

## Risk Factors Comparison 2025-03-21 to 2024-03-25 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

You should carefully consider the risks described below, as well as the other information in this Report, including our financial statements and the related notes and the section entitled “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations,” before investing in our ~~publicly traded~~ securities. The occurrence of any of the events or developments described below could harm our business, financial condition, operating results, and / or growth prospects. The risks described below are not the only ones facing us. Our business is also subject to the risks that affect many other companies, such as competition, labor relations, general economic conditions, geopolitical changes, and international operations. We operate in a rapidly changing environment that involves a number of risks, some of which are beyond our control. Additional risks not currently known to us or that we currently believe are immaterial also may impair our business operations and our liquidity. The risks described below could cause our actual results to differ materially from those contained in the forward- looking statements we have made in this Report, the information incorporated herein by reference, and those forward- looking statements we may make from time to time. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties. Risk Factor Summary Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information included in this Report. • We have a relatively limited operating history and may not be able to execute on our business strategy. • Our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months, which raises substantial doubt about our ability to continue as a going concern. • Our operating results may be volatile and may not be a reliable indicator of our future performance. • If we fail to manage our growth effectively, including with respect to **our recently in- licensed products from Statera or potential licenses from or** acquisitions of other companies, our business could be materially and adversely affected. • We have a history of net losses, and we may not achieve or maintain profitability in the future. • We have identified a material weakness in our internal control over financial reporting associated with staffing levels, which is common for the stage and size of the Company. • We expect that we will need additional capital, which, if obtainable, could dilute the ownership interest of investors . • **Cash expenditures associated with our recent in- license from Statera and developments of our ncVNS program may create liquidity and cash flow risks for us .** • Our business plan depends heavily on product revenues from our core technology **and recently in- licensed pharmaceutical products**, the clinical and consumer acceptance of which is at this time unproven . • **We have recently licensed biopharmaceutical products, a category in which we have limited to no prior experience. We may not be able to effectively integrate licensed or acquired technology into our operations. • Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or global health concerns could negatively impact our business .** • Economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, could harm our financial condition and results of operations. • **Changes in the relations of the United States with other countries, and China in particular, regulations and / or international trade disputes could have a material adverse effect on our business, financial condition and results of operations. • We rely on third- party service providers to manage our information systems which may not adequately protect the company; additionally, cybersecurity risks and cyber incidents could adversely affect us. •** We rely on third parties to supply and manufacture our devices, and we expect to continue to rely on third parties to manufacture and supply our devices . ~~• We may be adversely affected by the effects of inflation.~~ • We depend on our senior management team, and the loss of one or more key personnel or an inability to attract and retain highly skilled personnel may impair our ability to grow our business. • The guarantees and warranties we provide on our products could have a material adverse effect on our business, financial condition and results of operations. • Our markets are undergoing continuous change, and our future success will depend on our ability to meet the changing needs of our customers. • Developing medical technology **and biopharmaceutical products** entails significant technical, regulatory and business risks. • The size and expected growth of our available market has not been established with precision and may be smaller than we estimate. • Our insurance may not adequately cover our operating risk. • Our business could be disrupted by catastrophic occurrences and similar events. • Changes in the regulatory landscape for our products **and product candidates** could render our business model contrary to applicable regulatory requirements, and we may be required to seek additional clearance or approval for our products. Additionally, we have relied on guidance documents from FDA ~~and our EU Notified Body~~ to make determinations about the regulatory pathway for future products, which may be interpreted to a different effect by the ~~FDA governing regulatory bodies~~ . • We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. ~~Our actual or perceived failure~~ • **We may not be able to** ~~comply~~ **obtain regulatory approval in a timely manner or at all and the results of future clinical trials and pivotal efficacy studies may not be favorable. • Compensatory arrangements with such obligations** ~~our scientific advisors or consultants could harm~~ **result in increased regulatory scrutiny and ultimately lead to the delay our** ~~or denial of~~ **business, and changes in such regulations or laws could require us to modify our products or marketing approval or for advertising efforts** ~~our product candidates~~ . • **We may not be able** ~~Our reliance on vendors in foreign countries, including China, subjects us to risks~~ **obtain fast track designation, breakthrough therapy designation or other expedited pathways for FDA approval of our product candidates, and uncertainties relating even if we do, may not actually lead to foreign laws and a faster development or** ~~regulations~~ **regulatory review or approval process** ~~and changes in relations between the United States and~~

such foreign countries. • We are highly dependent on our intellectual property (“ IP ”) and our methods of protecting our IP may not be adequate or could be costly. In addition, we may face risks of claims for IP infringement. We may be unable to enforce our intellectual property rights throughout the world. • Our stock price has fluctuated significantly since our **initial public offering (“ IPO ”)**, and may continue to fluctuate significantly, and investors may not be able to resell the securities that they purchase at or above the price at which they purchased them. ~~An active trading market for our common stock may never develop or be sustained.~~ • We do not expect to pay any cash dividends for the foreseeable future. • Future issuances of stock or other securities could dilute the holdings of our stockholders and could materially affect the price of our common stock. **• If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock could be delisted, which could affect our common stock's market price and liquidity and reduce our ability to raise capital.** • We are an “ emerging growth company ” and a “ smaller reporting company, ” and the reduced public company reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors. • If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline. • If our operating and financial performance in any given period does not meet any guidance that we provide to the public, the market price of our common stock may decline. ~~• Actual or perceived failures to comply with applicable data privacy and security laws, regulations, policies, standards, contractual obligations and other requirements related to data privacy and security and changes to such laws, regulations, standards, policies and contractual obligations could adversely affect our business, financial condition and results of operations.~~ **Risks Related to Our Financial Condition and Business Model** We were originally incorporated in 2016 and began selling our first product in 2019. **Additionally, we entered into a license agreement with Statera in February 2025, pursuant to which we acquired a worldwide exclusive license rights from Statera to the late- stage TLR5 agonist Entolimod for the treatment of acute radiation syndrome. Prior to obtaining such license, the Company had no experience in the development of biopharmaceuticals.** Accordingly, we have a limited operating history, which makes an evaluation of our future prospects and execution ability difficult. Our revenue and income- producing potential is unproven, and our business model and strategy may continue to evolve. Future revenues are contingent upon several factors, including, without limitation, our ability to successfully develop and scale- up sales of the ClearUP line and future products, **including any ncVNS products and / or TLR5 products that we may develop and commercialize in the future,** our ability to develop relationships with channel partners and customers, as well as the clinical and market acceptance of our technology. We may need to make business decisions that could adversely affect our operating results, such as modifications to our pricing strategy, **research and development strategy,** business structure or operations. Our operating results will likely be volatile and may not be a reliable indicator of our future performance. Our future expenses, revenues and operating results may vary significantly from quarter to quarter due to a number of factors, including, without limitation: **• strategic transactions that we may enter into from time to time, including the recent license that we acquired from Statera in February 2025 and any other indications that we may choose to license from Statera in the future under the License Agreement, including our obligations related thereto;** • receptiveness of the market to a fundamentally new way of treating target conditions; • intrinsic variability in spending patterns associated with the conduct of clinical trials; • disruptions to the global supply chain and inflationary pressures; • fluctuations in demand for our technology, including seasonal variations; and • delays in introducing new technology to market, including product design, manufacturing, marketing cycles, sales and distribution related delays. We expect that our revenues may be volatile as we develop new technology and **product candidates and** obtain new customers in the future. The volume and timing of commercial outcomes **for our ClearUP product** are difficult to estimate, as the adoption of bioelectronic treatments is immature, and the sales cycle may vary substantially from forecasts. If we fail to manage our growth effectively, our business could be materially and adversely affected. We will not be successful unless we are able to generate additional revenues and grow our business, which will likely require us to hire additional employees and expand our technology, product, development and sales and marketing teams in order to achieve our business plan. Our management systems are emergent. The continued growth of our business may place demands on our management, financial, operational, technological and other resources, and we expect that our growth will require us to continue developing and improving our operational, financial and other internal controls. We may not be able to address these challenges in a cost- effective manner, or at all. If we do not effectively manage our growth, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, satisfy customer requirements or maintain high- quality product offerings, which could have a material adverse effect on our business, financial condition and results of operations. We have a history of net losses and we may not achieve or maintain profitability in the future. We have incurred net losses since inception. For the years ended December 31, **2024 and 2023 and 2022,** we incurred net losses of \$ **5.7 million and \$ 8.2 million and \$ 10.1 million,** respectively, and at December 31, **2023-2024,** we had working capital of \$ **3-2.3-4 million** and an accumulated deficit of \$ **37-43.9-5 million.** During the years ended December 31, **2024 and 2023 and 2022,** we used \$ **8-5.7 million and \$ 8.9-5 million** of cash, respectively, for operating activities. The net losses we incur may fluctuate significantly from quarter to quarter and may increase as a result of macroeconomic factors. Additionally, future costs relating to product development and operating activities, **including as a result of our obligations under the License Agreement recently entered into with Statera,** may be significantly higher than our historical costs. Management expects to incur substantial additional operating losses for the foreseeable future to expand our markets, complete development of new products, obtain regulatory approvals, launch and commercialize our products and continue research and development programs. Our future capital requirements will depend upon many factors, including, without limitation, progress with developing, manufacturing and marketing our technologies **and product candidates; the time and costs involved in obtaining regulatory approvals for our product candidates;** the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights; our ability to successfully execute our ~~acquisition~~ **strategy to expand our**

**business**, including **through** the closing of potential acquisitions **or licenses** and integrating new business into our own; our ability to establish collaborative arrangements; marketing activities; and competing technological and market developments. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products and services from customers currently identified in our sales pipeline as well as new customers. We will also be required to efficiently manufacture and deliver equipment on those purchase orders. These activities, including our planned research and development efforts, will require significant uses of working capital. There can be no assurance that we will generate revenue and cash as expected in our current business plan. We expect that we will need to raise additional capital to continue operating our business and fund our planned operations, including to execute on our **acquisition strategy to expand our business**, research and development, clinical trials and, if regulatory approval is obtained, commercialization of future product candidates. We may seek additional funds through equity or debt offerings and / or borrowings under notes payable, lines of credit or other sources. We do not know whether additional financing will be available on commercially acceptable terms, or at all, when needed. If adequate funds are not available or are not available on commercially acceptable terms, our ability to fund our operations, support the growth of our business or otherwise respond to competitive pressures could be significantly delayed or limited, which could materially and adversely affect our business, financial conditions, or results of operations. Our long-term success is dependent upon our ability to successfully develop, commercialize and market our products, earn revenue, obtain additional capital when needed and, ultimately, to achieve profitable operations. We will need to generate significant additional revenue to achieve profitability. Future products may require substantially higher levels of investment than initial products, including investments in research, development, regulatory and / or marketing and sales. It is possible that we will not achieve profitability or that, even if we do achieve profitability, we may not maintain or increase profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of our **securities common stock**. There is substantial doubt about our ability to continue as a going concern. Because we have incurred operating losses since inception, and based on our current cash levels and burn rate, amongst other things, we believe our cash and financial resources may be insufficient to meet our anticipated needs for the next twelve months, which raises substantial doubt about our ability to continue as a going concern within one year from the issuance date of the financial statements included elsewhere in this Report. These losses are expected to continue for at least a period of time. The financial statements included elsewhere in this Report have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within one year after the date the financial statements are issued. Our ability to obtain additional financing will depend on a number of factors, including, among others, the condition of the capital markets and the other risks described in these risk factors. If any one of these factors is unfavorable, we may not be able to obtain additional funding, in which case, our business could be jeopardized and we may not be able to continue our operations or pursue our strategic plans. If we are forced to scale down, limit or cease operations, our shareholders could lose all or part of their investment in our Company. We have identified a material weakness in our internal control over financial reporting. In connection with the audit of our financial statements for the years ended December 31, **2024 and 2023 and 2022**, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. **Due** ~~In 2022, we remediated deficiencies related to inventory cost accounting procedures, and to the extent possible, the segregation of duties. In addition, we completed our internal control design and formalized various internal control processes and procedures as of December 31, 2022. However, due~~ to the small size of our accounting and financial reporting team, as well as recent staff turnover, even with processes and procedures in place to mitigate the risk of a material misstatement, we believe that there is still a reasonable possibility that a material misstatement of our annual or interim financial statements may not be prevented or detected on a timely basis. If we are unable to remedy our material weakness, or if we generally fail to establish and maintain effective internal controls appropriate for a public company, we may be unable to produce timely and accurate financial statements, and we may continue to conclude that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price. We anticipate we will need additional capital to market our products, develop additional products and fund our operations, which we may raise through the sale and issuance of equity, equity- related or convertible debt, or other securities. Our future capital requirements depend on many factors, including our need to market our products, acquire or develop additional products and fund our operations. We cannot be certain that additional financing will be available to us on acceptable terms when required, or at all. If we issue additional equity securities or securities convertible into equity securities, our existing stockholders will be subject to dilution. Additionally, sales of substantial amounts of our equity securities could have an adverse effect on the value of our equity and our ability to raise additional capital through future capital increases. **We incurred significant transaction costs and expect to incur integration costs in connection with our recent in- license of rights to certain products from Statera. While we expected that the transactions costs would be incurred, there are many factors beyond our control that could affect the total amount of the integration expenses associated with the license. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. In addition to integration- related expenses that we will incur, pursuant to the License Agreement, we are obligated to develop and commercialize the licensed products, at our own cost and expense, to make payments to Statera upon achievement of certain milestones, and to make certain royalty payments. In addition, we have certain on- going commitments associated with the development of our ncVNS program. To the extent the integration and / or development and commercialization expenses are higher than anticipated, we may experience liquidity or cash flow issues.** Our business plan depends heavily on revenues from our **initial core technology and recently in- licensed pharmaceutical** products, the clinical and consumer acceptance of which is

unproven at this time. Our future growth depends on the commercial success of our technology and ~~initial~~ **our** products **and product candidates**. It is not certain that our target customers will choose our technology for technical, cost, support or commercial reasons. If our target customers do not widely adopt and purchase our technology, our future growth will be limited. Further, our resources and investments may not be adequate to achieve the targeted level of manufacturing and sales set out in our business plan. **We have recently licensed biopharmaceutical assets, a category in which we have limited to no prior experience. We may not be able to effectively integrate licensed or acquired assets into our operations (including regulatory, quality, product development, marketing and manufacturing operations). We have historically operated solely as a medical device company. We have recently in- licensed exclusive rights to late- stage biopharmaceutical products from Statera that will require us to operate in, among others, regulatory, quality, product development, manufacturing and marketing environments with which we have limited experience. While we have hired experienced staff to support this new dimension of the business, we may not be able to successfully create or integrate new capabilities into our overall business. This may ultimately limit or substantively damage our ability to capitalize on the licensed assets. Disruptions at the FDA and foreign regulatory authorities caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and foreign regulatory authorities to review or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s or foreign regulatory authorities' ability to perform routine functions including a rapid substantial influx of applications from numerous sponsors, as occurred with COVID- 19. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. For example, in recent years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities and, recently, the current administration has been implementing significant budget cuts, eliminating grant programs and terminating employees throughout many different sectors of the federal government. Disruptions at the FDA and other agencies may also slow the time necessary for new devices and drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business.**

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, ~~and~~ the ongoing military conflicts between Russia and Ukraine and Israel and Hamas, ~~and record inflation~~. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine and the Middle East, ~~and / or geopolitical tensions or record inflation~~. U. S. and global markets are experiencing volatility and disruption, ~~and~~ the global economy has been, and may continue to be, negatively impacted by Russia' s ongoing military conflict with Ukraine. As a result of Russia' s invasion of Ukraine in February 2022, the U. S., the European Union, the United Kingdom, other G7 countries, as well as various other countries, have imposed substantial financial and economic sanctions on certain industry sectors and parties in Russia. Broad restrictions on exports to Russia have also been imposed. These measures include: (i) comprehensive financial sanctions against major Russian banks; (ii) additional designations of Russian individuals with significant business interests and government connections; (iii) designations of individuals and entities involved in Russian military activities; and (iv) enhanced export controls and trade sanctions limiting Russia' s ability to import various goods. Russian military actions and the resulting sanctions could continue to adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. ~~In Addition, in October 2023, Hamas militants and members of certain other organizations infiltrated Israel' s southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Shortly thereafter, Israel' s security cabinet declared war against Hamas and launched an aerial bombardment of various targets within the Gaza Strip. It is possible that other countries and / or regional organizations will join the hostilities as well, including without limitation Hezbollah in Lebanon, and Palestinian military organizations in the West Bank, resulting in further expansion of the conflict. The conflict between Israel and Hamas is ongoing, and the length and impact of the ongoing military conflict is highly unpredictable. There are also current~~ **Although our business has not been materially impacted by the ongoing military conflicts between Russia and Ukraine or Israel and Hamas, geopolitical tensions, or record inflation to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the conflicts in Ukraine and the Middle East, geopolitical tensions, record inflation, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described herein. Changes in United States and China relations, as well as relations with other countries, and / or regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our shares. The U. S. government, including the SEC, has made statements and taken certain actions that led to changes to U. S. and international relations, and will impact companies with connections to the United States or China. Recently, the Biden administration has signed multiple including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China- based operations. It is unknown whether and to what extent new legislation, executive orders regarding, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the U. S. or to China, our industry or on us. Any unfavorable government policies on cross- border**

relations and / or international trade, including certain increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect our ability to raise capital and the market price of our shares. If any new legislation, executive orders, tariffs, laws that may impact the pharmaceutical industry and other similar industries in / or regulations are implemented, if existing trade agreements are renegotiated or if the U. S. Moreover, both or Chinese governments take retaliatory actions due to the recent U. S. and - China tension, such changes could have recently imposed sanctions upon certain companies and - an adverse effect individuals based in the other country, and have also imposed certain import and export restrictions and tariffs on products originating from the - our business, financial condition and results of operations, our ability to raise capital and other -- the country market price of our shares. Any additional executive action, legislative action or potential sanctions with China could materially impact our current manufacturing partners and our agreements with them. Although Additionally, any additional executive action, legislative action or potential sanctions with China could materially impact our current manufacturing partners and our agreements with them. International trade disputes could result in tariffs and other protectionist measures that could have a material adverse effect on our business, financial condition and results of operations. In recent years, including after the most recent presidential election, the U. S has not been materially impacted by instituted or proposed changes in trade policies that include the negotiation or termination of trade agreements, the imposition of higher tariffs on imports into the U. S., economic sanctions on individuals, corporations or countries, and the other ongoing military conflicts government regulations affecting trade between Russia the U. S. and Ukraine other countries where we conduct or our business Israel and Hamas, geopolitical tensions in particular China, Mexico and Canada. A number of other nations have proposed or instituted similar measures directed at trade with the United States in response. As a result of these developments, there may be greater restrictions and economic disincentives on international trade that could adversely affect or our record inflation to date business. As additional trade- related policies are instituted, it is impossible we may need to predict the extent modify our business operations to comply and adapt to such developments, which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the conflicts in Ukraine and the Middle East, geopolitical tensions, record inflation, sanctions and resulting market disruptions are impossible to predict, but could be time- consuming and expensive substantial. Any such disruptions may also magnify the impact of other risks described herein. Cybersecurity risks and cyber incidents, as well as other significant disruptions of our information technology networks and related systems and resources, could adversely affect our business, disrupt operations and expose us to liabilities to employees, customers, governmental regulators, and other third parties. We use information technology and other computer resources to carry out important operational activities and to maintain our business records. As part of our normal business activities, we permit certain employees to perform some or all of their business activities remotely, we collect and store certain personal identifying and / or confidential information relating to our employees, customers, vendors and suppliers, and we maintain operational and financial information related to our business. Furthermore, we rely on products and services provided by third- party suppliers to operate certain critical business systems, including without limitation, cloud- based infrastructure, encryption and authentication technology, email, and other functions, which exposes us to supply- chain attacks or other business disruptions. We face risks associated with security breaches through cyber- attacks or cyber- intrusions, malware, computer viruses and malicious codes, ransomware, attachments to e- mail, unauthorized access attempts, denial of service attacks, phishing, social engineering, persons with access to systems inside our organization, and other significant disruptions of our information technology networks and related systems. The risk of a security breach has generally increased as the frequency, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Even the most well protected information, networks, systems and facilities remain potentially vulnerable because the techniques, tools and tactics used in such attempted security breaches evolve and generally are not recognized until launched against a target, and in some cases are designed to not be detected and, in fact, may not be detected. Accordingly, we may be unable to anticipate these techniques or to implement adequate security barriers, disaster recovery or other preventative or corrective measures, and thus it is impossible for us to entirely counteract this risk or fully mitigate the harms after such an attack. We have implemented certain systems and processes intended to address ongoing and evolving cybersecurity risks, secure our information technology, applications and computer systems, and prevent unauthorized access to or loss of sensitive, confidential and personal data. Although we and our service providers employ what we believe are adequate security, disaster recovery and other preventative and corrective measures, our security measures, taken as a whole, may not be sufficient for all possible situations and may be vulnerable to, among other things, fraud, hacking, employee error, system error, and faulty password management. Additionally, we rely on third- parties for virtually all of our operating infrastructure, who may themselves have standards of materiality of cybersecurity risks that differ from the materiality standards of Tivic itself. Our ability to conduct our business may be impaired if our or our services providers' information technology networks, systems or resources, including our and their websites or e- mail systems, are compromised, degraded, damaged or fail, whether due to a virus or other harmful circumstance, fraud, intentional penetration or disruption of our or their information technology resources by: • a third party, • natural disaster, • a failure of hardware or software due to a design or programmatic flaw, • a failure of hardware or software security controls, • telecommunications system failure, • service provider error or failure, • fraudulent transactions, • intentional or unintentional personnel actions, • lost connectivity to our networked resources, or • a failure of disaster recovery system. A significant and extended disruption could damage our business or reputation and cause, amongst other things, loss of revenues or customer relationships, unintended and / or unauthorized public disclosure or the misappropriation of proprietary, personal identifying and confidential information, and us to incur significant expenses to address and remediate or otherwise resolve these kinds of issues. Our disaster recovery procedures and contingency planning rely heavily on third- party providers and may prove insufficient to fully protect Tivic operations and business interests The release of confidential information may also lead to litigation or other proceedings against us by affected individuals, business

partners and / or regulators, and the outcome of such proceedings, which could include losses, penalties, fines, injunctions, expenses and charges recorded against our earnings and cause us reputational harm and / or could have a material and adverse effect on our business, financial position or results of operations. We rely on third parties to supply and manufacture our devices, which could cause supply shortages, and we expect to continue to rely on third parties to manufacture and supply our devices. We encountered disruptions in our supply of various materials and components, and electronic components during 2022 due to the well- documented shortages and constraints in the global supply chain. This was exacerbated by the resurgence of the COVID- 19 pandemic in certain parts of China, which resulted in the temporary closure of manufacturing facilities, including those that make electronic parts like those that we included in our products, in certain parts of China. If we experience similar constraints in the future, the supply or manufacture of our devices could be stopped, delayed or made less profitable if any of these third parties fail to provide us with sufficient quantities at acceptable quality levels or prices, or fail to maintain or achieve satisfactory regulatory compliance. We rely on, and expect to continue to rely on, third- party providers for the supply and manufacturing of our devices, including components and electronic parts **, as well as materials for our licensed biopharmaceutical products**. Lead times for ordered components **and materials** may vary significantly, and some components used to manufacture our products are provided by a limited number of sources. We are continuously evaluating alternative and secondary source suppliers in order to ensure that we are able to source sufficient components and materials to manufacture our products **and product candidates**. In the event that we are unable source sufficient components and materials from our current suppliers, or to develop relationships with additional suppliers, to manufacture enough of our products to satisfy demand, we may have to cease or slow down production of our products. To the extent our current manufacturers or suppliers, or any manufacturers and suppliers that we engage in the future, are unable to meet our requirements in a timely and cost- effective manner, we may not be able to obtain an adequate supply of electronic parts ~~or~~, components **or materials** for our products **or product candidates**. Any shortage of materials caused by any disruption or unavailability of supply or an increase in the demand for our products, could harm our ability to satisfy customer demand, delay deliveries of our products to customers, lead to customer cancellations and returns, delay the **clinical trial and regulatory approval process, delay the** development and launch of new products, or increase our costs and decrease our revenue. Any such impacts or delays could adversely affect our sales, customer satisfaction, profitability, cash flows and financial condition –and our business may be adversely affected. Our efforts to mitigate supply chain weaknesses may not be successful or may have unfavorable effects. We do not control the operational processes of the contract manufacturing organizations with whom we contract and are dependent on these third parties for the production of our devices **and product candidates** in accordance with relevant regulations, which include, among other things, quality control, quality assurance and the maintenance of records and documentation. **We may be adversely affected by the effects of inflation.** Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure, particularly if we are unable to achieve commensurate increases in the prices we charge our customers. The existence of inflation in the economy has **recently** resulted in, and may ~~continue to~~ **in the future** result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. As a result of inflation, we have experienced ~~and may continue to experience~~, cost increases. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost inflation is incurred. We depend on our senior management team and the loss of one or more key personnel or an inability to attract and retain highly skilled personnel may impair our ability to grow our business. Our future success depends heavily upon the continued services of our executive officers and key personnel. The Company is headquartered in California, which is an at will employment state. Accordingly, the employment agreements that we have entered into with our executive officers and other key personnel do not require them to continue to work for us for any specified period and, therefore, they may terminate employment with us at any time, for any reason and with no advance notice. The replacement of members of our senior management team or other key personnel would likely involve significant time and costs, and the loss of these employees may significantly delay or prevent the achievement of our business objectives. In addition, our ability to recruit and retain talent in all areas of the business, including but not limited to skilled hires in marketing, product development, regulatory, clinical, quality, logistics, and finance, faces significant competition. We may not be able to hire or retain the type and number of managerial, sales and technical personnel necessary for future success. We will need to devote considerable resources to ensure that we retain our employees in the face of a highly competitive market for talented personnel. If we fail to attract and retain the skilled employees required, this could harm our business and hamper future expansion of our business operations. We rely on third parties for sales, marketing, manufacturing, distribution, and other business operations. For us to be successful, third parties providing us with sales, marketing, manufacturing, distribution and other business operations services must be able to provide us with such services in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs, and on a timely basis. While our service providers have generally met our expectations in the past, their ability and willingness to continue to do so going forward, and the ability and willingness of any new service provider to meet our expectations in the future, may be limited for several reasons, including our relative importance as a customer. Additionally, we rely on third- party ~~online retailers such as Amazon, BestBuy, Walmart, FSASore~~ **and other specialty** online retailers, as well as the parties that we have entered into distribution agreements with, to sell our products. We do not have long- term agreements in place with certain of these third parties and there is no guarantee that such third parties will continue to allow us to sell our products through their platforms or channels. Accordingly, we may be exposed to disruptions or reduced ~~quality~~ **quality** of services, including access to distribution channels, due to factors beyond our direct control, which may impact our ability to operate successfully. We may not be able to successfully identify, consummate or integrate **licensed assets or** acquisitions or to successfully manage the impacts of such transactions on our operations. Part of

our business strategy includes investigating growth through **in- licenses of assets, such as our recent in- license of assets from Statera, and** acquisitions. **We In connection with the recent license transaction with Statera, we have in- licensed new assets, created a new biopharmaceutical program and brought on new employees to help us develop our TLR5 program. In the future, we may further** expand our business **through additional licenses, including by exercising our option to license additional indications from Statera, or** by making strategic acquisitions ~~and seeking suitable acquisition targets~~ to enhance our growth. Material **in- licenses,** acquisitions, dispositions and other strategic transactions involve a number of risks, including: (i) the potential disruption of our ongoing business; (ii) the distraction of management away from the ongoing oversight of our existing business activities; (iii) incurring additional indebtedness; (iv) **increases in our capital expenditures;** (v) the anticipated benefits and cost savings of those transactions not being realized fully, or at all, or taking longer to realize than anticipated; ( ~~v-vi~~ ) an increase in the scope and complexity of our operations; ( ~~vi-vii~~ ) exposure to unknown liabilities, and ( ~~vii-viii~~ ) the loss or reduction of control over certain of our assets. The pursuit of ~~acquisitions~~ **strategic transactions** may pose certain risks to us. We may not be able to identify **license or** acquisition candidates that fit our criteria for growth and profitability. Even if we are able to identify such candidates, we may not be able to acquire them on terms or financing satisfactory to us. We may incur expenses and dedicate attention and resources associated with the review of ~~acquisition~~ **strategic transaction** opportunities, whether or not we consummate such ~~acquisitions~~ **transactions** , which may divert management' s attention from our day- to- day business. Additionally, even if we are able to ~~acquire suitable targets~~ **complete in- licenses or acquisitions** on agreeable terms, we may not be able to successfully integrate **the licensed assets and / or** their operations with ours. Achieving the anticipated benefits of any ~~acquisition~~ **transaction** will depend in significant part upon whether we integrate such ~~acquired~~ businesses in an efficient and effective manner. We may not be able to achieve the anticipated operating and cost synergies or long- term strategic benefits of our **in- licenses or** acquisitions within the anticipated timing, or at all. The benefits from any ~~acquisition~~ **such transactions** will be offset by the costs incurred in integrating the businesses and operations. We may also assume liabilities in connection with ~~acquisitions~~ **transactions** to which we would not otherwise be exposed. An inability to realize any or all of the anticipated synergies or other benefits of ~~an a~~ **license or** acquisition as well as any delays that may be encountered in the integration process, which may delay the timing of such synergies or other benefits, could have an adverse effect on our business, results of operations and financial condition. We provide product guarantees to our customers, pursuant to which we allow for the return of products from customers within 60 days after the original sale. We also provide ~~a one-~~ **and two-** year ~~warranty~~ **warranties** for any defective product. Existing and future product guarantees and warranties place us at the risk of incurring future returns and repair and / or replacement costs. While we engage in product quality programs and processes, including monitoring and evaluating the quality of our components sourced from our suppliers, our guaranty and warranty obligation is affected by actual product defect rates, parts and equipment costs and service labor costs incurred in correcting a product defect. During the years ended December 31, **2024 and 2023 and 2022**, we accrued return reserves equal to approximately ~~12-9.5~~ % and 10 %, respectively, of gross revenues. We believe our reserve as of December 31, **2023-2024** is adequate. However, our reserves set aside to cover warranty returns and customer returns may be inadequate due to an unanticipated number of customer returns, undetected product defects, unanticipated component failures or changes in estimates for material, labor and other costs we may incur to replace projected product defects. As a result, if actual customer returns, product defect rates, parts and equipment costs or service labor costs exceed our estimates, it could have a material adverse effect on our business, financial condition and results of operations. ~~Our~~ insurance may not adequately cover our operating risk or litigation exposure. We have insurance to protect our assets, operations and employees. While we believe our insurance coverage addresses the material risks to which we are exposed and is adequate and customary in our current state of operations, such insurance is subject to coverage limits and exclusions and may not be available for the risks and hazards to which we are exposed. Also, our insurance may be insufficient to cover the costs of any securities- related or other lawsuits or litigation, regardless of the merits of any such lawsuits or litigation. In addition, no assurance can be given that such insurance will be adequate to cover our liabilities or will be generally available in the future or, if available, that premiums will be commercially justifiable or affordable. If we were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if we were to incur such liability at a time when we are not able to obtain liability insurance, our business, results of operations and financial condition could be materially adversely affected. **Our** Risks Related to Our **Bioelectronic** Business and Markets Our ability to compete in the sinus, cold and allergy market is unproven. We currently compete in the sinus, cold and allergy market segment, a segment with large, entrenched players. We expect to experience competition from current and potential new competitors, some of which may be better established and have significantly greater financial, technical, marketing and distribution resources. We encounter competition from larger, well- established and well- financed entities that may continue to acquire, invest in, or form joint ventures with producers of alternate sinus care technologies. Our competitors may be able to respond more quickly to new or emerging technologies and changes in customer requirements than we can. Our market position could erode rapidly as a result of the development of new, superior products and technology by competitors. In addition, current and potential competitors may have greater name recognition, broader physician reach and more extensive customer bases. Increased competition could result in price reductions, lower volume sales, and reduced gross margins. There can be no assurance that we will be able to compete successfully against our current or future competitors or that competitive pressures will not have a material adverse effect on our business, financial condition and results of operations. For our business to survive and grow, we must continue to enhance and improve our products and technology to address a broader range of customers' needs. If customer behavior or new industry standards or practices emerge, our existing technology may become obsolete. Our future success will depend upon, among other things, our ability to: • develop and license new technologies that address the increasingly sophisticated and varied needs of prospective customers; • stay ahead of technological advances and emerging industry standards and practices on a cost- effective and timely basis; and • monitor and stay ahead of shifts in the competitive landscape . **Developing medical technology entails significant**

**technical, regulatory and business risks**. We may fail to adapt our technology to user requirements or emerging treatment standards. Microcurrent and other neuromodulation therapies are not currently considered standard of care for inflammation and may not ever be considered standard of care. Treatment standards may not evolve to incorporate our product. New industry standards for the development, manufacture and marketing of medical devices may evolve and we may not be able to conform to the changes, meet new standards in a timely fashion or maintain a competitive position in the market. In particular, regulatory standards for bioelectronic treatments of medical conditions are evolving. If we face material delays in introducing our products and new technology, we may fail to attract new customers. Customer or third- party complaints or negative reviews or publicity about our company or our products could harm our reputation and brand. We are heavily dependent on customers who use our ClearUP device to provide good reviews and word- of- mouth recommendations to contribute to our growth. Customers who are dissatisfied with their experiences with our products or services may post negative reviews. We may also be the subject of blog, forum or other media postings that include inaccurate statements and / or create negative publicity. In addition, any negative news regarding bioelectronic medicine may adversely impact our business. Any negative reviews or publicity, whether real or perceived, disseminated by word- of- mouth, by the general media, by electronic or social networking means or by other methods, could harm our reputation and brand and could severely diminish consumer confidence in our products. We may face risks associated with expanding to international markets. We may pursue marketing and selling our products internationally, which would likely be primarily done through e- commerce accelerators, distribution arrangements and regional licensing. We have limited experience operating outside the United States, and we will likely need to rely heavily on distributors and licensees in the event that we expand internationally. Expansion into international markets may expose us to, among other things, the following additional risks: • strain on our managerial resources; • pricing pressure that we may experience internationally; • a shortage of high- quality e- commerce accelerators, distributors, and licensees; • competitive disadvantage to competition with established business and customer relationships; • foreign currency exchange rate fluctuations; • the imposition of additional U. S. and foreign governmental controls or regulations; • economic instability; • changes in duties and tariffs, license obligations and other non- tariff barriers to trade; • the imposition of restrictions on the activities of foreign agents, representatives and distributors; • scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us; • laws and business practices favoring local companies; • difficulties in maintaining consistency with our internal guidelines; • difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • the imposition of costly and lengthy new export licensing requirements; • the imposition of U. S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and • the imposition of new trade restrictions. Our data on the available market for our current products and future products is based on a number of internal and third- party research reports, estimates and assumptions. While we believe that such research, our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct. In addition, the statements in this Report relating to, among other things, the expected growth in the market for our ClearUP device are based on a number of internal and third- party data, estimates and assumptions, and may prove to be inaccurate. If the actual number of consumers who would benefit from our products, the price at which we can sell future products or the available market for our products is smaller than we estimate, it could have a material adverse effect on our business, financial condition and results of operations. Our **insurance may not adequately cover our operating..... could be materially adversely affected.** Our headquarters are located in the San Francisco Bay Area, and we are vulnerable to interruption from catastrophic occurrences, such as earthquakes, floods, fires, power loss, telecommunication failures, terrorist attacks, criminal acts, sabotage, other intentional acts of vandalism and misconduct, geopolitical events, disease, such as the COVID- 19 pandemic, and similar events. The San Francisco Bay Area is a region known for seismic activity. Despite any precautions we may take, the occurrence of a natural disaster or other unanticipated problems at our facilities or the facilities of our suppliers and vendors could result in disruptions and other performance and quality problems. If we are unable to develop adequate plans to ensure that our business functions continue to operate during and after a disaster and / or to execute successfully on those plans in the event of a disaster or emergency, our business would be seriously harmed.

**Risks Relating to Regulatory Drug Approval The testing, marketing, and manufacturing of any product for use in the U. S. and the E. U. will require approval from the FDA and the EMA, respectively. We cannot predict with any certainty the amount of time necessary to obtain FDA approval and whether any such approval will ultimately be granted. Preclinical studies, animal efficacy studies, or clinical trials may reveal that one or more products are ineffective or unsafe, in which event, further development of such products could be seriously delayed, terminated or rendered more expensive. In addition, we expect to rely on the FDA Animal Rule to obtain approval for Entolimod' s biodefense indication in the U. S. The Animal Rule permits the use of animal efficacy studies together with human clinical safety trials to support an application for marketing approval of products when human efficacy studies are neither ethical nor feasible. These regulations have limited prior use and we have limited experience in the application of these rules to the product candidates that we are developing. We cannot guarantee that the FDA will review the data submitted in a timely manner, or that the FDA will accept the data when reviewed. If we are not successful in completing the development, licensure, and commercialization of Entolimod for its biodefense indication, or if we are significantly delayed in doing so, our business will be materially harmed. Even if we eventually complete clinical trials and receive approval for our product candidates, the FDA or EMA may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and / or the implementation of a REMS, which may be required to ensure safe use of the drug after approval. Delays in obtaining FDA, EMA, or any other necessary regulatory approvals of any proposed product or the failure to receive such approvals would have an adverse effect on our ability to develop such product, the product' s potential commercial success and / or on our business, prospects, financial condition and results of operations. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and**

receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between the Company and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates. Failure to obtain regulatory approval in international jurisdictions could prevent us from marketing our products abroad. We intend to market our product candidates, in the U. S., Europe, Ukraine and other countries and regulatory jurisdictions. In order to market our product candidates in the U. S., Europe, Ukraine, and other jurisdictions, we must obtain separate regulatory approvals in each of these countries and territories. The procedures and requirements for obtaining marketing approval vary among countries and regulatory jurisdictions and may involve additional clinical trials or other tests. In addition, we do not have in-house experience and expertise regarding the procedures and requirements to file for and obtain marketing approval for drugs in countries outside of the U. S., and may need to engage and rely upon expertise of third parties when we file for marketing approval in countries outside of the U. S. Also, the time required to obtain approval in markets outside of the U. S. may differ from that required to obtain FDA approval, while still including all of the risks associated with obtaining FDA approval. We may not be able to obtain all of the desirable or necessary regulatory approvals on a timely basis, if at all. Approval by a regulatory authority in a particular country or regulatory jurisdiction, such as the FDA in the U. S. or the EMA in the E. U., does not ensure approval by a regulatory authority in another country. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any or all of the countries or regulatory jurisdictions in which we desire to market our product candidates. At this time, to our knowledge, other countries do not have an equivalent to the Animal Rule and, as a result, such countries do not likely have established criteria for review and approval for this type of product outside their normal review process. The fast track designation for Entolimod may not actually lead to a faster development or regulatory review or approval process. Statera previously obtained a fast track designation from the FDA for Entolimod's biodefense indication. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply to the FDA for fast track designation. However, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw our fast track designation if the FDA believes that the designation is no longer supported by data from our clinical or pivotal development program. Our fast track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved. We may seek breakthrough therapy designation for some of our product candidates. The designation may not be granted and, even if granted by the FDA, such designation may not lead to a faster development of any product candidate or approval process for any product candidate. We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the BLA is submitted to the FDA. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive a breakthrough therapy designation, the receipt of such designation for a product candidate may not result in a faster development of any product candidate or approval process for product candidate. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505 (b) (2) regulatory approval pathway, or if the requirements for such product candidates under Section 505 (b) (2) are not as expected, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful. We plan to seek FDA approval through the Section 505 (b) (2) regulatory pathway for several of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the filing of a BLA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505 (b) (2), if applicable to the Company under the FDCA, would allow a BLA submitted by us to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505 (b) (2) regulatory pathway as anticipated,

**we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We may need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot guarantee that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505 (b) (2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact on our competitive position and prospects. Even if we are allowed to pursue the Section 505 (b) (2) regulatory pathway, there is no guarantee that our product candidates will receive the requisite approvals for commercialization. Moreover, even if our product candidates are approved under Section 505 (b) (2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the products. If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer. Even if we gain marketing approval of our drug candidates, government purchasers, physicians and / or patients may not accept and use them. Acceptance and use of these products may depend on a number of factors including: • perceptions by members of the government healthcare community, including physicians, about the safety and effectiveness of our drugs; • published studies demonstrating the safety and effectiveness of our drugs; • adequate reimbursement for our products from payors; and • effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any. The failure of our drugs, if approved for marketing, to gain acceptance in the market would harm our business and could require us to seek additional financing.**

**Risks** Related to Legal and Other Regulatory Matters Our ClearUP device is a US FDA Class II device with FDA clearance for over-the-counter purchase. We continue to expand our product offerings within the ClearUP brand based on the architecture used in the ClearUP product line. Such expansions may include design modifications of the ClearUP device. Given that current improvements to the ClearUP product line are a line extension of the ClearUP device, ~~and based on the approval by our designated EU Notified Body and our assessment of relevant FDA guidance (Guidance for Industry and Food and Drug Administration Staff “Deciding When to Submit a 510 (k) for a Change to an Existing Device” October 25, 2017),~~ we have determined that such current expansions of the ClearUP product line are covered under the same regulatory clearances as ClearUP. If the FDA were to determine that our products or product candidates do not properly satisfy the conditions for FDA clearance as Class II devices, or that our ClearUP product line expansion is not covered by the same regulatory clearances as our existing ClearUP device, we could be required to cease distribution of our products until we obtain regulatory clearance or approval, abandon new product launch plans, and / or we could be subject to additional enforcement action by the FDA. All existing FDA clearances, including those covering our ClearUP device, could be subject to change based on subsequent FDA review or changes in FDA regulations. In addition, many states have laws regarding the provision of medical devices, and if we are found to be in violation of the laws of any state in which our devices are sold, we could be subject to further sanctions at the state level. The laws and regulations applicable to the industries in which we operate are continuously evolving. Changes in our regulatory and legal landscape could substantially increase the costs of compliance, increase the time and resources required to bring new products to market, or otherwise negatively impact our business. There can be no assurance that new legislation or regulations will not impose significant additional costs or burdens on our business or subject us to additional liabilities. We may be or become subject to claims that our operations violate these laws or regulations. Our business is subject to risks arising from epidemic diseases, such as the recent ~~COVID-19~~ pandemic. The occurrence of regional epidemics or a global pandemic, such as COVID- 19, may adversely affect our operations, financial condition, and results of operations. The COVID- 19 pandemic had widespread, rapidly evolving, and unpredictable impacts on global society, economies, financial markets, and business practices ~~from 2020 into 2023~~. The extent to which global pandemics, including as a result of the lingering effects of COVID- 19 on the global economy, impact our business going forward will depend on various factors such as the duration and scope of the pandemic; governmental, business, and individuals’ actions in response to the pandemic; and the impact on economic activity including the possibility of recession or financial market instability. Measures taken by the governments of countries affected by future pandemics could adversely impact our business, financial condition, or results of operations. Potential disruptions may include, without limitations, delays in processing registrations or approvals by applicable state or federal regulatory bodies, delays in product development efforts and / or clinical trials, and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our ClearUP device or other products. **We are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business, and changes in such regulations or laws could require us to modify our products or marketing or advertising efforts.**

In connection with the marketing or advertisement of our products, we could be the target of claims relating to false, misleading, deceptive or otherwise noncompliant advertising or marketing practices, including under the auspices of the FTC and state consumer protection statutes. If we rely on third parties to provide any marketing and advertising of our products, we could be liable for, or face reputational harm as a result of, their marketing practices if, for example, they fail to comply with applicable statutory and regulatory requirements. If we are found to have breached any consumer protection, advertising, unfair competition or other laws or regulations, we may be subject to enforcement actions that require us to change our marketing and business practices in a manner that may negatively impact us. This could also result in litigation, fines, penalties and adverse publicity that could cause reputational harm and loss of customer trust, which could have a material adverse effect on our business, financial condition and results of operations. **We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws and anti- money**

**laundering laws and regulations. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, and various economic and trade sanctions regulations administered by the U. S. Treasury Department's Office of Foreign Assets Controls, and anti- corruption and anti- money laundering laws and regulations, including the FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the U. S., to sell our products abroad once it enters a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Our reliance on vendors in foreign countries, including China, subjects us to risks and uncertainties relating to foreign laws and regulations and changes in relations between the United States and such foreign countries.**

Electronic components for our ClearUP devices are sourced primarily from China, and we may in the future source components from vendors located in other foreign countries. Under its current leadership, the government of China has been pursuing economic reform policies, including by encouraging foreign trade and investment. However, there is no assurance that the Chinese government will continue to pursue such policies, that such policies will be successfully implemented, that such policies will not be significantly altered, or that such policies will be beneficial to our partnerships in China. China's system of laws, as well as the laws of other foreign countries where we may source components, can be unpredictable, especially with respect to foreign investment and foreign trade. The United States government has called for substantial changes to foreign trade policy with China and has raised, and has proposed to further raise in the future, tariffs on several Chinese goods. China has retaliated with increased tariffs on United States goods. Moreover, China's legislature has adopted a national security law to substantially change the way Hong Kong has been governed since the territory was handed over by the United Kingdom to China in 1997. This law increases the power of the central government in Beijing over Hong Kong, limits the civil liberties of residents of Hong Kong and could restrict the ability of businesses in Hong Kong to continue to conduct business or to continue to with business as previously conducted. The U. S. State Department has indicated that the U. S. no longer considers Hong Kong to have significant autonomy from China. The U. S. State Department previously enacted sanctions related to China's governing of Hong Kong, and the U. S. may impose the same tariffs and other trade restrictions on exports from Hong Kong that it places on goods from mainland China. Any further changes in United States trade policy could trigger retaliatory actions by affected countries, including China, resulting in trade wars. Changes to Chinese regulations affecting the manufacture of electronic components may also be unpredictable. For example, the Uyghur Forced Labor Prevention Act bans imports from China's Xinjiang Uyghur Autonomous Region unless it can be shown that the goods were not produced using forced labor and this legislation may have an adverse effect on global supply chains which could adversely impact our business and results of operations. Additionally, China has recently implemented significant restrictions on the export of gallium and germanium, both of which are used for the manufacture of computer chips. Changes to regulations in China and / or any other country where we may source components in the future may also be unpredictable and could affect the manufacture of electronic components in such countries and our ability to purchase components on a cost- effective basis. Any regulatory changes and changes in United States and China relations, or changes in relations with the United States any other country where we may source components in the future, may have a material adverse effect on our vendors in China and other such countries which could materially harm our business and financial condition.

~~International trade disputes could result in tariffs and other protectionist measures that could have a material adverse effect on our business, financial condition and results of operations. Tariffs could increase the cost of our products and raw materials that go into making them. These increased costs could adversely impact the gross margin that we earn on our products. Tariffs could also make our products more expensive for customers, which could make our products less competitive and reduce consumer demand. Countries may also adopt other protectionist measures that could limit our ability to offer our products. Political uncertainty surrounding international trade disputes and protectionist measures could also have a negative effect on consumer confidence and spending, which could have a material adverse effect on our business, financial condition and results of operations.~~

We may in the future become subject to the requirements of the Sunshine Act. We are not currently subject to the Physician Payment Sunshine Act ("Sunshine Act"), which was enacted as part of the Affordable Care Act. However, if we begin selling our products directly to governmental entities or our products become reimbursable by Medicare or Medicaid, then we may become subject to the Sunshine Act, which will require us to report annually to the Secretary of Health and Human Services: (i) payments or other transfers of value made by us, or by a third- party as directed by us, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals; and (ii) physician ownership and investment interests in our company. The payments required to be reported include the cost of meals provided to a physician, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from \$ 1, 000 to \$ 10, 000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of \$ 150, 000) and from \$ 10, 000 to \$ 100, 000 for each knowing failure to report (up to a

maximum per annual report of \$ 1. 0 million). Additionally, becoming subject to the Sunshine Act and the information we disclose could lead to greater scrutiny, which could result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide have either adopted or are considering adopting similar laws requiring transparency of interactions with healthcare professionals.

**Risks Related to Our Intellectual Property** We are highly dependent on our IP, and our methods of protecting our IP may not be adequate or could be costly. We rely on a combination of patent and trademark laws, trade secrets, confidentiality procedures and contractual provisions to protect our IP rights. We are building our IP portfolio, and may not be able to secure sufficient protection to prevent competition from entering the market or from creating competing products. We cannot be certain that we will be able to obtain patent protection on the key components of our technology or that we will be able to obtain patents in key jurisdictions, such as the United States, Europe and Asia. We cannot give assurances that we will develop new products or technologies that are patentable or (to the extent applicable) that any new products will be covered by existing patents, that any issued patent will provide us with any competitive advantages or will not be challenged by third parties, or that the patents of others will not impair our ability to do business. We cannot guarantee that the applicable governmental authorities will approve any of our future trademark applications. Even if the applications are approved, third parties may seek to oppose or challenge these registrations. A failure to obtain trademark registrations in key jurisdictions could limit our ability to use our trademarks and impede our marketing efforts in those jurisdictions. Despite our efforts to protect our IP, unauthorized parties may attempt to copy or obtain and use our technology. Policing the unauthorized use of our technology on a global basis is difficult, and there can be no assurance that the steps taken by us will prevent misappropriation of our technology. We cannot give assurances that our measures for preserving the secrecy of our trade secrets and confidential information will be sufficient to prevent others from obtaining our trade secrets. We generally require our employees, consultants and corporate partners to sign confidentiality and non- disclosure agreements prohibiting them from disclosing any of our trade secrets. Our employment agreements and consulting agreements also contain confidentiality undertakings, as well as non- compete provisions, which prohibit employees, advisors and consultants from acting contrary to our interests during the period of their relationship with us. Despite our efforts to preserve the secrecy of our trade secrets and confidential information, we may not have adequate remedies to preserve our trade secrets or to compensate us fully for our loss if employees, consultants or corporate partners breach confidentiality agreements with us. We cannot give assurances that our trade secrets will provide any competitive advantage, as they may become known to, or be independently developed by, competitors, regardless of the success of any measures we may take to try to preserve their confidentiality. Any failure or inability to protect any of our IP or confidential information, or to enforce our rights against any infringement or misappropriation of our IP or confidential information, could have a material adverse effect on our business, financial condition and results of operations. Additionally, we may be forced to litigate to enforce or defend our IP, to protect our trade secrets or to determine the validity and scope of other parties' proprietary rights. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence and / or outcome of any such litigation could harm our business. We may face risks of claims for IP infringement. Our competitors or other persons may have already obtained or may in the future obtain patents or other rights relating to one or more aspects of our technology. Because we have not conducted a formal freedom to operate analysis for patents related to our technology, we may not be aware of issued patents that a third party might assert are infringed by our current or any future technology, which could materially impair our ability to commercialize our current or any future technology. Even if we diligently search third- party patents for potential infringement by our current or any future technology, we may not successfully find patents that our current or any future technology may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our current or future technology. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any future technology, whether or not we are actually infringing, misappropriating or otherwise violating the rights of third parties. If we are sued for patent or other intellectual property right infringement, we may be forced to incur substantial costs in defending our self. If litigation were to result in a judgment that we infringed a valid and enforceable patent or other intellectual property right, a court may order us to pay substantial damages to the owner of the patent or other intellectual property right and to stop using any infringing technology or products. This could cause a significant disruption in our business and force us to incur substantial costs to develop and implement alternative, non- infringing technology or products, or to obtain a license from the patent or other intellectual property right owner. We cannot give assurance that we would be able to develop non- infringing alternatives at a reasonable cost that would be commercially acceptable, or that we would be able to obtain a license from any patent or other intellectual property right owner on commercially reasonable terms, if at all. We may be unable to enforce our IP rights throughout the world. The laws of some foreign countries do not protect IP rights to the same extent as the laws of the United States. The area of bioelectronic medicine, specifically, is a nascent and emerging industry. To the extent we demonstrate novel means to manage physiological functions, the nature and degree of IP protection we can obtain throughout the world may vary. Many companies have encountered significant problems in protecting and defending IP rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other IP rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our IP rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the

United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our IP. Risks Related to Our Common Stock We expect that our stock price may fluctuate significantly, and investors may not be able to resell their shares at or above the price at which they purchased them. ~~An active trading market for our common stock may never develop. Prior to our initial public offering, you could not buy or sell our common stock publicly. Even though our common stock is now listed on the Nasdaq Capital Market, an active trading market for our shares may not develop or be sustained following our initial public offering. If an active market for our common stock does not develop or is not maintained, it may be difficult for you to sell your shares depressing the market price for the shares, or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling additional shares of our common stock and may impair our ability to acquire other companies or technologies by using shares of our common stock as consideration.~~ The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including: • the effect of macroeconomic factors on our business and operations and on market conditions generally; • the success of our products and of competitive products or technologies; • regulatory or legal developments in the United States and other countries; • the level of expenses related to our products or development programs; • announcements by us, our partners or our competitors of new products or therapies, significant contracts, strategic partnerships, joint ventures, collaborations, commercial relationships, or capital commitments; • failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public; • issuance of new or updated research or reports by securities analysts or recommendations for our stock; • disputes or other developments related to proprietary rights (including patents), litigation matters, and our ability to obtain patent protection for our technologies; • commencement of, or our involvement in, litigation; • fluctuations in the valuation of companies perceived by investors to be comparable to us; • manufacturing disputes or delays; • any future sales of our common stock or other securities; • any change to the composition of the board of directors or key personnel; • general economic conditions and slow or negative growth of our markets; • share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; • announcement or expectation of additional debt or equity financing efforts; and • other factors described in this section of the Report. These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance. In addition, the stock market in general, and medical device companies in particular, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have on occasion instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. ~~We do not expect to pay dividends..... realize any return on their investment.~~ Future issuances of stock or other securities could dilute the holdings of stockholders and could materially affect the price of the shares of our common stock. In the year ended December 31, ~~2023~~ **2024**, we sold an aggregate of ~~1,470,220~~ **369,230** shares of our common stock to certain investors through ~~a registered public offerings~~ **offering and an at-the-market equity distribution program**, which resulted in aggregate net proceeds of approximately \$ ~~8.4~~ **5** million. **Additionally, after the end of the fiscal year, we issued Statera 55,635 shares of common stock and 359,669 shares of our Series A Nonvoting Convertible Preferred Stock, which (subject to certain limitations, including shareholder approval) shares are convertible into an aggregate of approximately 211,570 shares of our common stock**. We anticipate that we will issue additional shares of capital stock in conjunction with future funding requirements. Any issuance of shares of our common stock, or securities exercisable for or convertible into shares of our common stock, for the purpose of securing capital will result in the dilution of the ownership interests of our existing stockholders. We have used and intend to continue to use equity incentives for employees, advisors, directors, key consultants and select affiliates. Any issuance of stock upon the conversion of options and / or incentive rights will result in the dilution of the ownership interests of our existing stockholders. In addition, we may in the future decide to offer additional stock or other securities in order to finance new capital-intensive projects, in connection with unanticipated liabilities or expenses or for any other purposes. There is no assurance that we will not decide to conduct offerings of securities in the future. Depending on the structure of any future offering, certain existing stockholders may not have the ability to purchase additional equity securities. If we raise additional funds by issuing additional equity securities, the holdings and voting interests of existing stockholders could be diluted ~~capital~~. We do not expect to pay dividends to our stockholders at any time in the foreseeable future. Anyone considering investing in our stock should not rely on such investment to provide dividend income. Instead, we plan to retain any earnings to establish, maintain and expand our operations and product offerings. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our stock. Accordingly, investors must rely on sales of their shares after price appreciation, which may never occur, as the only way to realize any return on their **investment**. We qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”). For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These provisions include, but are not limited to: being permitted to have only two years of audited financial statements and only two years of management’s discussion and analysis of financial condition and results of operations disclosure; an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended (“Sarbanes-Oxley Act”); not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements and proxy statements; and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not

previously approved. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We intend to take advantage of certain of the exemptions discussed above. In addition, we are currently a “ smaller reporting company, ” as defined in the Securities Exchange Act of 1934, as amended (“ Exchange Act ”), and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. To the extent that we continue to qualify as a “ smaller reporting company ” as such term is defined in Rule 12b- 2 under the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an “ emerging growth company ” may continue to be available to us as a “ smaller reporting company, ” including exemption from compliance with the auditor attestation requirements pursuant to the Sarbanes- Oxley Act and reduced disclosure about our executive compensation arrangements. We will continue to be a “ smaller reporting company ” until we have more than \$ 250 million in public float (based on our common stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float (based on our common stock), annual revenues of more than \$ 100 million during the most recently completed fiscal year. As a result, the information we provide will be different than the information that is available with respect to other public companies. In this Report, we have not included all of the executive compensation- related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and the market price of our common stock may be more volatile. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. In addition, we are required to furnish a report by management on the effectiveness of our internal control over financial reporting, pursuant to Section 404 of the Sarbanes- Oxley Act. As of December 31, 2023-2024, based on an analysis completed by management, our internal controls were not effective due to the existence of a material weakness. The process of designing, implementing and testing the internal control over financial reporting required to comply with this obligation is time consuming, costly and complicated. If we identify material weaknesses in our internal control over financial reporting (as we have for the period covered by this Report), if we are unable to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the Commission or other regulatory authorities, which could require additional financial and management resources. We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward- looking statements subject to the risks and uncertainties described in this Report and in our other public filings and public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. If, in the future, our operating or financial results for a particular period do not meet any guidance we provide or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of our common stock may decline. Even if we do issue public guidance, there can be no assurance that we will continue to do so in the future. Anti- takeover provisions in our charter documents, and under Delaware law, could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock. Provisions in our amended and restated certificate of incorporation, as amended (“ Certificate of Incorporation ”), and amended and restated bylaws, as amended (“ Bylaws ”), may have the effect of delaying or preventing a change of control or changes in our management. Our Certificate of Incorporation and Bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our Chief Executive Officer or our President (in the absence of a Chief Executive Officer);
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- prohibit cumulative voting in the election of directors;
- establish that our board of directors will be divided into three classes — Class I, Class II, and Class III — with each class serving staggered three- year terms;
- provide that, so long as our board of directors is classified, directors may only be removed for cause;
- 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
- require the approval of our board of directors or the holders of two- thirds of our outstanding shares of voting stock to amend our bylaws and certain provisions of our certificate of incorporation. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any “ interested ” stockholder for a period of three years following the date on which the stockholder became an “ interested ” stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that you would receive a premium for your shares of our common stock in an acquisition. Our Certificate of Incorporation and Bylaws provide that the Court of Chancery of the State of Delaware or the federal district court for the District of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could result in increased costs for our stockholders to bring a claim and could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our Certificate of Incorporation and Bylaws provide that, unless the Company consents in writing to the selection

of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by, or other wrongdoing by, any director, officer, employee or agent of the Company to the Company or our stockholders, creditors or other constituents; (iii) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our Certificate of Incorporation or our Bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or our Bylaws; or (v) any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, or the Company consents in writing to the selection of an alternative forum, such action may be brought in another state or federal court sitting in the State of Delaware. Our Certificate of Incorporation and Bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act or Exchange Act. Nothing in our Certificate of Incorporation or Bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, this choice of forum provision could result in increased costs for our stockholders to bring a claim and could may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While 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, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our Certificate of Incorporation and Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. General Risk Factors If securities or industry analysts do not publish research or publish unfavorable or inaccurate research about our business, the market price and trading volume of our common stock could decline. The market price and trading volume of our common stock is heavily influenced by the way analysts interpret our financial information and other disclosures. We do not have control over these analysts. If few securities analysts commence coverage of us, or if industry analysts cease coverage of us, our stock price would be negatively affected. If securities or industry analysts do not publish research or reports about our business, downgrade our common stock, or publish negative reports about our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price to decline and could decrease the trading volume of our common stock. We have and will continue to incur ~~increased~~ **significant** costs and are subject to heightened regulations and requirements as a result of ~~becoming~~ **being** a public company, which could lower our profits or make it more difficult to run our business. As a public company, we incur significant legal, accounting and other expenses ~~that we did not incur as a private company~~, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes- Oxley Act, and related rules implemented by the Commission, and the Nasdaq Capital Market. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. These rules and regulations have increased and will continue to increase our legal and financial compliance costs and to make some activities more time- consuming and costlier, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations may also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, if we are unable to satisfy our ongoing obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

**Actual or perceived failures to comply with applicable data privacy and security laws, regulations, policies, standards, contractual obligations and other requirements related to data privacy and security and changes to such laws, regulations, standards, policies and contractual obligations could adversely affect our business, financial condition and results of operations.**

The global data protection landscape is rapidly evolving, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. We are subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, transmission, use, disclosure, storage, retention and security of personal and personally- identifying information, such as information that we may collect in connection with conducting our business in the United States and abroad. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards or perception of their requirements may have on our business. This evolution may create uncertainty in our business; affect our ability to operate in certain jurisdictions; or to collect, store, transfer use and share personal information; necessitate the acceptance of more onerous

obligations in our contracts; result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures, or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, fines, imprisonment of company officials and public censure, claims by third parties, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition and results of operations. Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial results. U. S. generally accepted accounting principles (“ GAAP ”) and related pronouncements, implementation guidelines and interpretations with regard to a wide variety of matters that are relevant to our business, such as, but not limited to, revenue recognition, stock- based compensation, trade promotions and income taxes are highly complex and involve many subjective assumptions, estimates and judgments by our management. Changes to these rules or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change our reported results. We are subject to anti- corruption, anti- bribery, anti- money laundering, and similar laws, and non- compliance with such laws could subject us to criminal or civil liability and harm our business, financial condition, and results of operations. We are subject to the U. S. Foreign Corrupt Practices Act of 1977, as amended (“ FCPA ”), U. S. domestic bribery laws, the UK Bribery Act 2010, and other anti- corruption and anti- money laundering laws in the countries in which we conduct business. Anti- corruption and anti- bribery laws have been enforced aggressively in recent years and are interpreted broadly to generally prohibit companies, their employees, and their third- party intermediaries from authorizing, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. As we increase our international sales and business and sales to the public sector, we may engage with business partners and third- party intermediaries to market our products and to obtain necessary permits, licenses, and other regulatory approvals. In addition, we or our third- party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state- owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. While we have policies and procedures to address compliance with such laws, there is a risk that our employees and agents will take actions in violation of our policies and applicable law, for which we may be ultimately held responsible. As we expand internationally, our risks under these laws may increase. Detecting, investigating, and resolving actual or alleged violations of anti- corruption laws can require a significant diversion of time, resources, and attention from senior management. In addition, noncompliance with anti- corruption, anti- bribery, or anti- money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, enforcement actions, fines, damages, other civil or criminal penalties or injunctions, suspension or debarment from contracting with certain persons, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal proceeding, our business, financial condition, and results of operations could be harmed.