcement of such laws or regulations, that require enhanced protection of certain types of data or new obligations with regard to data retention, transfer, or disclosure, could greatly increase the cost of providing our platform, require significant changes to our operations, or even prevent us from providing our platform in jurisdictions in which we currently operate and in which we may operate in the future. We may face audits or investigations by one or more domestic government agencies or our customers pursuant to our contractual obligations relating to our compliance with these regulations. Complying with changing regulatory requirements requires us to incur substantial costs, exposes us to potential regulatory action or litigation, and may require changes to our business practices in certain jurisdictions, any of which could materially adversely affect our business operations and operating results. Despite our efforts to comply with applicable laws, regulations, and other obligations relating to privacy, data protection, and information security, it is possible that our interpretations of the law, practices, or platform could be inconsistent with, or fail or be alleged to fail to meet all requirements of, such laws, regulations, or obligations. Risks Related to Our Common Stock, Internal Controls and Governance Matters ~~If we are unable to maintain effective~~ **We have identified material weaknesses in our** internal controls over financial reporting ~~or if, if we fail to properly remediate these~~ material weaknesses ~~or if we are otherwise unable~~ discovered in our internal accounting procedures, the accuracy and timing of our financial reporting may be adversely affected, which may adversely affect investor confidence in us and, as a result, the value of our common stock. Any failure to develop ~~or and~~ maintain an effective system of internal controls over financial reporting, **material misstatements in or our** difficulties encountered in implementing financial statements could occur and we may not be able to accurately or timely report ~~or our~~ improving financial results, which may adversely affect investor confidence in us, our business, results of operations and financial condition, and the trading price of our common stock. As further described in Item 9A. Controls and Procedures of this Annual Report, and Note 2 to the financial statements included under Item 8 of this Annual Report, we have identified material weaknesses in our internal controls over financial reporting ~~could harm,~~ which include (i) inadequate review of certain account reconciliation ~~our— or~~ operating results and prevent us from meeting our controls over financial statement closing process; (ii) errors made related to reporting recording obligations. Moreover and calculating revenue and following our policy regarding principal versus agent consideration, and effective ineffective controls to identify exceptions; and (iii) inadequate controls over identifying discrepancies relating to the calculation and recording of deferred costs and cost of sales, as of December 31, 2023. A material weakness is a deficiency, or a combination of deficiencies, in our internal controls, particularly those related to over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be revenue-prevented recognition, or detected and corrected on a timely basis. Effective internal controls are necessary for us to produce reliable financial reports. If we cannot

provide reliable financial reports and prevent fraud. We are evaluating and intend to implement steps to remediate the material weaknesses. These remediation measures may be time consuming and costly and there is no assurance that these initiatives will ultimately have the intended effects. The material weaknesses in our internal control over financial reporting will not be considered remediated until the controls operate for a sufficient period of time and management has concluded, through testing that these controls operate effectively. If we do not successfully remediate the material weaknesses, or if other material weaknesses or other deficiencies arise in the future, we may be unable to accurately report our financial results, which could cause our financial results to be materially misstated and require restatement. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, in addition to applicable stock exchange listing requirements and requirements under certain of our agreements, which could adversely affect investor confidence in us, our business, and operating results of operations and could be harmed, investors could lose confidence in our reported financial information condition, and the trading price of our common stock could drop significantly. In addition, investors Investors relying upon this misinformation could make an uninformed investment decision, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities or to stockholder class action securities litigation. In addition, these material weaknesses may also have the effect of heightening other risks described in this “ Risk Factors ” section. Future sales of shares of our common stock in the public market could adversely affect the trading price of shares of our common stock and our ability to raise funds in future offerings. Future sales of substantial amounts of shares of our common stock in the public market, or the perception that such sales are likely to occur, could adversely affect the prevailing trading prices of our common stock. Moreover, the perceived risk of potential dilution could cause stockholders to attempt to sell their shares and investors to “ short ” our stock, a practice in which an investor sells shares that he or she does not own at prevailing market prices, hoping to purchase shares later at a lower price to cover the sale. All of these events could combine to make it difficult for us to sell equity or equity- related securities in the future at a time and price that we deem appropriate. If securities or industry analysts do not publish research or reports about our business or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline. The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, products or stock performance, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, the unpredictability of our financial results likely reduces the certainty, and therefore reliability, of the forecasts by securities or industry analysts of our future financial results, adding to the potential volatility of our stock price. Our Chief Executive Officer and Chairman of the Board of Directors owns a substantial amount of our common stock any may be able to exert significant influence over the outcome of matters submitted to stockholders for approval. As of March 17-12, 2023-2024, our Chief Executive Officer and Chairman of the Board of Directors beneficially owned approximately 18-20. 1-2 % of our common stock. As such, our Chief Executive Officer may exert significant influence over the outcome of matters submitted to stockholders for approval. Consequently, he exercises substantial influence over major decisions including major corporate actions such as mergers and other business combinations transactions which could result in or prevent a change of control of the Company. Circumstances may occur in which the interests of our Chief Executive Officer could be in conflict with the interests of other stockholders. Accordingly, a stockholder’ s ability to influence us through voting their shares may be limited. Our Certificate of Incorporation and By-laws Bylaws contain certain provisions that may be barriers to a takeover. Our Certificate of Incorporation and By-laws Bylaws contain certain provisions which may deter, discourage, or make it difficult for another person or entity to gain control of the Company through a tender offer, merger, proxy contest or similar transaction or series of transactions, including provisions that: • authorize our board of directors to authorize “ blank check ” preferred stock without stockholder approval, which may provide for voting, liquidation, dividend, and other rights superior to our common stock; • specify that special meetings of our stockholders can be called only by our chairman or the board of directors; • prohibit stockholder action by written consent; • establish an advance notice procedure for stockholder matters to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors; • provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and • expressly authorized our board of directors to make, alter, amend, or repeal our amended and restated bylaws. These provisions may deter a future tender offer or other takeover attempt which could include a premium over the market price of our common stock at the time. Such provisions could depress the trading price of our common stock. Our Bylaws amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, executive officers, or employees. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation’ s stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the Certificate of Incorporation or Bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine shall be the Court of Chancery in the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware). This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933 or the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Although the

Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our ~~amended and restated certificate~~ **Certificate of incorporation-Incorporation**. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, executive officers, or other employees, which may discourage lawsuits against us and our directors, executive officers, and other employees. If a court were to find the exclusive forum provision in our ~~amended and restated certificate~~ **Certificate of incorporation-Incorporation** to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business. We have agreed to indemnify our officers and directors from liability. Our Certificate of Incorporation and our ~~By-laws~~ **Bylaws** provide that we will indemnify, to the fullest extent permitted by the Delaware General Corporation Law, any person who is or was made a party to, or is or was threatened to be made a party to, any pending, completed, or threatened action, suit or proceeding because he or she is or was a director, officer, employee or agent of the Company or is or was serving at the Company's request as a director, officer, employee or agent of any corporation, partnership, joint venture, trust or other enterprise. These provisions permit us to advance expenses to an indemnified party in connection with defending any such proceeding, upon receipt of an undertaking by the indemnified party to repay those amounts if it is later determined that the party is not entitled to indemnification. We entered into indemnity agreements with each member of our board of directors. These agreements provide, among other things, that we will indemnify each officer and director in the event they become a party or otherwise a participant in any action or proceeding on account of their service as a director or officer of the Company (or service for another corporation or entity in any capacity at the request of the Company) to the fullest extent permitted by applicable law. The indemnification provisions may reduce the likelihood of derivative litigation against directors and officers and discourage or deter stockholders from suing directors or officers for breaches of their duties to the Company, even though such an action, if successful, might otherwise benefit the Company or its stockholders. In addition, to the extent that we expend funds to indemnify directors and officers, funds will be unavailable for operational purposes.