Risk Factors Comparison 2024-03-08 to 2023-04-03 Form: 10-K

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~~Please carefully consider the following discussion of significant factors, events, and uncertainties that make an investment in our securities risky. The events and consequences discussed in these risk factors could, in circumstances we may or may not be able to accurately predict, recognize, or control, have a material adverse effect on our business, growth, reputation, prospects, financial condition, operating results (including components of our financial results), cash flows, liquidity, and stock price. These risk factors do not identify all risks that we face; our operations could also be affected by factors, events, or uncertainties that are not presently known to us or that we currently do not consider to present significant risks to our operations. In addition, the global economic climate amplifies many of these risks. Risks related to our limited operating history, financial position, and need for additional capital We have a history of operating losses that are expected to continue for the foreseeable future, and we are unable to predict the extent of future losses, or whether we will generate significant revenues or achieve or sustain profitability. We are focused on product development and have generated $ 3, 519, 627 and $ 594, 563 in revenues from COVID- 19 antigen test kit sales in 2022 and 2021, respectively. We expect to continue to incur operating losses until we are able to commercialize or license our other products. These operating losses have adversely affected and are likely to continue to adversely affect our working capital, total assets and stockholders' equity. We have generated operating losses of $ 13, 976, 212 and $ 3, 867, 426 in the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and December 31, 2021, we had cumulative losses of $ 24, 115, 606 and $ 10, 108, 916, respectively. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability. We believe that our cash on hand, along with the anticipated net proceeds from products and additional financing, will enable us to fund our operations over the short and medium terms based on our current plan. We are dependent on obtaining, and are continuing to pursue, necessary funding from outside sources, including obtaining additional funding from the issuance of securities in order to continue our operations. Without adequate funding, we may not be able to meet our obligations. The successful commercialization of any of our products will require us to perform a variety of functions, including: · continuing to undertake preclinical and clinical development ; · engaging in the development of product candidate formulations and manufacturing processes ; · interacting with the applicable regulatory authorities and pursuing other required steps for regulatory approval ; · engaging with payors and other pricing and reimbursement authorities ; · submitting marketing applications to and receiving approval from the applicable regulatory authorities ; and · manufacturing the applicable products and product candidates in accordance with regulatory requirements and, if ultimately approved, conducting sales and marketing activities in accordance with health care, Taiwan Food and Drug Administration, or TFDA, U. S. Food and Drug Administration, or FDA, and similar foreign regulatory authority laws and regulations. 11Our revenue for at least the near term will almost exclusively depend on sales of the Ainos COVID- 19 test kits until we can develop, obtain regulatory clearance or other appropriate authorization for, and commercialize additional product candidates. We expect that sales of the Ainos COVID- 19 antigen rapid test kits will account for majority of our revenue until at least such time as we can commercialize additional tests or other products. As a result, our ability to execute our growth strategy and become profitable in the near term will depend upon consumer adoption of the Ainos COVID- 19 test kits. COVID- 19 infection is moderating and we currently have a very small number of customers for the Ainos COVID- 19 antigen rapid test kits in Taiwan. If infection rates remain low and if we are unable to expand our customer base, we may not be able to increase our revenue. Adoption and use of the Ainos COVID- 19 antigen rapid test kits will depend on several factors, including, but not limited to the accuracy, affordability and ease of use of our product as compared to other products and products that compete with the Ainos COVID- 19 antigen rapid test kits. Because we expect virtually all of our revenue for at least the near term to be generated from sales of the Ainos COVID- 19 antigen rapid test kits in Taiwan, our the failure to increase sales volume or retain regulatory authorization under our EUA in Taiwan for the Ainos COVID- 19 antigen rapid test kits may have a material adverse effect on our business, operating results and financial condition. We have generated very little revenue from product sales and may never become profitable. Our ability to generate product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our current and future product candidates. Our product candidates will require additional clinical, manufacturing, and non- clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we generate significant product sales. We cannot assure you that we will meet our timelines for our development programs, which may be delayed or not completed for a number of reasons. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators' ability to successfully: · complete research and obtain favorable results from preclinical and clinical development of our current and future product candidates, including addressing any clinical holds that may be placed on our development activities by regulatory authorities; · seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials, as well as their manufacturing facilities ; · launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner ; · qualify for coverage and establish adequate reimbursement by government and third- party payors for any of our product candidates for which we obtain regulatory and marketing approval ; ·~~

develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop ; · establish and maintain supply and manufacturing capabilities or capacities internally or with third parties that can provide adequate, in both amount and quality, products, and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval ; · obtain market acceptance of current or any future product candidates and effectively compete to establish market share ; · maintain a continued acceptable safety and efficacy profile of our product candidates following launch ; · address competing technological and market developments ; · implement internal systems and infrastructure, as needed ; · negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations ; · maintain, protect, enforce, defend, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know- how ; · avoid and defend against third- party interference, infringement, and other intellectual property claims ; and · attract, hire, and retain qualified personnel. 12Even if one or more of our current and future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our expectations if we are required by the TFDA, the FDA or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. If we are required to conduct additional clinical trials or other testing of our product candidates that we develop beyond those that we currently expect, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may be delayed in obtaining marketing approval for our product candidates, not obtain marketing approval at all, or obtain more limited approvals. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our Company also could cause you to lose all or part of your investment. Our business, operations and clinical development plans and timelines and supply chain could be adversely affected by the effects of epidemics, including the ongoing COVID- 19 pandemic. Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third- party manufacturers, contract research organizations and other third parties upon whom we rely. For example, the COVID- 19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the U. S. economy and financial markets. Many geographic regions have imposed, or in the future may impose, " shelter- in- place " orders, quarantines or similar orders or restrictions to control the spread of COVID- 19. These measures may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. We are dependent on a worldwide supply chain for products to be used in our clinical trials and, if approved by the regulatory authorities, for commercialization. Quarantines, shelter- in- place and similar government orders, or the expectation that such orders, shutdowns or other restrictions could occur, whether related to COVID- 19 or other infectious diseases, could impact personnel at third- party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain. For example, any manufacturing supply interruption of any product candidate could adversely affect our ability to conduct ongoing and future clinical trials of such product candidate. In addition, closures of transportation carriers and modal hubs could materially impact our clinical development and any future commercialization timelines. If our relationships with our suppliers or other vendors are terminated or scaled back as a result of the COVID- 19 pandemic or other health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays could generally occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. See " Risks Related to Our Dependence on Third Parties. " In addition, our clinical trials may be affected by the COVID- 19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID- 19 pandemic or concerns among patients about participating in clinical trials during a pandemic and public health measures imposed by the respective national governments of countries in which the clinical sites are located. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our inability to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID- 19 or experience additional restrictions by their institutions, city or state governments could adversely impact our clinical trial operations. We are continuing to monitor the potential impact of the pandemic, but we cannot be certain the future impact on our business, financial condition, results of operations and prospects. Depending on developments relating to the pandemic, including the emergence of new variants, the pandemic may affect our ability to initiate and complete research studies, delay the initiation of our future research studies, disrupt regulatory activities or have other adverse effects on our business, results of operations, financial condition and prospects. 13The global pandemic of COVID- 19 continues to evolve rapidly. The ultimate impact of the COVID- 19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID- 19 situation closely. We need to raise additional capital to operate our business. If we fail to obtain the

~~capital necessary to fund our operations, we will be unable to continue or complete our product development. We are a company primarily focused on product development and our product revenues may not sufficient to fund our operations. Until, and if, we receive approval from the TFDA, FDA and other regulatory authorities for our product candidates, our revenues generated from products may be limited. We had cash and cash equivalents of $ 1, 853, 362 as of December 31, 2022, and we will need to continue to seek capital from time to time to continue to capitalize the development and commercialization of our product candidates and to acquire and develop other product candidates. Our actual capital requirements will depend on many factors. For instance, our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in COVID- 19 treatment modalities. If we experience unanticipated cash requirements, we may need to seek additional sources of financing, which may not be available on favorable terms, if at all.~~ However, we may not be able to secure funding when we need it or on favorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale- back or eliminate our research and development activities, clinical studies or future operations, we may be unable to complete planned nonclinical studies and clinical trials or obtain approval of our product candidates from the TFDA and FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and attractive business opportunities, reduce overhead, or discontinue operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. We may further have to license our technology to others. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations. The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs ; the progress, timing and scope of our nonclinical studies and clinical trials ; the time and cost necessary to obtain regulatory approvals ; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing ; our ability to enter into and maintain collaborative, licensing and other commercial relationships ; and our partners' commitment of time and resources to the development and commercialization of our products. We may be unable to access the capital markets and even if we can raise additional funding, we may be required to do so on terms that are dilutive to you. The capital markets have been unpredictable in the recent past for unprofitable companies such as ours. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we cannot assure you that we will be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, results of operations, financial condition and our continued viability will be materially adversely affected. Our operating results may fluctuate significantly, which will make our future results difficult to predict and could cause our results to fall below expectations. Our quarterly and annual operating results may fluctuate significantly, which will make it difficult for us to predict our future results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including: · the scalability of our **product** ~~COVID- 19 test~~ sales **,** which is **difficult to predict** ~~dependent on the severity of COVID- 19 infections~~ · the timing and cost of, and level of investment in, research, development and commercialization activities, which may change from time to time ; · the timing and status of enrollment for our clinical trials ; · the timing of regulatory approvals, if any, in the United States and internationally ; · the timing of expanding our operational, financial and management systems and personnel, including personnel to support our clinical development, quality control, manufacturing and commercialization efforts and our operations as a public company ; ~~14~~ **18** · the cost of manufacturing, as well as building out our supply chain, which may vary depending on the quantity produced, and the terms of any agreements we enter into with third- party suppliers ; · the timing and amount of any milestone, royalty or other payments due under any current or future collaboration or license agreement ; · coverage and reimbursement policies with respect to any future approved products, and potential future drugs that compete with our products ; · the timing and cost to establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators ; · expenditures that we may incur to acquire, develop or commercialize additional products and technologies ; · the level of demand for any future approved products, which may vary significantly over time ; · future accounting pronouncements or changes in accounting principles or our accounting policies ; and · the timing and success or failure of nonclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or collaboration partners. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. Risks related to product development and regulatory process We are early in our development efforts of some of our product candidates, and our business is dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed. Our product candidates are in different stages of clinical development. Our current and future product candidates may never achieve expected levels of efficacy or an acceptable safety profile. Our use of clinically validated targets to pursue treatments does not guarantee efficacy or safety or necessarily reduce the risk that our current or future product candidates will not achieve expected levels of efficacy or an acceptable safety profile. The success of our business, including our ability to finance our Company and generate revenue from products in the future will depend heavily on the successful development and

eventual commercialization of our product candidates, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional nonclinical and clinical development, management of clinical, nonclinical and manufacturing activities, marketing approval in the United States and other markets, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales. As a company, we have limited experience in preparing, submitting and prosecuting regulatory filings. We have no prior experience in developing or securing regulatory approvals for veterinary drugs or treatments. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, third- party reimbursement and adoption by physicians. We plan to seek regulatory approval to commercialize our product candidates both in the United States and in select foreign countries. While the scope of regulatory approval in other countries is generally similar to that in the United States, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries. We may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions. ~~The~~ **19The** success of our current and future product candidates will depend on many factors, which may include the following: · sufficiency of our financial and other resources to complete the necessary nonclinical studies and clinical trials, and our ability to raise any additional required capital on acceptable terms, or at all ; · the timely and successful completion of our nonclinical studies and clinical trials for which the TFDA, FDA, or any comparable foreign regulatory authority, agree with the design, endpoints, or implementation ; · receipt of regulatory approvals or authorizations to conduct future clinical trials or other studies beyond those planned to support approval of our product candidates ; · successful enrollment and completion of clinical trials ; · successful data from our clinical program that supports an acceptable risk- benefit profile of our product candidates in the intended populations ; ~~15~~ · timely receipt and maintenance of marketing approvals from applicable regulatory authorities ; · establishing, scaling up and scaling out, either alone or with third-party manufacturers, cGMP **(Current Good Manufacturing Practice)** compliant manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing (including licensure), if any of our product candidates are approved ; · entry into collaborations to further the development of our product candidates in select indications or geographies ; · obtaining and maintaining regulatory exclusivity for our product candidates as well as establishing competitive positioning amongst other therapies; and · successfully launching commercial sales of our product candidates and obtaining and maintaining healthcare coverage and reimbursement from third party payors, if approved. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully obtain regulatory approval of or commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current or future product candidates, we may not be able to continue our operations. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any products. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of products to continue our business. ~~If the FDA or other regulatory bodies revoke or terminate our Emergence Use Authorization (" EUA ") or other regulatory authorizations for Ainos COVID- 19 test kits, we will be required to stop commercialization of COVID- 19 test kits unless we, or our manufacturing collaborators, can obtain 510 (k) or other clearance or approval for our COVID- 19 test and its currently authorized uses. Taiwan Carbon Nano Technology (" TCNT "), our manufacturing collaborator and our affiliate company, intend to submit EUAs to the FDA for Ainos COVID- 19 test kits. We cannot predict if TCNT' s submission will be approved or, if approved, how long either of the EUAs will remain in effect, and TCNT may not receive advance notice from the TFDA or FDA regarding revocation of either or both of our EUAs. If EUAs are terminated or TCNT' s submissions are not accepted, we will be required to cease commercialization of Ainos COVID- 19 test kits in the United States, unless and until TCNT has obtained marketing authorization from the FDA through another regulatory pathway, possibly requiring us to obtain a 510 (k) or other marketing authorization from the FDA for the Ainos COVID- 19 test kits. Changing policies and regulatory requirements could limit, delay or prevent further commercialization of Ainos COVID- 19 test kits and could materially adversely impact our business, financial condition, results of operations and future prospects.~~ Clinical product development involves a lengthy and expensive process, with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current and future product candidates, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our business, financial condition, results of operations and prospects. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate that our products are safe and effective in humans and animals with respect to our veterinary drug candidates ~~in Taiwan~~ . Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. We may experience delays in completing current and future clinical trials. We may also experience numerous unforeseen events prior to, during, or as a result of our nonclinical studies or clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including: · regulators, Institutional Review Boards (" IRBs ") or ethics committees may not authorize us to conduct the clinical study ; · we may experience delays due to challenges with third-party contractors and contract research organizations (" CROs "), including negotiating agreement terms, compliance with regulatory requirements, compliance with clinical trial protocols; · it may be difficult to enroll a sufficient number of suitable patients, or enrollment may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate ; · the supply or quality of materials for product candidates we develop or other materials necessary to conduct clinical trials may be insufficient or inadequate ; and · we may experience disruptions by man- made or natural disasters or public health pandemics or epidemics or other business interruptions, including **any future significant outbreaks of diseases similar to** the ~~current~~ COVID- 19 pandemic ~~and future outbreaks of the disease~~ .

~~We~~ **20We** could encounter delays if a current or future clinical trial is suspended or terminated by us, by the TFDA, FDA or other regulatory authorities and / or review boards. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the TFDA, FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. ~~16If~~ **If** we experience termination or delays in the completion of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates may be delayed. In addition, any delays in completing our clinical trials will likely increase our costs, slow down our product candidate development and approval process and impact our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do, shorten any periods during which we may have the exclusive right to commercialize our product candidates, impair our ability to commercialize our product candidates and harm our business and results of operations. Any of these occurrences may harm our business, financial condition and prospects significantly. Delays in clinical product development present material uncertainty and risk with respect to our clinical trials, business, and financial condition. We and our collaboration partners have conducted and intend to conduct clinical trials for selected product candidates at sites outside the United States, and for any of our product candidates for which we seek approval in the United States, the FDA may not accept data from trials conducted in such locations or may require additional U. S.- based trials. We and our collaboration partners have conducted and plan to continue to conduct, clinical trials outside the United States, ~~particularly~~ **including** in Taiwan. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any clinical trials that we or our collaboration partners conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time- consuming and delay or permanently halt our ability to develop and market these or other product candidates in the United States. In other jurisdictions, for instance, in Taiwan, there is a similar risk regarding the acceptability of clinical trial data conducted outside of that jurisdiction. Our long- term prospects depend in part upon discovering, developing and commercializing additional products, including POCT ~~testing devices~~ and VELDONA candidates, which may fail in development or suffer delays that adversely affect their commercial viability. Our future operating results are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates, including POCT ~~testing devices~~ and VELDONA candidates, beyond those we currently have in development. The success of a product candidate is unknown and initial product development success may not result in a viable commercial product. The product development process may require changes in manufacturing methods and formulation / design or additional validation testing. We may also make changes as we work to optimize our manufacturing processes, but we cannot be sure that even minor changes in our processes will result in products that are safe and effective or that will be approved for commercial sale. If a product candidate fails to develop as expected, or we experience additional and / or unforeseen development costs and / or delays, we could face additional costs and / or loss of expected future revenue, which would adversely affect our current financial position and future prospects may be adversely affected. ~~Even~~ **21Even** if we complete the necessary nonclinical studies and clinical trials, the marketing approval process is expensive, time consuming and uncertain, which may prevent us or any of our future collaboration partners from obtaining approvals for the commercialization of our current product candidates and any other product candidate we develop. Any current or future product candidates, including medical device products, we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in Taiwan and other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. It is possible that some of our current or future product candidates will not obtain regulatory approval in the jurisdiction we are targeting. We have limited experience in filing and supporting the applications necessary to gain marketing approvals, but we expect to rely on third- party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive applications to the various regulatory authorities. Product candidates we develop may not be effective or may prove to have adverse characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. ~~17The~~ -- **The** process of obtaining marketing approvals, in Taiwan, the United States and other jurisdictions, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other studies. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments. If we experience delays in obtaining marketing approval or if we fail to obtain marketing approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired. Even if a current or future product candidate, including POCT and VELDONA, receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any current or future product candidate we develop receives marketing approval, whether as a single agent or in combination with

other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors, and others in the medical community, or such participants may prefer existing treatment options. If the product candidates we develop, including medical device products, do not achieve an adequate level of market acceptance, we may not generate expected levels of revenues associated with such products, which may prevent those products from becoming profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including: · efficacy and potential advantages compared to alternative tools; · the ability to offer our products, if approved, for sale at competitive prices ; · convenience and ease of use; · the willingness of the target market to adopt new technologies; and · the strength of marketing and distribution support. ~~The~~ **22The** total addressable market opportunity for our current and future products may be much smaller than we estimate. Our estimates of the total addressable market for our product candidates are based on internal and third- party estimates as well as a number of significant assumptions. Market opportunity estimates and growth forecasts ~~included in this report~~ are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including market research and our own internal estimates, may prove to be incorrect. Further, the continued development of, and approval or authorizations for, vaccines and therapeutic treatments may affect these market opportunity estimates. Our market opportunity may also be limited by new ~~POCT tests or other~~ products that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for platform and products could be significantly less than we estimate. If this turns out to be the case, our potential for growth may be limited and our business and future prospects may be materially adversely affected. We may not obtain approval for our product candidates in any jurisdictions. Approval of a product candidate in one jurisdiction by a regulatory authority, such as the TFDA or FDA, does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. Commercialization of our product candidates will be subject to the regulatory requirements governing marketing authorization in the jurisdiction in which they are sold. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in Taiwan and the United States, including additional nonclinical studies or clinical trials. In many countries outside Taiwan and United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for any product candidates, if approved, is also subject to approval. For example, obtaining approval for our product candidates in the European Union (the EU) from the European Commission following the opinion of the EMA, would be a lengthy and expensive process. The EMA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time- consuming additional clinical trials or reporting as conditions of approval. Approval of certain product candidates outside of Taiwan and the United States, particularly those that target diseases that are more prevalent outside of the United States, will be particularly important to the commercial success of such product candidates. Obtaining regulatory approvals in various jurisdictions and complying with the regulatory requirements of multiple jurisdictions could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. ~~18Even~~ -- **Even** if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, which would harm our business. The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to successfully commercialize any product candidates, whether as a single agent or in combination, will also depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments is available from government authorities, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, and establish reimbursement levels. It is difficult to predict at this time what government authorities and third- party payors may decide with respect to coverage and reimbursement for our programs (if approved). A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities, particularly in the European Union, and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and requiring substitutions of generic products and / or biosimilars. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. ~~If~~ **23If** product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any approved products. We face an inherent risk of product liability as a result of the clinical testing of product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product candidate we develop is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of any approved products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: · decreased demand for any approved product ; · injury to our reputation ; · withdrawal of clinical trial participants ; · initiation of investigations by regulators ; · costs to defend litigation ; · a diversion of management' s time and our resources ; · substantial monetary payments to trial participants or patients ; · product recalls, withdrawals or labeling, marketing or promotional restrictions ; · loss of revenue ; · exhaustion of any available insurance and our capital resources ; · adverse effects to our results of operations and

business ; · the inability to commercialize any product candidate ; and · a decline in our share price. Our inability to obtain sufficient product liability insurance at an acceptable cost or at all to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaboration partners. Additionally, insurance coverage is increasingly expensive. We may not be able to maintain insurance, including product liability insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all, that could have an adverse effect on our business and financial condition. Our product liability insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Similar challenges to obtaining coverage and reimbursement will apply to companion POCTs that we or our collaborators may develop. Even if our agreements with current or future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. ~~19Our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us, or similar requirements and laws of regulatory authorities in other jurisdictions. In particular, sales, marketing, and business arrangements in the healthcare industry in the US and other jurisdictions are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.~~ Any disruption in our research and development facility could adversely affect our business, financial condition and results of operations. Our facility may be affected by natural or man- made disasters. We are vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fires, floods, and similar events. If our facilities are affected by a natural or man- made disaster, we may be forced to curtail our operations and / or rely on third- parties to perform some or all of our research and development activities. Although we believe we possess adequate insurance in light of our current operations, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. In the future, we may choose to expand our operations in either our existing facilities or in new facilities. Our business and operations would be adversely affected in the event that our computer systems or those of our partners, contract research organizations, contractors, consultants or other third parties we work with were to suffer system failures, cyber- attacks, loss of data or other security incidents. Despite the implementation of security measures, our computer systems, as well as those of our partners, contract research organizations, contractors, consultants, law and accounting firms and other third parties we work with, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, ransomware attacks, denial- of- service attacks, cybercriminals, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on our partners and third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risks of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments and cyber- terrorists, have increased significantly and are becoming increasingly difficult to detect. ~~If~~ **24If** a failure, accident or security breach were to occur and cause interruptions in our operations, or the operations of our partners or third- party providers, it could result in a misappropriation of confidential information, including our intellectual property or financial information or clinical trial participant personal data, a material disruption or delay in our drug development programs, and / or significant monetary losses. For example, the loss of preclinical or clinical trial data from completed, ongoing or planned trials, or chemistry, manufacturing and controls data for our product candidates could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties under the privacy laws of the European Union or other countries as well as state and federal privacy laws in the United States. ~~20Risks~~ -- **Risks** related to reliance on third parties We rely ~~substantially~~ on **third parties to manufacture our product and product candidates, and we intend to rely on third parties which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or**

impair our development or commercialization efforts. We do not own or operate manufacturing facilities. Our current strategy is to outsource all manufacturing of our product and product candidates to other companies, including Taiwan Carbon Nano Technology (" TCNT "), ~~an~~ **our** affiliate **and product** ~~of our Company, to~~ co- **developer, and Swiss Pharmaceutical Co., Ltd. Our manufacturers may be unable to successfully increase the manufacturing capacity for any of our product and product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities and at any other time. If our manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials, if applicable, of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business. If we engage additional manufacturers in the future, our use of new manufacturers increases the risk of delays in production or insufficient supplies of our product candidates. Even after a third- party manufacturer has gained significant experience in manufacturing our product and product candidates or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities for us in a timely manner or continuously over time, or at all. We may be delayed if we need to change the manufacturing process used by our manufacturers. Further, if we change an approved manufacturing process, then we may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used. Our failure, or the failure of our manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and / or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our future product candidates and any products that we may** develop **may compete with other product candidates and** products **for access to manufacturing facilities** . ~~We rely substantially,~~ **If the third parties that we engage to supply any materials or manufacture product for our preclinical tests** and ~~intend~~ **clinical trials should cease** to continue to ~~rely substantially~~ **do so for any reason, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies** on ~~, TNCT~~ **terms that are favorable** to **us** ~~co- develop our products~~ . **In addition, if we are not able to obtain adequate supplies of** ~~Our Product Development Agreement (" TCNT Agreement ") with TCNT is effective until mid- 2026. Any termination or~~ **our** ~~loss of rights under the TCNT Agreement would harm our ability to commercialize, sell and distribute~~ product candidates ~~, which in turn would have a material adverse effect on our~~ - **or the substances used** ~~business, operating results and prospects. If we were~~ to **manufacture** ~~lose our rights under the~~ **them** ~~TCNT Agreement~~ , ~~we believe~~ it ~~would~~ **will** be **more** difficult for us to ~~find an alternative development~~ ---- **develop** ~~partner. In addition, to the extent TCNT or~~ **our product candidates and compete effectively. 25Our current and anticipated future dependence upon others for** the ~~alternative manufacturer~~ - **manufacture** ~~has not secured applicable regulatory approvals, we would have~~ **of our product candidates may adversely affect our future profit margins and our ability** to ~~expend significant resources to obtain regulatory approvals~~ **develop product candidates and commercialize any products** that **receive marketing approval** ~~may never be obtained or require several years to obtain, which could significantly delay commercialization. We may be unable to raise additional capital to fund our operations during this extended time~~ on ~~terms acceptable to us or at all. In addition, if we were to commercialize product candidates and later experience manufacturing delays as~~ a **timely** ~~result of a dispute with TCNT or otherwise, the supply of our products could be harmed. In addition, the manufacture of medical devices~~ and **competitive basis** ~~pharmaceutical products are complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. It may be difficult to predict the cost of manufacturing our products. TCNT may not be able to manufacture our products at expected prices. There may also be unforeseen occurrences that increase our costs, such as increased prices of the components of our products, changes to labor costs or less favorable terms with third- party suppliers or contract manufacturing partners. In addition, quarantines, shelter- in- place and similar government orders related to COVID- 19 or other infectious diseases, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could impact personnel at TCNT' s facilities. Further, TCNT may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If TCNT were to encounter any of these difficulties, or otherwise fail to comply with its contractual obligations, our ability to commercialize our products would be jeopardized~~ . We currently have limited marketing capabilities. If we are unable to expand sales and marketing capabilities on our own or through third parties, or are delayed in establishing these capabilities, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue. We currently have limited marketing capabilities. To commercialize our product candidates, if approved, in the United States and other jurisdictions we seek to enter, we must expand our marketing, sales, distribution, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing, distribution and pricing / reimbursement / access capabilities would impact adversely the commercialization of these products. To commercialize our products, we also intend to leverage the commercial infrastructure of our ~~preferred distributor~~ **distributors** ~~in Japan and non- exclusive global distributor, Inabata, which will provide us with resources and expertise in certain areas that are greater than we could initially build ourselves~~ . We may choose to collaborate with additional third parties in various countries that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may

not be able to successfully commercialize our product candidates, especially in other countries where we currently do not have a foreign legal presence. The inability to commercialize successfully our product candidates, either on our own or through collaborations with one or more third parties, would harm our business, financial condition, operating results and prospects. Our employees, independent contractors, consultants, commercial or strategic partners, principal investigators or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, contract manufacturing organizations ~~or~~ **(** CROs **)** could include intentional, reckless, negligent, or unintentional failures to comply with TFDA or FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the TFDA or FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and declines to intervene, which could require us to incur costs defending against such a claim. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, stock price and prospects, including the imposition of significant fines or other sanctions. ~~21We~~ **We** may form or seek strategic partnerships in the future, and we may not realize the benefits of such alliances or licensing arrangements. From time to time, we may form or seek strategic partnerships, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any such relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. These relationships also may result in a delay in the development of our product candidates if we become dependent upon the other party and such other party does not prioritize the development of our product candidates relative to its other development activities. Additionally, any joint ventures, collaborations, or licensing arrangements would be subject to the same product candidate development and compliance risks and obligations as we would be if we were to develop the product candidate on our own. Should any third party with which we enter into any of these arrangements not comply with the applicable regulatory requirements, we or they may be subject to regulatory enforcement action and we or they may be delayed or prevented from obtaining marketing approval for the applicable product candidate. ~~In~~ **26In** addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangement for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. Any licensed products or acquired businesses may also subject us to the risk of regulatory enforcement should the product or business not be compliant with applicable regulatory requirements. We cannot be certain that, following a strategic transaction or licensing arrangement, we will achieve the revenue or specific net income that justifies such a transaction. Risks related to intellectual property, patents, and data privacy Intellectual property rights vary across foreign jurisdictions, and we may not be able to protect our intellectual property rights throughout the world. We cannot assure you that any intellectual property rights that we currently have or may receive can be successfully asserted in the future or that they will not be invalidated, circumvented or challenged. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent, as do the laws of the United States. Our means of protecting any proprietary rights we may receive in the United States or abroad may not be adequate. Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and may export otherwise infringing products to territories where we have patents, but enforcement rights are not as strong as those in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. We ~~do~~ **may** not have patent rights in certain foreign countries in which a market may exist in the future. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our product. ~~22Many~~ **Many** companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement or protection of patents, trade secrets and other

intellectual property, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. ~~Many~~ **27Many** foreign countries, including some EU countries, India, Japan, and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of the applicable patents and limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations and prospects. If we and our collaborators are unable to obtain and maintain sufficient patent and other intellectual property protection for our product candidates and technology, our competitors could develop and commercialize products and technology similar or identical to ours, and we may not be able to compete effectively in our market or successfully commercialize any product candidates we may develop. Our success depends in significant part on our ability and the ability of our current or future collaborators and licensors to obtain, maintain, enforce and defend patents and other intellectual property rights with respect to our product candidates and technology and to operate our business without infringing, misappropriating, or otherwise violating the intellectual property rights of others. If we and our current or future collaborators and licensors are unable to obtain and maintain sufficient intellectual property protection for our product candidates or other future product candidates that we may identify, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors and other third parties could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize our product candidates and other product candidates that we may pursue may be impaired. The process of applying for patent protection itself is time consuming and expensive and we cannot assure you that we have prepared or will be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. In addition, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. We cannot be certain that there is no invalidating prior art of which we and the patent examiner are unaware or that our interpretation of the relevance of prior art is correct. Failure to obtain issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates. Even if our patent applications do issue as patents, third parties may be able to challenge the validity and enforceability of our patents on a variety of grounds, including that such third party' s patents and patent applications have an earlier priority date, and if such challenges are successful we may be required to obtain one or more licenses from such third parties, or be prohibited from commercializing our product candidates. We may not be able to obtain these licenses on acceptable or commercially reasonable terms, if at all, or these licenses may be non- exclusive, which could result in our competitors using the same intellectual property. We seek to protect our proprietary positions by, among other things, filing patent applications in the United States and in relevant foreign jurisdictions related to our current product candidates and other future product candidates that we may identify. Obtaining, maintaining, defending and enforcing pharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, under certain of our license or collaboration agreements, we may not have the right to control the preparation, filing, prosecution and maintenance of patent applications, or to maintain the rights to patents licensed to or from third parties. ~~23Although~~ **28Although** we enter into confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Further, we may not be aware of all third- party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The patent position of biotech companies generally is highly uncertain, involves complex legal, technological and factual questions and has, in recent years, been the subject of much debate and litigation throughout the world. The subject matter claimed in a patent application can be significantly reduced or eliminated before the patent issues, if at all, and its scope can be reinterpreted or narrowed after issuance. Therefore, our pending and future patent applications may not result in patents being issued in relevant jurisdictions that protect our product candidates, in whole or in part, or that effectively prevent others from commercializing competitive product candidates, and even if our patent applications issue as patents in relevant jurisdictions, they may not issue in a form that will provide us with any meaningful protection for our product candidates or technology, prevent competitors from competing

with us or otherwise provide us with any competitive advantage. Additionally, our competitors may be able to circumvent our patents by challenging their validity or by developing similar or alternative product candidates or technologies in a non-infringing manner. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. An adverse determination in any such submission, proceeding or litigation could result in loss of exclusivity or ability to sell our products free from infringing the patents of third parties, patent claims being narrowed, invalidated or held unenforceable, in whole or in part, and limitation of the scope or duration of the patents directed to our product candidates, all of which could limit our ability to stop others from using or commercializing similar or identical product candidates or technology to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates or approved products (if any) without infringing third- party patent rights. In addition, if the breadth or strength of the claims of our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates, or could have a material adverse effect on our ability to raise funds necessary to continue our research programs or clinical trials. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming and unsuccessful, and issued patents directed towards our technology and product candidates could be found invalid or unenforceable if challenged. Competitors and other third parties may infringe or otherwise violate our issued patents or other intellectual property or the patents or other intellectual property of our licensors and collaborators. In addition, our patents or the patents of our licensors and collaborators may become involved in inventorship or priority disputes. To counter infringement or other unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. Significantly, our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issue from such applications. Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor' s or potential competitor' s product or service. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. In a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated, held unenforceable or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties. ~~If~~ **29If** we were to initiate legal proceedings against a third party to enforce a patent directed to our product candidates, or one of our future product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the **United States Patent and Trademark Office (** USPTO **)** or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO or an equivalent foreign body, even outside the context of litigation. Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technology or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent rights directed towards the applicable product candidates or technology related to the patent rendered invalid or unenforceable. Such a loss of patent rights would materially harm our business, financial condition, results of operations and prospects. ~~24Interference~~ -- **Interference** and / or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be materially harmed if the prevailing party does not offer us a license on commercially reasonable terms. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Some of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or in- license needed technology or other product candidates. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline. Any of the foregoing events could harm our business, financial condition, results of operation and prospects. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. The USPTO and various foreign governmental patent

agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our product and technologies. ~~Patents~~ **30Patents** have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a utility patent is generally 20 years from its earliest non- provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory- related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions including patent term extension, or PTE, and patent term adjustment, or PTA, may be available, but the lives of such extensions, and the protections they afford, are limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars and generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed. In addition to seeking patents for our technologies and product candidates, we also rely on trade secret protection, as well as confidentiality agreements, non- disclosure agreements and invention assignment agreements with our employees, consultants and third- parties, to protect our know- how and other confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. ~~25It~~ **It** is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party' s relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third- party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self- executing, or assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not be able to obtain adequate remedies for any breaches of such agreements. Ultimately, enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know- how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, our trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs and we cannot guarantee a successful outcome. Even if we are successful, these types of lawsuits may consume significant amounts of our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. ~~We~~ **31We** may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non- competition or non- solicitation agreements with our competitors. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers, competitors, or other third parties. Although we endeavor to ensure that our employees and consultants do not use the intellectual property, proprietary information, know- how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non- competition or non- solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to

management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our product, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers or other third parties. An inability to incorporate technologies or features that are important or essential to our product may prevent us from selling our product. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product. Changes in U. S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other pharmaceutical and biotech companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in our licensor' s patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the U. S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future. Additionally, the application and interpretation of China' s intellectual property right laws and the procedures and standards for granting patents, copyrights, know- how or other intellectual property rights in China are still evolving and are uncertain, and we cannot assure you that PRC courts or regulatory authorities would agree with our analysis. If we were found to have violated the intellectual property rights of others, we may be subject to liability and penalties for our infringement activities or may be prohibited from using such intellectual property, and we may incur licensing fees or be forced to develop alternatives of our own. As a result, our business and results of operations may be materially and adversely affected. ~~26Risks --~~ **Risks** related to our business We will need to increase the size of our Company and may not effectively manage our growth. Our success will depend upon growing our business and our employee base. Over the next twelve months, we plan to add additional employees to assist us with research and development and our commercialization efforts. Our future growth, if any, may cause a significant strain on our management, and our operational, financial and other resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition, and results of operations. ~~Our~~ **32Our** future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on the research and development, clinical, financial, operational and other business expertise of our executive officers, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. **As we are actively involved in marketing VELDONA Pet supplements within a fiercely competitive industry, any inability to effectively compete may adversely impact our operational results.** The **pet health supplement industry is highly competitive. We compete on the basis of product and ingredient quality, product availability, brand awareness, loyalty and trust, product variety and innovation, price and convenience and promotional efforts. The pet products are increasingly competitive due to the expansion of pet- related product offerings by incumbents and new entrants. We face direct competition from companies that sell various products at a lower price point and distribute such products to traditional retailers, which are larger than we are and have greater financial resources. Price gaps between products may result in market share erosion and harm our business. Our current and potential competitors may also establish cooperative or strategic**

relationships amongst themselves or with third parties that may further enhance their resources and offerings. Further, it is possible that domestic or foreign companies, some with greater experience in the pet health and wellness industry or greater financial resources than we possess, will seek to provide products or services that compete directly or indirectly with ours in the future. Many of our competitors may have longer operating histories, greater brand recognition, larger fulfillment infrastructures, greater technical capabilities, significantly greater financial, marketing and other resources and larger customer bases than we do. These factors may allow our competitors to derive greater net sales and profits from their existing customer base, acquire customers at lower costs or respond more quickly than we can to new or emerging technologies and changes in consumer preferences or habits. These competitors may engage in more extensive research and development efforts, undertake more far- reaching marketing campaigns and adopt more aggressive pricing policies, which may allow them to build larger customer bases or generate net sales from their customer bases more effectively than we do. Our competitors may be able to identify and adapt to changes in consumer preferences more quickly than us due to their resources and scale. They may also be more successful in marketing and selling their products, better able to increase prices to reflect cost pressures and better able to increase their promotional activity, which may impact us and the entire pet health and wellness industry. Increased competition as to any of our products could result in price reduction, increased costs, reduced margins and loss of market share, which could negatively affect our profitability. There can be no assurance that we will be able to successfully compete against these other companies. Expansion into markets served by our competitors and entry of new competitors or expansion of existing competitors into our markets could materially adversely affect our business, financial condition and results of operations. 33The point- of- care testing (" POCT ") market is extremely competitive and rapidly evolving, making it difficult to evaluate our business and future prospects. The market for POCT testing is extremely competitive. Further, the POCT testing industry, as well as the manner in which healthcare services are delivered more broadly, is currently experiencing rapid change, technological and scientific breakthroughs, new product introductions and enhancements and evolving industry standards, as well as the emergence of telehealth and other changes in the way healthcare services are delivered. All of these factors could affect the degree to which our products gain market acceptance or approval or result in our products being less marketable or becoming obsolete. Our future success will depend on our ability to successfully compete with established and new market participants and to keep pace with scientific and technological changes and the evolving needs of customers and the healthcare marketplace. We will be required to continuously enhance our products and develop new tests to keep pace with evolving standards of care. If we do not update our products to keep pace with technological and scientific advances, our products could become obsolete and sales of our products could decline or fail to grow as expected. ~~27Many~~ -- **Many** of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise than we do in research and development, manufacturing, obtaining regulatory clearances and approvals and regulatory compliance, and sales and distribution. Mergers and acquisitions involving POCT testing or other healthcare companies may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies or customer networks. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize POCT products or services that are more accurate, more convenient to use or more cost- effective than our products. Our competitors also may obtain FDA or other regulatory clearance or approval for their products more rapidly than we may obtain clearance or able to enter a particular market. Further, some of our competitors' products may be sold at prices that may be lower than our pricing, which could adversely affect our sales or force us to reduce our prices, which could harm our revenue, operating income or market share. If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability and our future growth prospects may be materially harmed. Central labs continue to represent the most significant portion of the POCT testing market, and as a result we will be competing against very large and well- established lab companies such as Quest ~~POCTs~~ **Diagnostics** , Inc. and Laboratory Corporation of America. These companies have also expanded beyond centralized laboratory testing into home sample collection. In addition, we also face intense competition from other companies that develop or already have molecular tests, whether at point- of- care or at- home, as well as companies that have or are developing antigen and antibody tests. To remain competitive, we will need to develop improvements to our products and other offerings. We cannot assure you that we will be able to successfully compete in the marketplace or develop and commercialize new tests or improvements to our products and other offerings on a timely basis. Our competitors may develop and commercialize competing or alternative products or services and improvements faster than we are able to do so, which would negatively affect our ability to increase or sustain our revenue or achieve profitability and could materially adversely affect our future growth prospects. ~~Research~~ **34Research** and development of drug candidates as VELDONA is extremely expensive and complex and its difficult to evaluate the likelihood of the outcome of clinical trials, regulatory approvals, and our business and future prospects. The discovery and development of new products such as our VELDONA candidates, as well as the development of additional uses for existing products, are necessary for the continued strength of our business. Our product lines must be replenished over time to offset revenue losses when products lose exclusivity or market share, as well as to provide for earnings growth, primarily through internal R & D or through collaborations, acquisitions, JVs, licensing or other arrangements. Growth depends in large part on our ability to identify and develop new products or new indications for existing products that address unmet medical needs and receive reimbursement from payers. However, balancing current growth, investment for future growth and the delivery of shareholder return remains a major challenge. The costs of product development continue to be high, as are regulatory requirements in many therapeutic areas, which may affect the number of candidates we are able to fund as well as the sustainability of the R & D portfolio. Decisions made early in the development process of a drug or vaccine candidate can have a substantial impact on the marketing strategy and payer reimbursement possibilities if the candidate receives regulatory approval. We try to plan clinical trials prudently and to reasonably anticipate and address challenges, but there is no assurance

that an optimal balance between trial conduct, speed and desired outcome will be achieved. Additionally, our product candidates can fail at any stage of the R & D process, and may not receive regulatory approval even after many years of R & D. We may fail to correctly identify indications for which our science is promising or allocate R & D investment resources efficiently, and failure to invest in the right technology platforms, therapeutic areas, product classes, geographic markets and / or licensing opportunities could adversely impact the productivity of our pipeline. Further, even if we identify areas with the greatest commercial potential, the scientific approach may not succeed despite the significant investment required for R & D, and the product may not be as competitive as expected because of the highly dynamic market environment and the hurdles in terms of access and reimbursement. For example, our VELDONA product candidates are based on a novel technology with only a few gene therapies approved to date, which makes it difficult to predict the time and cost of development and the ability to obtain regulatory approval. Further, our VELDONA therapies may face difficulties in gaining the acceptance of patients or the medical community. **If we fail to develop and maintain our brand, or the quality of our products that customers have come to expect, our business could suffer. We believe that developing and maintaining our brand and the quality of our products may affect our success. The importance of our brand recognition and the quality of our products may become even greater as competitors offer more products similar to ours.** ~~28Our~~ -- **Our financial success may depend on our target customers' perception of our brand and our products. Our brand- building activities involve providing high- quality products, increasing awareness of our brand, creating and increasing the availability of our products. The success of our brand may suffer if our marketing plans or product initiatives do not have the desired impact on our brand' s image or its ability to attract customers. Further, our brand value could diminish significantly due to a number of factors, including consumer perception that we have acted in an irresponsible manner, adverse publicity about our products (whether or not valid), our failure to maintain the quality of our products, product contamination, the failure of our products to deliver consistently positive consumer experiences, or the products becoming unavailable to consumers. The growing use of social and digital media by consumers increases the speed and extent that information and opinions can be shared. Negative posts or comments about us or our brands or products on social or digital media could damage our brands and reputation. If we fail to maintain the favorable perception of our brands, our business, financial condition and results of operations could be negatively impacted. Our business, operations, clinical development plans and timelines, and supply chain could be adversely affected by the effects of epidemics, including but not limited to COVID-19. Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third- party manufacturers, contract research organizations and other third parties upon whom we rely. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge worldwide. Besides the COVID- 19 pandemic, the United States and other countries have experienced, and may experience in the future, public health outbreaks such as Zika virus, Avian Flu, SARS, and H1N1 influenza. A prolonged occurrence of contagious diseases such as these could result in significant challenges affecting employees, patients, communities, supply chains, business operations, as well as the U. S. economy and financial markets. These challenges may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition. 35Our** business activities are subject to the Foreign Corrupt Practices Act, or the FCPA, and similar anti- bribery and anti- corruption laws of other countries in which we operate, including Taiwan, ~~w~~ as well as U. S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them. Our business activities are subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition. In addition, our products and technology may be subject to applicable foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products and technology, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business. Risks

related to our securities Our financial statements disclose that there is substantial doubt regarding our ability to continue as a going concern, in which case you could lose your investment. Our independent registered public accounting firm, ~~PWR CPA, LLP~~ **KCCW Accountancy Corp.** , has expressed substantial doubt about our ability to continue as a going concern in their audit opinion of our financial statements for the year ended December 31, ~~2022~~ **2023** . See audit report for more information. You could lose **all or substantially all of** your investment if we cease operations. An active trading market for our common stock may not develop and the market price of our common stock and warrants could be volatile. Our common stock and **public** warrants are currently quoted on the Nasdaq Capital Market. ~~The~~ **36The** trading market for our common stock in the future could be subject to wide fluctuations in response to several factors, including, but not limited to: · actual or anticipated variations in our results of operations; · our ability or inability to generate revenues or profit; · the number of shares in our public float; and · increased competition. Furthermore, our stock price may be impacted by factors that are unrelated or disproportionate to our operating performance. These market fluctuations, as well as general economic, political and market conditions, such as recessions, interest rates or international currency fluctuations may adversely affect the market price of our common stock. Additionally, moving forward we anticipate having a limited number of shares in our public float, and as a result, there could be extreme fluctuations in the price of our common stock. We do not intend to pay dividends for the foreseeable future and, as a result, our ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We have not declared or paid any cash dividends on our capital stock in ~~2022~~ **2023** , and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our Board of Directors and may be restricted by the terms of any then- current credit facility. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. ~~29We~~ **We** have acquired, and may in the future acquire, assets and technologies as part of our business strategy. If we acquire companies or technologies in the future, they could prove difficult to integrate, disrupt our business, dilute stockholder value, and adversely affect our operating results and the value of our common stock. As part of our business strategy, we may acquire, enter into joint ventures with, or make investments in complementary or synergistic companies, services, and technologies in the future. Acquisitions and investments involve numerous risks, including without limitation: · difficulties in identifying and acquiring products, technologies, proprietary rights or businesses that will help our business ; · difficulties in integrating operations, technologies, services, and personnel ; · diversion of financial and managerial resources from existing operations ; · the risk of entering new development activities and markets in which we have little to no experience ; · risks related to the assumption of known and unknown liabilities ; · risks related to our ability to raise sufficient capital to fund additional operating activities ; and · the issuance of our securities as partial or full payment for any acquisitions and investments could result in material dilution to our existing stockholders. If we fail to integrate our patent assets into our operations, or if we fail to properly evaluate other acquisitions or investments, we may not achieve the anticipated benefits of any such acquisitions, we may incur costs in excess of what we anticipate, and management resources and attention may be diverted from other necessary or valuable activities. Any failure to maintain effective internal control over financial reporting could harm us. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U. S. generally accepted accounting principles. If our management is unable to conclude that we have effective internal control over financial reporting, or to certify the effectiveness of such controls, or if material weaknesses in our internal controls are identified in the future, we could have difficulty in timely and accurately reporting our financial results and could be subject to regulatory scrutiny and a loss of public confidence, any of which could have a material adverse effect on our business and our stock price. Our management has concluded there were deficiencies in the design and implementation of our internal controls as of December 31, 2021. If we are unable to remediate the deficiencies identified adequately or otherwise fail to maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common stock price and adversely affect our results of operations and financial condition. ~~Our~~ **37Our** issuance of additional capital stock in connection with financings, acquisitions, investments, our ~~2021~~ **2023** Stock Incentive Plan or otherwise will dilute all other stockholders. We may need to raise additional capital through equity and debt financings in order to fund our operations. If we raise capital through equity financings in the future, that will result in dilution to all other stockholders. We also expect to grant equity awards to employees, directors, and consultants under our ~~2021~~ **2023** Stock Incentive Plan. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. These, and any additional such issuances of capital stock will cause stockholders to experience significant dilution of their ownership interests and the per- share value of our common stock to decline. Our stock price has in the past and may in the future fail to meet minimum requirements for continued listing on the Nasdaq Capital Market. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the Nasdaq Capital Market or if we are unable to transfer our listing to another stock market. On January 5, 2023, the Company received a deficiency letter from the Nasdaq Listing Qualifications Department (the " Staff ") of The Nasdaq Stock Market LLC (" Nasdaq ") notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company' s common stock has been below the minimum $ 1. 00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550 (a) (2) (the " Minimum Bid Price Requirement "). ~~The~~ **On December 29, 2023,** Nasdaq ~~deficiency letter~~ **Staff informed the Company that it** has **determined that for** ~~no immediate effect on~~ the ~~listing~~ **last 10 consecutive business days, the closing bid price** of the Company' s common stock **has been** ~~, and its common stock will continue to trade on The Nasdaq Capital Market under the symbol " AIMD "~~ at ~~this time~~ **$ 1** . ~~If~~ **00 per share or greater. Accordingly,** the Company **has** ~~does not regain~~ **regained** compliance with **Listing Rule 5550 (** ~~the Minimum Bid Price Requirement by July 5, 2023, the Company may be afforded~~ a **)**

(2) ~~second 180 calendar day period to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the Minimum Bid Price Requirement. In addition, the Company would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period. If the Company meets these requirements, Nasdaq will inform the Company that it has been granted an additional 180 calendar days. However, if it appears to Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq will provide notice that the Company' s securities are subject to delisting~~ . There can be no assurance that we will continue to maintain compliance with the requirements for listing our common stock on Nasdaq. Any potential delisting of our common stock from the Nasdaq Capital Market would likely result in decreased liquidity and increased volatility for our common stock and would adversely affect our ability to raise additional capital or to enter into strategic transactions. Any potential delisting of our common stock from the Nasdaq Capital Market would also make it more difficult for our stockholders to sell our common stock in the public market. **ITEM 1B. UNRESOLVED STAFF COMMENTS.**