Ainos

Ainos, Inc.

2024 Annual Report

U.S. Securities and Exchange Commission

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Fiscal Year Ended **December 31, 2024**

☐ Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission File Number **001-41461**

AINOS, INC.

(Exact name of registrant as specified in its charter)

Texas	**75-1974352**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
8880 Rio San Diego Drive, Ste.800, San Diego, CA	**92108**
(Address of principal executive offices)	Zip Code
Issuer's telephone number, including area code:	**(858) 869-2986**

Securities registered under Section 12(b) of the Exchange Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	AIMD	The Nasdaq Stock Market LLC (Nasdaq Capital Market)
Common Stock Purchase Warrants	AIMDW	The Nasdaq Stock Market LLC (Nasdaq Capital Market)

Securities registered under Section 12(g) of the Exchange Act. None

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

As of March 7, 2025, there were issued and outstanding 15,433,257 shares of the registrant's common stock, par value $0.01, which is the only class of common or voting stock of the registrant. As of June 30, 2024, the aggregate market value of the shares of common stock outstanding, other than shares held by persons who may be deemed affiliates of the Registrant, computed by reference to the closing price of $ 0.8136 for the Registrant's common stock on June 30, 2024, as reported on Nasdaq Capital Market, was approximately $3,350,118. Shares of common stock held by officers, directors and each shareholder owning 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates.

TABLE OF CONTENTS

[This page intentionally left blank]

PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act) and, as such, may involve unknown risks, uncertainties and assumptions.

Forward-looking statements are those that predict or describe future events or trends and that do not relate solely to historical matters. You can generally identify forward-looking statements as those statements containing the words "anticipate," "believe," "plan," "estimate," "expect," "intend," "may," "will," "would," "could," "should," "might," "potential," "continue" or other similar expressions.

There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the section entitled "Risk Factors" in Part I, Item 1A that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

As used in this Annual Report on Form 10-K, "Ainos" "the Company," "we," "us," and "our" refer to Ainos, Inc. and our consolidated subsidiaries, except where the context otherwise requires.

ITEM 1. BUSINESS.

Overview

Ainos, Inc. (the "Company"), incorporated in the State of Texas in 1984, is a diversified healthcare company focused on the development of novel point-of-care testing (the "POCT"), therapeutics based on very low-dose interferon alpha (the "VELDONA"), and synthetic RNA-driven preventative medicine. Our product pipeline includes commercial-stage VELDONA Pet supplements, clinical-stage VELDONA human therapeutics and telehealth-friendly POCTs powered by the AI Nose technology platform. Our vision for AI Nose is to digitize smell, extend application beyond healthcare, and ultimately become AI's nose.

We have historically involved in the research and development of therapeutics based on VELDONA. Building on our research and development on VELDONA since inception, we are focused on commercializing a suite of VELDONA-based product candidates. Our priority pipeline includes drug candidates for treating oral warts for human immunodeficiency virus (HIV) seropositive patients, Sjögren's syndrome, and feline chronic gingivostomatitis (FCGS), a cat oral infection.

In 2021 and 2022, we acquired certain types of intellectual property from a controlling shareholder, Ainos Inc., a Cayman Island corporation ("Ainos KY"), to expand product portfolio into POCTs aimed to provide connected, rapid, and convenient testing for a broad range of health conditions. Pivoting from the sales of COVID-19 POCT, we aim to commercialize POCTs that detect volatile organic compounds (the "VOC") emitted by the body, powered by our AI Nose technology platform. In 2024, we licensed certain patents and patent applications from Taiwan Carbon Nano Technology Corporation ("TCNT"), a controlling shareholder, to further expand our intellectual properties on our VOC and POCT technologies.

We believe the following attributes differentiate us from other diversified life science companies:

- intuitive, telehealth-friendly point-of-care testing
- AI-powered VOC testing platform

- decades of proprietary low-dose oral interferon clinical research
- capital-efficient business model
- outsourced manufacturing
- global distribution relationships

Our Technologies

VELDONA

Interferons are proteins made by host cells in response to the presence of pathogens. Interferons allow for communication between cells to trigger the protective defenses of the immune system. VELDONA formulation, delivered into the oral cavity as a lozenge in low doses, is designed to enhance autoimmunity to resist virus damages, potentially reducing side effects and risks caused by high-dose interferon and other small molecule drugs.

We believe VELDONA has shown to be safe and effective in the clinical studies for treatment of intended human and animal diseases. Since our inception to date, 68 human clinical trials have been conducted with low-dose oral IFNα. 63 studies were Phase 2 trials, and 3 Phase 1 and 2 Phase 3 studies have also been conducted.

In 28 studies performed by Ainos, VELDONA was found to exhibit systemic effects in mice, cats, dogs, ferrets, chickens, rats, guinea pigs, horses, calves/cows, and particularly pigs. VELDONA aided in boosting feed conversion efficiency and fighting deadly viral infections in these species, including canine parvovirus, equine herpesvirus, feline coronavirus, and others. We believe the studies demonstrate VELDONA's therapeutic or preventive effect via the oral mucosa and shows VELDONA modulates systemic and mucosal immunity without serious side effects.

We are developing VELDONA for a broad range of human and animal health conditions. Our planned drug pipeline includes: oral warts for HIV-seropositive patients, Sjogren's Syndrome, mid COVID-19 syndromes, common cold, influenza, aphthous stomatitis, chemotherapy-induced stomatitis and FCGS. Our priorities are HIV-seropositive patients, Sjogren's Syndrome and FCGS. The United States Food and Drug Administration (the "U.S. FDA") have granted Orphan Drug Designation ("ODD") for our VELDONA formulation as a potential treatment for oral warts in HIV-seropositive patients. We marketed a series of health supplements for dogs and cats under the brand name "VELDONA Pet" in Taiwan in 2024.

Point-of-Care Tests (POCTs)

Our POCT technologies aim to provide a simple, effective and telehealth-friendly tests that can deliver results within minutes. Our POCT detection technologies consists of VOC sensing, lateral flow immunochromatographic assay and nucleic acid. Currently we prioritize developing products based on VOC sensing. We intend to evaluate our lateral flow and nucleic acid test technologies for potential applications for other disease indication.

VOC Sensing Powered by AI Nose

We believe the analysis of VOC is a powerful, non-invasive option for disease detection and health monitoring. Our VOC sensing technology aims to detect the target VOCs within few minutes. AI Nose, the key enabler of our VOC sensing, consists of three key technologies: 1) a "digital nose" detects the target VOCs; 2) a trained artificial intelligence ("AI") algorithm analyzes the target VOCs; 3) a "Smell ID" stores the VOC's digital profile in the cloud.

We believe VOC sensing powered by AI Nose is scalable into a broad range of industries for two reasons. First, digital nose sensors can be made small and at low cost through semiconductor manufacturing technology. Second, as we train our AI with more Smell IDs, our VOC sensing can continue to improve. While health testing is our near-term focus, we believe we can broaden VOC sensing powered by AI Nose to other applications including telehealth, automotive, industrial, and environmental safety. To address these additional opportunities, we are codeveloping a VOC POCT solution for the elderly care market. We are also codeveloping a VOC sensing solution to address the industrial market, as our first move to expand the application of AI Nose beyond healthcare. Our vision is to leverage digital nose sensors and our proprietary VOC sensing AI algorithm, to digitize smell and ultimately become AI's nose.

Our Pipeline

An integral part of our operating strategy is to create multiple revenue streams through sales of commercially ready products, out-licensing or forming strategic relationships to develop and commercialize our products. As of December 31, 2024, we have commercialized the following products:

- **COVID-19 Antigen Rapid Test Kit**. Our first commercialized product line was COVID-19 antigen rapid test kits marketed in Taiwan under emergency use authorization (EUA) issued by the Taiwan Food and Drug Administration (TFDA) to TCNT, the product manufacturer. We discontinued selling this product in the first quarter of 2024.
- **VELDONA Pet supplement.** VELDONA Pet is formulated to address a variety of health issues in dogs and cats, including skin, gum, emotion, discomfort caused by allergies, eye, and weight-related issues. We launched VELDONA Pet supplement in Taiwan in the second quarter of 2023.

From time to time, we assess our development plan based on available resources and market dynamics. Our pipeline of the products, which are under development, includes the following:

- **VELDONA human and animal drugs.** Our human drug pipeline includes treatments for oral warts in HIV-seropositive patients, Sjögren's syndrome, common cold, and influenza. The United States Food and Drug Administration (U.S. FDA) has granted orphan drug designation for our VELDONA formulation as a potential treatment for oral warts in HIV-seropositive patients. We have completed Phase 2 studies for these programs. Within the human drug pipeline, we are prioritizing treatments for HIV oral warts and Sjögren's syndrome. As of December 31, 2024, we were in the process of initiating clinical studies for HIV oral warts and Sjögren's syndrome in Taiwan. In 2024, we also initiated a clinical study for FCGS to explore further opportunities for VELDONA in the animal drug market.
- **VOC POCT – Ainos Flora.** Ainos Flora, powered by AI Nose technology, is designed to offer a quick, non-invasive test for female vaginal health and common STIs. We are also developing a companion app for managing test results. We aim to provide fast, private, and convenient testing at the point of care. To enhance at-home testing, we are developing a second generation Ainos Flora device with CUDA technology. We are conducting clinical studies in Taiwan, and we are also exploring commercialization opportunities.
- **VOC platform – NISD co-development.** We are collaborating with Nisshinbo Micro Devices Inc. ("NISD") and Taiwan Inabata Sangyo Co. ("Taiwan Inabata") to develop a VOC sensing platform based on AI Nose. This platform is designed for applications in telehealth, automotive, industrial, and environmental safety sectors. We are co-developing a VOC POCT solution for elderly care and a VOC sensing solution for industrial use.
- **VOC POCT – Ainos Pen.** The device is intended to be a cloud-connected, multi-purpose, portable breath analyzer that is intended to monitor health conditions within minutes, powered by AI Nose. We expect consumers to be empowered to share test results with their physicians through in-person and telehealth medical consultations.
- **VOC POCT – CHS430.** The CHS430 device, powered by AI Nose, is intended to provide non-invasive testing for ventilator-associated pneumonia within few minutes, as compared to current standard of care invasive culture tests that typically take more than two days to provide results.
- **Synthetic RNA ("SRNA")**. We plan develop a SRNA technology platform in Taiwan with a long-term goal of developing next-generating precision treatments and rapid tests.

Our Business Model

We believe our business model is capital efficient based on the following:

Operation in Taiwan. We have constructed our operation to be capital efficient by choosing Taiwan as our R&D and operating center. We believe Taiwan has been a key center of the global technology supply chain and it is also home to high-caliber engineers, scientists and healthcare professionals. We believe maintaining operations in Taiwan, at least in the near-term, allows us to access high-caliber talent while staying cost effective, enabling us to develop high quality, affordable, consumer-friendly products.

Outsourced Manufacturing. We believe our outsourced manufacturing strategy potentially saves us the time and resources required to establish our own infrastructure. We outsource manufacturing of our POCT product candidates to TCNT. We outsource manufacturing of VELDONA drugs for human-use to Swiss Pharmaceutical Co., Ltd., a Taiwan-based company. We outsource manufacturing of VELDONA Pet supplements to a Taiwan-based third party and to TCNT.

Distribution Relationships. We work with distributors to sell products. We appointed Inabata & Co. Ltd. ("Inabata"), a Japanese corporation, as our non-exclusive worldwide distributor and preferred distributor for customers based in Japan. Inabata's Taiwan subsidiary (Taiwan Inabata Sangyo Co.) coordinates business logistics and working capital for our designated programs. Topmed International Biotech Co., Ltd. ("Topmed"), a Taiwanese biotech company, is a distributor of our VELDDONA Pet supplements in Taiwan.

Intellectual Property

We own a portfolio of patents covering various aspects of our core technologies. As of December 31, 2024, we had sixty-five (65) issued patents and nineteen (19) pending patent applications. Fifty-seven (57) of the issued patents relate to acquired VOC and POCT technologies, five (5) relate to interferon technologies and three (3) relate to our smart drug injection technology. Fifty-six (56) of the issued patents are foreign patents and nine (9) are U.S. patents. Eleven (11) issued patents are licensed patents. Of the issued patents, forty-three (43) are invention patents, fourteen (14) are utility model patents and eight (8) are design patents. Of our issued patents, five (5) shall expire between 2026 and 2029; twenty-two (22) between 2030 and 2034, thirty-eight (38) between 2035 and 2046.

We also have exclusive use of twenty three (23) patents and patent applications related to VOC, POCT and nitrogen-oxygen separation technologies for twelve months from October 16, 2024, pursuant to Product Development Agreement, effective August 1, 2021, as amended on January 9, 2024, July 8, 2024, and October 16, 2024, with TCNT. Please refer to "Part III, Item 13".

We own a registered trademark for VELDONA in Taiwan, Europe, Japan and China, as well as certain trademarks for our VELDONA Pet supplement in Taiwan. We have trademark applications for certain countries outside of Taiwan.

Employees

As of December 31, 2024, we had 44 full-time employees, of which 23 are in research and development. Majority of our employees are in Taiwan. None of our employees are represented by a labor union or are a party to a collective bargaining agreement. We plan to continue expand our manpower in research development, sales and marketing, and general operations to support our business programs. Please refer to Part 3 Item 10 and 11 for executive profile and compensation.

Additional Information

Under our former name, Amarillo Biosciences, Inc., we completed an initial public offering on the Nasdaq SmallCap Market in August 1996 and have traded on the U.S. over-the-counter market since October 1999. On October 31, 2013, we filed a voluntary petition for reorganization under Chapter 11 of the United States bankruptcy code. We emerged from bankruptcy on January 23, 2015. We established a Taiwan branch office in 2017. We renamed as Ainos, Inc in April 2021.

On August 9, 2022, our common stock and warrants began trading on the Nasdaq Capital Market under the trading symbols "AIMD" and "AIMDW," respectively. We effectuated a 1-for-15 reverse stock split of our common stock on August 8, 2022, and a 1-for-5 reverse stock split on December 14, 2023.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports are available free of charge on the Company's website at www.ainos.com as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission.

Government Regulation

Regulation of Medical Devices in Taiwan

Our product candidates and operations are subject to the Taiwan Medical Devices Act and its implementation regulations (collectively the "**Taiwan MDA**"), which govern the development, design, pre-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution of medical devices. Under the Taiwan MDA, medical devices, depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to provide reasonable assurance of its safety and effectiveness, will be subject to differentiated level of review and examination of TFDA before marketing the device. Unless an exemption applies, each medical device requires either (a) an approval granted by TFDA or (b) a registration with TFDA before launching distribution or marketing in Taiwan. The latter is a simplified premarket review process applicable to some medical devices classified as "lower risk level" items listed in the TFDA announcement. Our product candidates are not on the list of "lower risk level" and the approval of TFDA will be required for us to launch distribution or marketing of such products in Taiwan.

Additionally, the TFDA may grant emergency use authorizations ("EUA") to allow commercial distribution of medical devices intended to address the public health emergency during public emergencies. The TFDA needs to assess the potential effectiveness of such medical device on a case-by-case basis using a risk-benefit analysis and will require the submission of pre-clinical studies and clinical trials. The TFDA also may revise or revoke an issued EUA if the circumstances justifying such granting no longer exist, the criteria for its granting of EUA are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety. The EUA granted by TFDA to TCNT for COVID-19 antigen test kits ended in March 2023.

Concerning the post-marketing regulatory requirements, a company engaging in medical devices business will be required to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design and manufacturing process and report to TFDA when the device it markets has or may have caused or contributed to a death or serious injury. The TFDA also has broad discretion to take compliance and enforcement actions, such as requiring a safety surveillance report to be submitted regularly for review, ordering corrections, and conducting on-site inspection if it has any regulatory concerns. Failure to comply with applicable requirements under the Taiwan MDA may subject a device and/or manufacturers to a variety of administrative sanctions, such as the TFDA's refusal to approve pending premarket applications, mandatory product recalls, import detentions, business suspension or license/listing cancellation, administrative fines, product seizures and destruction, civil monetary penalties and/or criminal prosecution and criminal penalties. Any company engaging in medical devices business may be additionally subject to ten times the criminal fines for each violation made by its authorized representative and/or employees.

As of December 31, 2024, Ainos Fora, our lead POCT candidate, has not been approved to sell by the TFDA.

Personal Data Protection Laws in Taiwan

Under the Taiwan Personal Data Protection Act ("**PDPA**"), each individual or governmental or non-governmental agencies, including our affiliate in Taiwan, should be subject to certain requirements and restrictions for collecting, processing or using personal data. The definition of "personal data" is extended to cover a broad scope, including name, birthday, ID, special features, fingerprints, marriage status, family, education, occupation, medical records, medical history, genetic information, sex life, health examination report, criminal records, contact information, financial status, social activities, and any other data which is sufficient to directly or indirectly identify a specific person. Due to the nature of the use of medical devices, our operation and the operation of our partners might collect, process, or use the data pertaining to a person's medical records and healthcare, genetics (collectively, sensitive data), which is subject to stricter scrutiny. Generally, we can only obtain such sensitive data when the person consents in writing or electronically. Furthermore, in January 2022, the TFDA published the Regulations for the Security and the Maintenance of Personal Information Files in Wholesaling and Retailing Medical Devices authorized under the PDPA, which requires the medical devices wholesalers and retailers to adopt necessary data security/protection measures, and establish prevention and reporting mechanisms in relation to any data breach. The bill also empowers the TFDA to conduct regular inspections and audits. If we fail to comply with the PDPA, we may be subject to punishment for civil claims, criminal offenses and administrative liabilities; the defendant may be subject to an imprisonment; and the penalty for administrative liabilities, and may be imposed consecutively if such violation continues.

Regulation of Veterinary Drugs in Taiwan

Our veterinary product candidates are subject laws and regulations in Taiwan including, but not limited to, the Veterinary Drugs Control Act, Enforcement Rules under the Veterinary Control Act, Guidelines of Good Manufacture Practice for Veterinary Drug Manufacturers, and Taiwan Regulations for Pet Foods and Supplements. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, quality testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, sales and distribution, promotion and advertising, import and export and post-marketing surveillance.

Under Taiwan law, a "veterinary drug" refers to one of the following substances in the form of bulk chemical compound, formulated preparation, or over the counter drug: Biologics specifically made for preventing and treating animal diseases based on microbiology, immunology or molecular biology; Antibiotics specifically made for preventing and treating animal diseases; Diagnostics announced and designated by the central competent authority for the diagnosis of animal diseases; and drugs that enhance or regulate animal physical functions specifically for preventing and treating animal diseases.

The competent authorities with licensing and enforcement authority under the Veterinary Drugs Control Act include the Council of Agriculture of the central government, the municipal government of a special municipality, or a local city or county.

As of December 31, 2024, our VELDONA FCGA candidate has not been approved to sell by TFDA.

Regulation of Medical Devices in the United States

Our product candidates and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938 and its implementing regulations, collectively referred to as the FDCA, as well as other federal and state regulatory bodies in the United States. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export and post-marketing surveillance.

The FDA regulates the development, design, pre-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution of medical devices in the United States to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as FDA refusal to approve pending premarket applications, issuance of warning letters, mandatory product recalls, import detentions, civil monetary penalties, and/or judicial sanctions, such as product seizures, injunctions, and criminal prosecution.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a premarket approval, or PMA, or grant of a de novo request for classification. During public emergencies, FDA also may grant emergency use authorizations to allow commercial distribution of devices intended to address the public health emergency. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to provide reasonable assurance of its safety and effectiveness.

Class I devices include those with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's "general controls" for medical devices. Some Class I or low risk devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below.

Class II devices are moderate risk devices that require premarket review and clearance by the FDA through the 510(k) premarket notification process, though certain Class II devices are exempt from this premarket review process. Unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. If the FDA determines that the device, or its intended use, is not substantially equivalent to a legally marketed device, the FDA will place the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous premarketing requirements.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices and devices deemed not substantially equivalent to a predicate device following a 510(k) submission. Submission and FDA approval of a PMA application is required before marketing of a Class III device. As with 510(k) submissions, unless an exemption applies, PMA submissions are subject to user fees.

We intend to position Ainos Flora, our lead POCT candidate, as Class II device. As of December 31, 2024, our Ainos Flora, has not been approved to sell by the FDA.

Emergency Use Authorization

In emergency situations, such as a pandemic, the FDA has the authority to allow unapproved medical products or unapproved uses of cleared or approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, or nuclear warfare threat agents when there are no adequate, approved, and available alternatives.

Under this authority, the FDA may issue an EUA for an unapproved device if the following four statutory criteria have been met: (1) a serious or life-threatening condition exists; (2) evidence of effectiveness of the device exists; (3) a risk-benefit analysis shows that the benefits of the product outweigh the risks; and (4) no other alternatives exist for diagnosing, preventing, or treating the disease or condition.

Once issued, an EUA will remain in effect and generally terminate on the earlier of (1) the determination by the Secretary of Health and Human Services that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed and one of the FDA's non-emergency premarket pathways would be necessary to resume or continue distribution of the subject product.

The FDA also may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.

510(k) Clearance Marketing Pathway

To obtain 510(k) clearance for a medical device, an applicant must submit to the FDA a 510(k) submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed device, known as a "predicate device." A showing of substantial equivalence sometimes, but not always, requires clinical data. Once the 510(k) submission is accepted for review, by regulation, the FDA has 90 calendar days to review and issue a determination. As a practical matter, clearance may take and often takes longer. Upon review, the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments.

Before the FDA will accept a 510(k) submission for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information within 180 days before the FDA will proceed with additional review of the submission.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, for example, due to a finding of a lack of a predicate device, that the device has a new intended use or different technological characteristics that raise different questions of safety or effectiveness when the device is compared to the cited predicate device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. If the FDA determines that the information provided in a 510(k) submission is insufficient to demonstrate substantial equivalence to the predicate device, the FDA generally identifies the specific information that needs to be provided so that the FDA may complete its evaluation of substantial equivalence, and such information may be provided within the time allotted by the FDA or in a new 510(k) submission should the original 510(k) submission have been withdrawn.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why a new 510(k) submission is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) marketing clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products.

As of December 31, 2024, we have not made any 510(k) submission for our POCT candidates.

De novo Classification

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. To market low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, a manufacturer may request a de novo down-classification on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. In the event the FDA determines the data and information submitted demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request for classification. When the FDA grants a de novo request for classification, the device is granted marketing authorization and further can serve as a predicate for future devices of that type, through a 510(k) premarket notification.

As of December 31, 2024, we were not seeking a de novo classification for any device in development.

Clinical Trials

Clinical trials are typically required to support a PMA, oftentimes for a de novo request for classification, and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. The clinical trials must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. If an IDE application is approved by the FDA and one or more IRBs, clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA.

If the device is considered a "non-significant risk," IDE submission to FDA is not required. Instead, only approval from the IRB overseeing the investigation at each clinical trial site is required. After a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- Establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers and contract manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design and manufacturing process;
- Labeling regulations and FDA prohibitions against the promotion of investigational products, or "off-label" uses of cleared or approved products;
- Clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- Medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- Post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications for repair, replacement, refunds;
- recall, withdrawal, administrative detention, or seizure of our test kits;
- operating restrictions or partial suspension or total shutdown of production;

- refusal of or delay in granting our requests for 510(k) clearance or PMA approval of new test kits or modified test kits;
- withdrawing 510(k) clearance or PMA approvals that are already granted;
- refusal to grant export approval for our test kits; or
- criminal prosecution.

U.S. drug and biological product development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations and biologics under the FDCA, the Public Health Service Act (PHSA), and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations. Failure to comply with applicable U.S. requirements at any time during the product development process, approval process or following approval may subject us to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, license revocation, a clinical hold, untitled or warning letters, product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

Our VELDONA product candidates for human use must be approved by the FDA through a BLA or new drug application (NDA), or supplemental BLA or supplemental NDA, process before they may be legally marketed in the United States. As of December 31, 2024, none of our VELDONA candidates have been approved by the FDA.

Preclinical studies

Before any of our development candidates may be tested in humans, the development candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as in vitro and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Unless the FDA raises concerns, an IND automatically becomes effective 30 days after receipt by the FDA. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials

The clinical stage of development involves the administration of the investigational medicine to healthy volunteers or patients under the supervision of qualified investigators and in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an Institutional Review Board (IRB) for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to clinical trial subjects and monitors the clinical trial until completed. Further, progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and more frequently in other situations, including the occurrence of serious adverse events. Information about certain clinical trials must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of a BLA if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data.

Clinical trials generally are conducted in three sequential phases, which may overlap:

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients to assess the metabolism, pharmacologic action, side effect tolerability, and safety of the investigational medicine.

- Phase 2 clinical trials generally involve disease-affected patients to evaluate proof of concept and/or determine the dosing regimen(s) for subsequent investigations. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of disease-affected patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the investigational medicine for its intended use, its safety in use and to establish the overall benefit/risk relationship of the investigational medicine, and provide an adequate basis for product labeling.

The FDA may also require post-approval Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of a drug.

The FDA or the clinical trial site may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a clinical trial may move forward at designated check points based on access to certain data from the clinical trial.

FDA review process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA or NDA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. A BLA is a request for approval to market a biologic for one or more specified indications and must contain proof of the biologic's safety, purity, and potency. An NDA for a new drug must contain proof of the drug's safety and efficacy. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA or NDA must be obtained before a biologic or drug may be marketed in the United States.

Before approving a BLA or NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee of expert advisors for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The committee makes a recommendation to the FDA that is not binding but is generally followed.

After the FDA evaluates a BLA or NDA, it will grant marketing approval, request additional information or issue a complete response letter (CRL) outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data, for the FDA to reconsider the BLA or NDA. Even if such additional information and data are submitted, the FDA may decide that the BLA or NDA still does not meet the standards for approval. If the FDA grants approval, it issues an approval letter that authorizes commercial marketing of the product with specific prescribing information for specific indications.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in very limited circumstances, such as if the latter product is shown to be clinically superior to the orphan product.

Health Insurance Portability and Accountability Act

We may be subject to compliance with the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Healthcare Information Technology for Economic and Clinical Health Act of 2009, or HIPAA, among other things, established federal protection for the privacy and security of protected health information, or PHI. The HIPAA privacy regulations protect PHI by limiting its use and disclosure, giving patients the right to access certain information about them, and limiting most disclosures of PHI to the minimum amount necessary to accomplish an intended purpose. The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures.

In addition, various states, such as California and Massachusetts, have implemented similar privacy and security laws and regulations. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely, and new privacy and security laws in this area are evolving. Requirements of these laws and penalties for violations vary widely.

Failure to comply with HIPAA, Healthcare Information Technology for Economic and Clinical Health Act of 2009 or their implementing regulations, and similar state laws, may result in significant penalties, including civil, criminal and administrative penalties, fines, imprisonment and exclusion from participation in federal or state healthcare programs, and the curtailment or restructuring of our operations.

U.S. Federal, State and Foreign Fraud and Abuse Laws

The U.S. federal and state governments have enacted, and actively enforce, a number of laws to address fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

Anti-Kickback Statutes

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order, arrangement for, or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid. Many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare products or services reimbursed by any source, not only government healthcare programs, and may apply to payments made directly by the patient.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal False Claims Laws

The FCA prohibits any person or entity, among other things, to knowingly present, or cause to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. The qui tam provisions of the FCA allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the FCA and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the FCA, and many of these state laws apply where a claim is submitted to any third-party payor and not only a federal healthcare program.

Violations of the FCA may result in treble damages and significant mandatory penalties, civil monetary penalties, and violators may be subject to exclusion from participation in federal healthcare programs such as Medicare and Medicaid. Many medical device manufacturers and healthcare companies have reached substantial financial settlements with the federal government for a variety of alleged improper activities and have entered into corporate integrity agreements with OIG, under which the companies undertake certain compliance, certification and reporting obligations, to avoid exclusion from federal health care program.

Our activities, including those relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our test kits (once approved) and the sale and marketing of our test kits (once approved), may be subject to scrutiny under the federal Anti-Kickback Statute and the FCA. We are also subject to other criminal federal laws that prohibit making false or fictitious claims and false statements to the federal government.

HIPAA Fraud Statute

HIPAA, among other things, imposes criminal liability for knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal healthcare Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

Open Payments

The federal Physician Payments Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to payments and other "transfers of value" to physicians, and teaching hospitals, and requires applicable manufacturers to report annually ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information and transfers of value provided (beginning in 2021) to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. Failure to submit timely, accurate and complete reports may result in substantial monetary penalties. We are subject to the Open Payments Program and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act of 1977, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring them to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

U.S. Health Reform

Changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products once approved. The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our test kits profitably once approved. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our test kits once approved. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our test kits once approved.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs and potentially affect individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors.

ITEM 1A. RISK FACTORS.

Investors should 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 $20,321 and $256 in revenues from pet supplements sales and $408 and $102,256 in revenues from COVID 19 antigen rapid test kits in 2024 and 2023, 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 $13,841,204 and $13,206,396 in the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, we had cumulative losses of $52,749,316 and $37,886,155, 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 sales 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.

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.

Even 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.

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 be 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 approximately $3.9 million as of December 31, 2024, and we will need to continue to seek capital from time to time 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 disease 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 sales, which is difficult to predict
- 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;
- 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 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;
- 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.

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. 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 COVID-19 pandemic.

We 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.

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, 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 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 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 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.

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 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 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 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.

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 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.

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 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.

Risks related to reliance on third parties

We rely 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 TCNT, our affiliate and product 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.

If the third parties that we engage to supply any materials or manufacture product for our preclinical tests and clinical trials should cease to continue to 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 terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

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 distributors. 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 (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.

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 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 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.

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 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.

Although 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 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.

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 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.

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 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.

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 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.

The 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.

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 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 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. 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.

Our 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, 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.

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 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 2024, 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.

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 issuance of additional capital stock in connection with financings, acquisitions, investments, our 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 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 July 15, 2024, 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 Nasdaq deficiency letter has no immediate effect on the listing of the Company's common stock, and its common stock will continue to trade on The Nasdaq Capital Market under the symbol "AIMD" at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been given 180 calendar days, or until January 13, 2025, to regain compliance with the Minimum Bid Price Requirement. If at any time before January 13, 2025, the bid price of the Company's common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, the Staff will provide written confirmation that the Company has achieved compliance. If the Company does not regain compliance with the Minimum Bid Price Requirement by January 13, 2025, the Company may be afforded a 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. The Company intends to monitor the closing bid price of its common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement. However, there can be no assurance that the Company will be able to regain compliance with the Minimum Bid Price Requirement or will otherwise be in compliance with other Nasdaq Listing Rules. On July 19,2024 the Company filed a Form 8-K with the SEC disclosing the herein matters.

On January 14, 2025, the Company received written notification from Nasdaq notifying the Company that it had received another 180-day extension, until July 14, 2025, to regain compliance with the Minimum Bid Price Requirement.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY

Risk management and strategy

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats. We assess risks from cybersecurity threats against our information systems that may result in adverse effects on our information systems or any information residing therein. We conduct periodic and ad-hoc assessments to identify cybersecurity threats.

Following these risk assessments, we evaluate whether and how to re-design, implement, and maintain reasonable safeguards to mitigate identified risks and reasonably address any identified gaps in existing safeguards. IT leadership reports to our Chief Executive Officer (CEO) to manage the risk assessment and mitigation process. We monitor and test our safeguards and train our employees on these safeguards, in collaboration with human resources, IT, and management. We promote a company-wide culture of cybersecurity risk management.

Risks from Cybersecurity Threats

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing during the fiscal year ended December 31, 2024.

Governance

Our board of directors is responsible for monitoring and assessing strategic risk exposure. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through the Audit Committee. Our executive management team inform the Audit Committee on cybersecurity risks on a regular basis, with a minimum frequency of once per year.

Our internal cybersecurity coordinator is responsible for assessing and managing our material risks from cybersecurity threats, in close collaboration with our IT team and report to our CEO. This ensures that the senior management are kept abreast of the cybersecurity posture and potential risks faced by the Company.

ITEM 2. DESCRIPTION OF PROPERTY.

Our administrative offices are located at San Diego, California and in Taiwan. Our product development facility is in Taiwan.

ITEM 3. LEGAL PROCEEDINGS.

There are currently no legal proceedings involving the Company.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Effective August 9, 2022, our common stock and public warrants began trading on the Nasdaq Capital Market under the symbols "AIMD" and "AIMDW", respectively. Prior to August 9, 2022, the Company's common stock traded on the OTCPK.

In connection with the above uplisting to Nasdaq Capital Market, we effectuated a 1-for-15 reverse stock split of our common stock on August 8, 2022. Further, to comply with Nasdaq's minimum $1.00 per share continued listing rules, we filed a Certificate of Amendment to its Restated Certificate of Formation on November 27, 2023, to apply for another reverse stock split of our common stock at a ratio of 1-for-5 which was effectuated on December 14, 2023 after receiving required approvals.

The par value of $0.01 and authorized shares of the Company's common stock were not adjusted as a result of the reverse stock splits. All issued and outstanding common stock, restricted stock units, outstanding convertible notes, warrants and options to purchase common stock and per share amounts contained in this report have been retroactively adjusted to give effect to the reverse stock splits for all periods presented.

Holders of Common Stock

As of March 7, 2025, there were approximate 241 shareholders of record of the Company's common stock based upon the records of the shareholders provided by the Company's transfer agent. Since many of the shares of our common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial stockholders represented by these record holders.

Stock Performance Graph

Not applicable.

Recent Sales of Unregistered Securities

Not applicable.

Use of Proceeds from Registered Securities

Not applicable.

Issuer Purchases of Equity Securities

None.

Dividends

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We do not anticipate paying any dividends in the foreseeable future, and we currently intend to retain all available funds and any future earnings for use in the operation of our business, to finance the growth and development of our business and for future repayment of debt. Future determinations as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Part III, Item 12 of this Annual Report.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, as well as the Risk Factors contained in Part I, Item 1A of this Annual Report on Form 10-K, and other information provided from time to time in our other filings with the SEC.

Overview

Ainos, Inc. (the "Company"), incorporated in the State of Texas in 1984, is a diversified healthcare company focused on the development of novel point-of-care testing (the "POCT"), therapeutics based on very low-dose interferon alpha (the "VELDONA"), and synthetic RNA-driven preventative medicine. Our products pipeline include commercial-stage VELDONA Pet supplements, clinical-stage VELDONA human therapeutics and telehealth-friendly POCTs powered by the AI Nose technology platform. Please refer to "Business" in Part I, Item 1 for description of our business.

Key Developments in 2024

The following highlights major corporate milestones in 2024 that we believe will serve as catalysts for us to develop and commercialize our product pipeline over the next several years:

In December 2024, we announced the signing of a Memorandum of Understanding (MOU) with Taiwan Tanabe Seiyaku Co., Ltd. ("Taiwan Tanabe"), a subsidiary of Mitsubishi Tanabe Pharma Corporation in Japan. The parties may work under the terms of the MOU to further define the partnership for manufacturing and Taiwan market promotion of our Sjögren's syndrome drug based on VELDONA.

In September 2024, we announced a plan to conduct a Taiwan clinical study for VELDONA in 2025 on treating human immunodeficiency virus (HIV)-related oral warts. We also announced a plan to conduct a Taiwan clinical study in 2025 for VELDONA on treating Sjögren's syndrome. We were also granted an invention patent in Taiwan and has filed for global patent protection under the Patent Cooperation Treaty (PCT) for treatment and prevention of coronavirus infection based on VELDONA.

In August 2024, we announced that our VOC co-development program, initiated in 2023, with Nisshinbo Micro Devices Inc. ("NISD") and Taiwan Inabata Sangyo Co. ("Taiwan Inabata") achieved several key milestones. First, we have developed a solution targeting the elderly care market. Second, we marked a key milestone in expanding AI Nose application in industrial use-case, with our solution delivering 79% accuracy in 22 different volatile organic compounds (VOCs) in semiconductor factories. We secured an exclusive, perpetual license of 10 invention patents and patent applications related to gas sensors and medical devices, covering the U.S., Germany, China, Japan and Taiwan.

In June 2024, we announced that our Taiwan clinical studies for Ainos Flora have tested 75 cases with meaningful insights, laying ground for development of second-generation Ainos Flora intended to be optimized for at-home testing. We have implemented CUDA to accelerate development.

In May 2024, we initiated a Taiwan clinical study to evaluate VELDONA's clinical efficacy in treating feline chronic gingivostomatitis ("FCGS"), a chronic painful oral disease characterized by inflammation or abnormal proliferation in the oral cavity.

Factors Affecting Our Business

We have pivoted away from sale of COVID-19 antigen rapid test kits, which were the main source of our revenues in 2023. In 2024 our business activities focused on sales and marketing of VELDONA Pet, advancing our lead VOC POCT candidate, Ainos Flora, co-developing VOC sensing platform with our Japan partners, as well as advancing clinical studies and pursuing out-licensing of VELDONA human drug candidates.

Through our marketing of VELDONA Pet, we gathered insights into the behavior of pet owners. These insights have influenced our choice to allocate resources toward developing animal drugs. We identified a market opportunity in FCGS, a cat oral disease currently facing limited treatment options. In 2024, we started a clinical study in Taiwan for our FCGS program. Its success could impact our business plan.

For our VELDONA human drug development, we prioritize HIV oral warts and Sjogren's syndrome due to limited treatment options for these conditions. In 2024, we prepared for clinical studies in Taiwan expected to commence in 2025. We have also progressed in out-licensing our drug candidates through a MOU with Taiwan Tanabe. These developments may affect our business.

We believe that consumers have become increasingly familiar with at-home tests, and people may seek additional at-home tests to manage other infections. Home self-testing have become increasingly available for other infections such as vaginal infections or sexually transmitted infections (STIs). We believe this new user behavior, supported by a variety of telehealth platforms, will facilitate consumer adoption of our other POCT product candidates. Our lead candidate Ainos Flora is under clinical studies and we plan to explore strategic relationships to commercialize the product. The result of clinical studies and our success in exploring strategic relationships, and the likelihood of regulatory approvals, may affect our business, at least in the near-term.

We are co-developing a VOC sensing platform, powered by AI Nose technology, with our Japanese partners. This project underscores our commitment to digitizing smell by pioneering VOC sensing's potential across diverse industries, thereby broadening our addressable market. Under this program, we are developing solutions for the elderly care market and for industrial use-case. The progress may affect our business, at least in the near-term.

As of December 31, 2024, we had available cash and cash equivalents of $3,892,919. We anticipate business revenues and further potential financial support from external sources to fund our operations over the next twelve months. We have based this estimate on assumptions that may prove to be incorrect, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources" for additional information. To finance our continuing operations, we will need to raise additional capital, which cannot be assured.

Recent Financing

On May 03, 2024, The Company entered into Convertible Note and Warrant Purchase Agreement with the ASE Test, Inc. ("ASE"), a shareholder of Ainos KY, for the issuance of convertible promissory notes with 6% compound interest in the aggregate principal amount of $9,000,000 (collectively the "Notes") convertible into shares of common stock, par value $0.01 per share, of the Company, payable three (3) years from May 03, 2024 as well as the issuance of warrants for the purchase of up to 500,000 shares of Common Stock at a price per share of $4.50, exercisable until May 03, 2029. As of December 31, 2024, the Company received the full amount of the payment.

On August 2, 2024, the Company retired its remaining senior secured convertible debt (the "Note") with Lind Global Fund II LP, an institutional investment fund managed by The Lind Partners (together the "Investor"), as a result of conversions by the Investor and payments by the Company, which aggregates at a total of approximately US$1.67 million. The repayment was made with $1,439,754 in cash and $224,842 through the issuance of 382,384 shares of Common Stock, valued at $0.588 per share.

On August 16, 2024, the Company repaid the remaining note payable principal amount of $42,000 with accrued interest to i2China Management Group, LLC ("i2China").

On October 7, 2024, the Company repaid the remaining note payable principal amount of $270,000 with accrued interest to Ainos KY, the controlling shareholder of the Company.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Years ended December 31,		Change	
	2024	2023	Amount	%
Revenues	$ 20,729	$ 122,112	$ (101,383)	(83)%
Cost of revenues	(52,595)	(375,845)	323,250	(86)%
Gross loss	(31,866)	(253,733)	221,867	(87)%
Operating expenses:				
Research and development expenses	8,413,923	7,317,388	1,096,535	15%
Selling, general and administrative expenses	5,395,415	5,635,275	(239,860)	(4)%
Total operating expenses	13,809,338	12,952,663	856,675	7%
Loss from operating	(13,841,204)	(13,206,396)	(634,808)	5%
Non-operating (expenses) income				
Interest expense	(616,467)	(144,193)	(472,274)	328%
Issuance cost of senior secured convertible note measured at fair value	(308,336)	(525,643)	217,307	(41)%
Fair value change for senior secured convertible note	(275,624)	94,207	(369,831)	(393)%
Other income, net	179,270	12,276	166,994	1,360%
Total non-operating expenses, net	(1,021,157)	(563,353)	(457,804)	81%
Net loss before income taxes	(14,862,361)	(13,769,749)	(1,092,612)	8%
Provision for income taxes	800	800	-	-
Net loss	$ (14,863,161)	$ (13,770,549)	$ (1,092,612)	8%

Revenues, Cost and Gross Loss

The Company reported $20,729 of revenues for the year ended December 31, 2024, as compared to $122,112 for the year ended December 31, 2023 from the sales of in Taiwan. The decrease of revenue in 2024 was primarily caused by COVID-19 Antigen Rapid Test Kits in lower sales volume and was offset by the exchange rate fluctuations. We generated $20,321 and $256 in revenues from pet supplements and $408 and $102,256 in revenues from COVID-19 Antigen Rapid Test Kits in 2024 and 2023, respectively.

The cost of revenues relating to product sales for the year ended December 31, 2024 was $52,595 compared to $375,845 for the year ended December 31, 2023. The decrease of cost of revenues primarily caused by the decline in sales volume of COVID-19 Antigen Rapid Test Kits.

The share-based compensation expense and the depreciation expense for manufacturing in the year ended December 31, 2024 and 2023 were $9,032 and $80,655, respectively. When excluding these non-cash cost, cost of revenue decreased to $43,563 during the year ended December 31, 2024 compared to $295,190 for the same period in 2023.

Gross loss from product sales for the year ended December 31, 2024 was $31,866 as compared to $253,733 for the year ended December 31, 2023. The gross loss was due to a low sales volume for newly launched products, and a lower cost of revenue.

When excluding these non-cash costs, gross loss decreased to $(22,834) during the year ended December 31, 2024 compared to $(173,078) for the same period in 2023.

Research and Development (R&D) Expenses

R&D expenses for the years ended December 31, 2024 and 2023 were $8,413,923 and $7,317,388, respectively. The increase $1,096,535 (15%) was due to increased staffing expenditures (including share-based compensation) and co-research expenses, but offset by a decrease in impairment loss and material expenses. We expect that our R&D expenses related to clinical trials will continue to grow as we further develop VOC POCT and VELDONA drug candidates and increase the pace of clinical trials previously delayed during the COVID-19 pandemic.

The share-based compensation expense and the depreciation and amortization expense in 2024 and 2023 were $5,600,037 and $5,252,730, respectively. When excluding these non-cash expenses, R&D expenses increased to $2,813,886 in 2024 from that of $2,064,658 in 2023 primarily caused by increasing in non-exclusive use of certain patents related to VOC and POCT technologies.

Selling, General and Administrative (SG&A) Expenses

SG&A expenses were $5,395,415 and $5,635,275 for the years ended December 31, 2024 and 2023, respectively. The $239,860 (4%) slight decrease was due to decreased professional expenses, public relations and investor relations fees, and D&O insurance expenses, but offset by staffing expenditures (including share-based compensation).

The share-based compensation expense and the depreciation and amortization expense in 2024 and 2023 were $2,824,743 and $2,886,216, respectively. When excluding these non-cash expenses, SG&A expenses slight decreased to $2,570,672 in 2024 compared to $2,749,059 in 2023 mainly due to decreased professional expenses, expenditures to public relations and investor relations fees, and D&O insurance expenses.

Operating Loss

The Company's operating loss was $13,841,204 and $13,206,396 during the years ended December 31, 2024 and 2023, respectively, reflecting a $634,808 increase in operating losses between the years. We incurred a gross loss in product sales but reduced the professional expense and material expenses in 2024. We continued to invest resources to execute our growth strategy and product roadmap to improve our profitability.

Non-operating expenses

The interest expense was $616,467 and $144,193 during the years ended December 31, 2024 and 2023, respectively. The increase in interest expense was due to accrued interest for convertible notes issued in May 2024 bearing a higher interest rate as compared with those interest bearing debts in 2023.

Net Loss

Net loss was $14,863,161 in 2024 compared to $13,770,549 in 2023, resulting in a $1,092,612 (8%) increase in net loss attributable to common stockholders due to the increase in non-exclusive use of certain patents related to VOC and POCT technologies despite offset by the decrease in professional expenses.

Liquidity and Capital Resources

As of December 31, 2024 and 2023, the Company had available cash and cash equivalents of $3,892,919 and $1,885,628, respectively.

The following table summarizes our cash flow during the years ended December 31, 2024 and 2023:

	Years ended December 31,		Change	
	2024	2023	Amount	%
Net cash used in operating activities	$ (5,808,267)	$ (4,694,668)	$ (1,113,599)	24%
Net cash used in investing activities	$ (125,292)	$ (101,525)	$ (23,767)	23%
Net cash provided by financing activities	$ 8,025,746	$ 4,923,673	$ 3,102,073	63%

Operating activities

Net cash used in operating activities increased by $1,113,599 during the year of 2024 compared to the year of 2023. The increase in cash used in operations primarily resulted from our net loss for the year of 2024 due to swift product but offset by cash inflow contributed by the operating assets and liabilities.

Investing activities

Net cash used in investing activities during the year of 2024 was $125,292 compared to $101,525 during the year of 2023. The increase was due to increase in refundable deposits and other noncurrent assets offset by decrease in purchase of property and equipment.

Financing activities

Cash received from financing activities were $8,025,746 and $4,923,673 during the years of 2024 and 2023, respectively. The $3,102,073 increase was primarily reflected by the following:

- Repayment of convertible notes and other notes payable increased by $1,065,728;
- Proceeds from convertible notes and other notes payable financing increased by $3,875,000; and
- Payments of issuance cost of senior secured convertible note measured at fair value decreased by $292,801.

As disclosed in Note 6 (Debt) to our accompanying financial statements, we received $875,000 in proceeds from the Lind Note transaction in January 2024.

As disclosed in Note 6 (Debt) to our accompanying financial statements, we received $9,000,000 in proceeds from the ASE Note transaction in May 2024.

As disclosed in Note 6 (Debt) to our accompanying financial statements, we repaid $1,439,754 in cash to retired senior secured convertible notes from the Lind Note transaction in August 2024.

As disclosed in Note 6 (Debt) to our accompanying financial statements, we repaid $42,000 to retire the i2China Note transaction in August 2024.

As disclosed in Note 6 (Debt) to our accompanying financial statements, we repaid $270,000 to retire the KY Note transaction in October 2024.

The Company anticipates that cash reserves, business revenues, and potential debt financing through convertible and non-convertible notes will fund the Company's operations over the next twelve months. There can be no assurance that we will be successful in our efforts to make the Company profitable. If those efforts are not successful, the Company may raise additional capital through the issuance of equity securities, debt financings or other sources to further implement its business plan. However, if such financing is not available when needed and at adequate levels, the Company will need to reevaluate its operating plan.

At The Market Offering Agreement

On May 31, 2024, the Company entered into an At The Market Offering Agreement (the "ATM Agreement"), with H.C. Wainwright & Co., LLC or the Agent, pursuant to which the Company may issue and sell, from time to time, shares of its Common Stock, depending on market demand, with the Agent acting as the sales agent or principal (the "ATM Offering"). Sales of the Common Stock may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made directly on or through the Nasdaq Capital Market. The Agent will use its commercially reasonable efforts to sell the Shares requested by the Company to be sold on its behalf, consistent with the Agent's normal trading and sales practices, under the terms and subject to the conditions set forth in the ATM Agreement. The Company has no obligation to sell any of the Shares. The Company may instruct the Agent not to sell the Shares if the sales cannot be effected at or above the price designated by the Company from time to time and the Company may at any time suspend sales pursuant to the ATM Agreement.

The Company will pay the Agent placement fee of 3.0% of the gross sales price of the Shares sold by the Agent under the ATM Agreement. The Company has also agreed to reimburse the Agent for the fees and disbursements of its counsel, payable upon execution of the Sales Agreement, in an amount not to exceed $35,000 in addition to certain ongoing disbursements of its legal counsel up to $2,500 per calendar quarter. In addition, the Company has agreed to provide customary indemnification rights to the Agent.

The aggregate market value of Shares eligible for sale in the ATM Offering and under the ATM Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3, to the extent required under such instruction. The prospectus supplement filed with the SEC on July 11, 2024, is offering Shares having an aggregate offering price of $1,840,350.

The Company intends to use the net proceeds from the offering to fund the continued development of its product candidate and for general corporate purposes and working capital. The precise amount and timing of the application of these proceeds will depend upon a number of factors, such as the timing and progress of our research and development efforts, our funding requirements and the availability and costs of other funds.

As of December 31, 2024, there have been no shares sold under the ATM Agreement.

Sources of Liquidity

Since our uplisting and public offering in August 2022, our operations have been financed primarily by proceeds from private placements of convertible notes issued to third party or related party. As disclosed in Note 6 Debts to our accompanying financial statements, we received $3,000,000 in proceeds from the March 2025 convertible note financing, $3,875,000 in proceeds from the Lind Note financing in September and December of 2023 and January 2024 out of total of $10 million financing agreement and $9,000,000 in proceeds from the May 2027 convertible note financing. We anticipate that cash reserves, business revenues, and potential debt financing through convertible and non-convertible notes will fund our operations over the next twelve months. There can be no assurance that we will be successful in our efforts to make the Company profitable. If those efforts are not successful, we may raise additional capital through the issuance of equity securities, debt financings or other sources to further implement its business plan. However, if such financing is not available when needed and at adequate levels, we will need to reevaluate our operating plan.

Uses of Liquidity

In the near-term, we expect an increase in the pace of clinical trial spending to advance our VOC POCT and VELDONA drug candidates and expect to invest more in R&D activities. We also plan to allocate sales and marketing efforts for VELDONA Pet.

For future liquidity consideration, we expect primary uses of cash are to fund our operations as we continue to grow our business. We may require a significant amount of cash to fund working capital and capital expenditures as we grow our commercial infrastructure. We may continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our selling, general and administrative expenses, and research and development expenses will continue to increase our internal sales force to move forward our product development and commercialization roadmaps. We may also have cash requirements related to capital expenditures to support the planned growth of our business, including investments in corporate facilities and equipment.

Contractual Obligations and Commitments

For a discussion of our contractual obligations and commitments, refer to Part II, Item 8, Note 13, “Commitments and Contingencies” to the financial statements in this Annual Report on Form 10-K.

Critical Accounting Policies and Estimate

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Impairment Testing of Intangible Assets

Our intangible assets mainly consist of acquired patents which are initially recorded at fair value and stated net of accumulated amortization and, if applicable, impairments. We amortize our intangible assets that have finite lives using the straight-line method. Amortization is recorded over the estimated useful lives ranging from 5 to 19 years. We evaluate the recoverability of the definite lived intangible assets whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group in accordance with ASC 360-10, *Property, Plant and Equipment—Impairment or Disposal of Long-Lived Assets* (ASC 360-10). If the carrying value of an asset or asset group exceeds its undiscounted cash flows, we estimate the fair value of the assets using market participant assumptions pursuant to ASC 820, *Fair Value Measurements*.

During the fourth quarter of 2024, we reassessed our short-term and long-term commercial plans for the VOC POCT related products which is identified as an asset group being assigned the major intangible assets and identified that an impairment testing is warranted for the intangible assets. As a result, we performed an undiscounted cash flow analysis pursuant to ASC 360-10 to determine if the cash flows expected to be generated by the VOC POCT products over the estimated remaining useful life of its primary assets were sufficient to recover the carrying value of the asset group. Based on this analysis, the undiscounted cash flows were sufficient to recover the carrying value of the intangible assets. Thus, no impairment loss was recorded.

To estimate the undiscounted cash flow of the asset group, we used assumptions require significant judgment, including judgment about when the in-development product can be commercialized, estimated selling price and sales volume of the in-development product and the amount and timing of other cash outflows required to complete the development, commercialization and sales of the product. The forecasted cash flows were based on the Company's most recent strategic plan and for periods beyond the strategic plan, our estimates were based on assumed growth rates expected as of the measurement date. We believe our assumptions were consistent with the strategic plans and business goals.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2024.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable to a "smaller reporting company" as defined in Item 10(f)(1) of SEC Regulation S-K.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The financial statements and notes of the Company are set forth beginning on page F-1 immediately following the signature page of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our chief executive officer and chief financial officer, to allow timely decisions regarding required disclosure. We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13(a)-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2024, our disclosure controls and procedures were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework in "*Internal Control - Integrated Framework (2013)"* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "2013 COSO Framework"). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2024.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during the period covered by this Yearly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.

As of March 7, 2025, the directors and executive officers of the Company were as follows:

Name	Age	Position
Chun-Hsien Tsai	55	Chairman, President & Chief Executive Officer
Wen-Han Chang	62	Director
Yao-Chung Chiang	73	Director
Pao-Sheng Wei	67	Director
Ting-Chuan Lee	42	Director
Chun-Jung Tsai	53	Director
Chung-Yi Tsai	49	Director
Hsin-Liang Lee	54	Chief Financial Officer

Chun-Hsien Tsai. Mr. Tsai has served as our Chairman, President, and Chief Executive Officer since April 2021. From April 2021 to August 2021, he also served as Chief Financial Officer. He has served as the chairman and CEO of Taiwan Carbon Nano Technology Corporation (TCNT) since July 2018, as a director of Ainos Inc. (Cayman Islands) since October 2017, as director and CEO of AI Nose Corporation since 2016, and as a director of TCNT since 2012. Mr. Tsai holds an EMBA degree from National Yang Ming Chiao Tung University.

Wen-Han Chang. Mr. Chang has served as a Director of the Company since April 2021 and has served as the Chairperson of our Compensation Committee and a member of our Audit Committee since August 2021. He is the superintendent at Mackay Memorial Hospital since May 2023, and was deputy superintendent between August 2015 and May 2019. He has devoted his expertise at the department of emergency medicine for approximately 30 years. Mr. Chang advocates better public health and AI's development in the healthcare sector through his leadership roles in industry groups in Taiwan. Mr. Chang is the current chairman of Health Intelligent Medical Development Society. From 2019 to 2021, he was the president of the Childhood Burn Foundation of R.O.C. Mr. Chang holds a Ph.D in public health from Saint Louis University.

Yao-Chung Chiang. Mr. Chiang has served as a Director of the Company since April 2021 and has served as a member of our Audit Committee since August 2021. Mr. Chiang has served as the chairman of Taiwan High Speed Rail Corporation October 2016 to January 2025, and as an independent director for Radiant Opto-Electronics Corporation since June 2012. From June 2015 to July 2021, Mr. Chang was an independent director for Tyntek Corp. Mr. Chiang served as the chairman for other Taiwan-incorporated companies including China Steel Chemical Corporation, Kaohsiung Rapid Transit Corporation, China Steel Corporation and China Airlines. Mr. Chiang holds a Ph.D. in Mechanical Engineering from University of Wisconsin-Madison.

Pao-Sheng Wei. Mr. Wei has served as a Director of the Company, Chairperson of the Audit Committee and as a member of the Compensation Committee since June 2022. He has served as the chairman of Shin Kong Financial Holding Co., Ltd since June 2024, the chairman of Shin Kong Life Insurance Co., Ltd since June 2023 and as an independent director of Nuvoton Technology Corporation since June 2022. From September 2014 to June 2022, Mr. Wei served as the chairman of KGI Bank Co., Ltd. Mr. Wei held leadership roles in the banking, securities and insurance sectors in Taiwan. He was a securities regulator as the Division Director of Corporate Finance of the Securities and Futures Bureau of the Financial Supervisory Commission, R.O.C. (Taiwan). Mr. Wei holds an MBA degree from George Washington University.

Ting-Chuan Lee. Ms. Lee has served as a Director of the Company since April 2021. She is also a manager at the CEO office. She has served as the chairperson of AI Nose Corporation since March 2016, and as a member of the board of director of Taiwan Carbon Nano Technology Corporation (TCNT) since July 2012. Ms. Lee holds a master's degree of science from National Taiwan University.

Chun-Jung Tsai. Mr. Tsai has served as a Director of the Company since April 2021. He is also a manager of the Company's sales team. He has served as a director of Ainos Inc. (Cayman Islands) since 2019, a director of AI Nose Corporation since March 2016, and a director of Taiwan Carbon Nano Technology Corporation (TCNT) since July 2012.

Chung-Yi Tsai. Mr. Tsai has served as a member of our Board of Directors since April 2021 and as a director of TCNT since July 2012. Mr. Tsai is a seasoned executive in product and business development in the technology hardware sector. From May 2023 to present, he has served as a senior product marketing director at Alpha & Omega Semiconductor. Prior to that, he has

served as a senior product marketing manager in Renesas Electronics from June 2020 to May 2023, executive business manager at Maxim Integrated from November 2019 to June 2022, and as a senior product marketing manager at Intersil Corporation from October 2013 to November 2019. Mr. Tsai has a master's degree in business administration from Golden Gate University.

Hsin-Liang Lee. Mr. Lee has served as our Chief Financial Officer since March 2024. Mr. Lee brings over 25 years of experience in accounting and finance, encompassing US GAAP, PCAOB standards, and SEC rules and regulations. Before joining the Company, Mr. Lee served as CFO of a Nasdaq-listed company for 10 years, was a partner at KEDP CPA Group from August 2009 to June 2011, and operated as a self-employed accountant from July 2011 to August 2014. He has served on the Board of Directors of Aixin Life International Inc. since February 2021. Mr. Lee holds a BS degree in accounting from Ohio State University and an MS degree in business taxation from Golden Gate University. He is licensed as a Certified Public Accountant (CPA) in the United States.

Family relationships.

Mr. *Chun-Hsien Tsai* and Ms. Ting-Chuan Lee are husband and wife. Mr. *Chun-Hsien Tsai*, Mr. Chun-Jung Tsai, and Mr. Chung-Yi Tsai are brothers. Ms. Ting-Chuan Lee is the sister-in-law of Mr. Chun-Jung Tsai and Mr. Chung-Yi Tsai.

Term of Office

Our directors shall hold office for the term for which he is elected and until his successor shall have been elected and qualified in accordance with our bylaws. Our officers shall hold office until his successor shall have been duly elected and qualified or until his death or until he shall resign or shall have been removed by the board in accordance with our bylaws.

Audit Committee

Our Audit Committee consists of Mr. Wen-Han Chang, Mr. Yao-Chung Chiang and Mr. Pao-Sheng Wei, each of whom has been determined to be "independent" under applicable rules and regulations of the SEC and the listing standards of Nasdaq, and also meets the financial literacy requirements of the listing standards of Nasdaq. Mr. Wei currently serves as Chairperson of our Audit Committee.

Our Board has determined that the three audit committee members qualify as "audit committee financial experts" as defined in Item 407(d) of Regulation S-K by considering their formal education and experience in financial management.

The duties and responsibilities of the Audit Committee are set forth in its charter include the following:

- selecting our independent registered public accounting firm and reviewing its qualifications, independence and performance;
- reviewing the audit plans of our internal auditors and any significant reports prepared by our internal auditors as well as management's responses;
- in consultation with management and the Company's internal and external auditors, reviewing the Company's guidelines and policies with respect to risk assessment, risk management and internal financial and disclosure controls; and
- reviewing any material written communications between the independent registered public accounting firm and management, including any management or internal control letter issued or proposed to be issued by the independent registered public accounting firm and management's response, if any.

Compensation Committee

Our Compensation Committee currently consists of Mr. Wen-Han Chang and Mr. Pao-Sheng Wei. Mr. Chang currently serves as the Chairperson of our Compensation Committee. Our Board has determined that each member of our compensation committee meets the requirements for independence for compensation committee members under the rules and regulations of the SEC and the listing standards of Nasdaq. Each member of the compensation committee is also a non-employee director, as defined pursuance to Rule 16b-3 promulgated under the Exchange Act.

The duties and responsibilities of the Compensation Committee are set forth in its charter include the following:

- reviewing, modifying (as needed) and approving the salary, variable compensation, equity compensation and any other compensation and terms of employment of the Company's Chief Executive Officer;
- reviewing and approving corporate performance goals, the structure and method for determining the terms of overall executive variable compensation or other compensatory plans, method of determination of individual goals for executives and other senior management, and payment of individual executive variable compensation to the extent such variable compensation contains a discretionary component; and
- reviewing, modifying (as needed) and approving the Company's overall compensation plans and structure, including the Company's overall compensation philosophy.

Code of Business Conduct and Ethics

We adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer or persons performing similar functions. A copy of the code is posted on our corporate website at www.ainos.com and is filed hereto as Exhibit 14.1 and is incorporated herein by this reference. In addition, we intend to post on our website all disclosures that are required by law or listing standards concerning any amendments to, or waivers from, any provision of the code. The information contained in, or accessible through, our website does not constitute a part of this report. We have included our website address in this report solely as an inactive textual reference.

Insider Trading Policy

We have adopted an insider trading policy filed hereto as Exhibit 19.1 and is incorporated herein by this reference.

Compliance with Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") requires directors and officers of the Company and persons who own more than 10% of the Company's common stock to file with the Securities and Exchange Commission (the "Commission") initial reports of ownership and reports of changes in ownership of the common stock. Directors, officers and more than 10% shareholders are required by the Exchange Act to furnish the Company with copies of all Section 16(a) forms they file.

To the Company's knowledge based solely on a review of the copies of such reports furnished to the Company, all reports required to be filed under Section 16(a) during were filed on a timely basis during the most recent fiscal year.

The dates reported in "Item 3. Date of Earliest Transaction," "Table I — Item 2, Transaction Date," and "Table II — Item 3, Transaction Date" for the transaction regarding the grant of special stock awards on the Form 4s filed on November 27, 2024, by Chun-Hsien Tsai, Ting-Chuan Lee, Chun-Jung Tsai, and Hsin-Liang Lee should have listed November 26, 2024 instead of November 22, 2024.

ITEM 11. EXECUTIVE COMPENSATION.

As a "smaller reporting company" under SEC rules, our named executive officers during the fiscal year January 1, 2024 through December 31, 2024 (collectively, the "Named Executive Officers") were as follows:

- Mr. Chun-Hsien Tsai, Chairman, President & Chief Executive Officer;
- Mr. Hsin-Liang Lee, Chief Financial Officer;
- Ms. Meng-Lin Sung, Former Chief Financial Officer; and
- Mr. Lawrence K. Lin, Former Executive Vice President of Operations.

Summary Compensation Table

The following table provides information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us for the years set forth below. The amounts below for Stock Awards and Option Awards and reflect the grant date fair value of these awards during the years:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Options Awards ($)	All other compensation	Total ($)
Chun-Hsien Tsai [1]	2024	122,517	115,313	63,692	-	-	301,522
Chairman of the Board & Chief Executive Officer	2023	95,912	16,212	1,172,899	-	-	1,285,023
Hsin-Liang Lee[2]	2024	79,927	-	13,696	-	-	93,623
Chief Financial Officer	2023	-	-	-	-	-	-
Meng-Lin Sung [3]	2024	21,553	9,369	-	-	-	30,922
Former Chief Financial Officer	2023	57,363	9,728	218,910	-	-	286,001
Lawrence K. Lin[4]	2024	84,000	-	-	-	-	84,000
EVP Operations	2023	144,000	-	-	14,790	-	158,790

(1) Includes 4,000 shares of special stock awards as President and CEO.

(2) Mr. Lee appointed Chief Financial Officer effective as of March 18, 2024.

(3) Ms. Sung was appointed Chief Financial Officer, effective as of May 17, 2023, and resign on March 13, 2024.

(4) Mr. Lin was appointed Executive Vice President of Operations effective as of August 1, 2021, and transitioned the position on August 9, 2024.

(5) All other compensation includes commuting expense.

Narrative Disclosure to Summary Compensation Table

Chun-Hsien Tsai

Effective April 15, 2021, our Board appointed Mr. Chun-Hsien Tsai to serve as Chief Executive Officer. Mr. Tsai receives a monthly salary of NT$250,000 (equivalent to approximately $7,800), subsequently on September 1, 2024, monthly salary was increased to NT479,810 (equivalent to approximately $15,000), a year-end bonus of two months' salary, and a variable compensation based on Company profit targets decided by the Company's Compensation Committee, and payable as 10% to 100% of total annual compensation in the form of cash, securities and/or other discretionary remuneration. Mr. Tsai was granted RSUs pursuant to 2021 Stock Incentive Plan. Other benefits, including labor insurance, health insurance and other benefits, will be based on local regulations and the Company's policies. In 2024, Mr. Tsai was granted RSUs pursuant to 2023 Stock Incentive Plan and received a special stock award. Mr. Tsai's employment agreement is attached hereto as Exhibit 10.22.

Hsin-Liang Lee

We entered into an employment agreement with Mr. Hsin-Liang Lee as Chief Financial Officer in March 2024. The agreement provides for a monthly salary of NT$200,000 (equivalent to approximately $6,200), subsequently on September 1, 2024, monthly salary was increased to NT$364,150 (equivalent to approximately $11,500), a year-end bonus of two months' salary and other statutory employee benefits. Mr. Lee was offered a special stock award as the sign-on bonus for his onboarding in late 2024 after shareholder approvals. Mr. Lee was granted RSUs under 2023 Stock Incentive Plan. Mr. Lee's employment agreement is attached hereto as Exhibit 10.25.

Outstanding Equity Awards at December 31, 2024

There is no outstanding shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2024.

Director Compensation Table

The following table provides information regarding the total compensation that was earned by or paid to each person who served as our directors, other than executive directors, during the year ended December 31, 2024. Mr. Chun-Hsien Tsai is not included in the table below as he is employed as our President, Chief Executive Officer and Chairman of our Board whose compensation information is provided in the "Summary Compensation Table" above.

Name	Fees earned or paid in cash [2] ($)	Stock awards [1] ($)	All other compensation ($)	Total ($)
Wen-Han Chang	$ 20,500	$ -	$ -	$ 20,500
Yao-Chung Chiang	16,000	-	-	16,000
Pao-Sheng Wei	22,000	-	-	22,000
Chung-Yi Tsai	12,000	-	-	12,000
Chung-Jung Tsai	-	81,372	-	81,372
Ting-Chuan Lee	-	84,067	-	84,067
Total	$ 70,500	$ 165,439	$ -	$ 235,939

(1) The value shown reflects the grant date fair value in accordance with FASB ASC Topic 718.

(2) Each member of the Board of who is not an employee of the Company or any of subsidiaries receives the cash compensation set forth below the 2021 NEDCP for service on the Board.

Non-Employee Director Compensation Policy (the "2021 NEDCP")

On September 28, 2021, the Company's Board of Directors adopted the Company's Non-Employee Director Compensation Policy (the "2021 NEDCP" or "Policy"). On appointment to the Board, and without any further action of the Board or Compensation Committee of the Board, at the close of business on the day of such appointment, each Non-Employee Director will automatically receive an award of 22,000 restricted stock units ("RSUs"), adjusted to 4,400 shares giving effect to the 1 for 5 reverse stock split on December 14, 2023, over Common Stock (the "Appointment Grant"). The Appointment Grant shall vest in three equal annual installments, with the first installment vesting on the last day of the six-month period commencing on the grant date and each subsequent installment vesting on the last day of the six-month period commencing on the next two subsequent anniversaries of the grant date, subject to the Director's continuous service with us on each applicable vesting date. The RSUs shall be granted pursuant to the Company's 2021 Stock Incentive Plan and shall be subject to such other provisions set forth in the agreement evidencing the award of the RSUs, in the form adopted from time to time by the Board or the Compensation Committee of the Board.

In addition to the RSU grants, each member of the Board of who is not an employee of the Company or any of subsidiaries will receive the cash compensation set forth below for service on the Board. The annual cash compensation amounts will be payable in equal quarterly installments, in arrears following the end of each quarter in which the service occurred, pro-rated for any partial months of service. All annual cash fees are vested upon payment.

Annual Board Service Retainer:		
All Eligible Directors:	$	12,000
Chairperson of the Board:	$	14,000
Annual Committee Chair Service Retainer:		
Chairperson of the Audit Committee:	$	7,000
Chairperson of the Compensation Committee:	$	4,500
Annual Committee Member Service Retainer:		
Member of the Audit Committee:	$	4,000
Member of the Compensation Committee:	$	3,000

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information, as of March 7, 2025, with respect to the holdings of (1) each person who is the beneficial owner of more than 5% of our common stock, (2) each of our directors, (3) each of our named executive officers, and (4) all of our current directors and executive officers as a group.

Beneficial ownership of the common stock is determined in accordance with the rules of the SEC and includes any shares of common stock over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days of March 7, 2025. Applicable percentage ownership in the following table is based on 15,433,257 shares of common stock plus, for each individual, any securities that individual has the right to acquire within 60 days of March 7, 2025.

The information in the table below is based on information known to us or ascertained by us from public filings made by the stockholders. Except as otherwise indicated in the table below, addresses of the director, executive officers and named beneficial owners are in care of Ainos, Inc. at 8880 Rio San Diego Drive, Suite 800, San Diego, CA, 92108.

We are not aware of any arrangements, including any pledge by any person of securities of our Company or any of its parents, the operation of which may at a subsequent date result in a change in control of our Company.

Name of beneficial owner	Number of shares beneficially owned	Percentage of shares of common stock	Percentage of voting power
Security ownership of certain beneficial owners:			
Ainos Inc. ("Ainos KY") [1]	2,456,319	15.92%	75.73%
Taiwan Carbon Nano Technology Corporation ("TCNT") [2]	5,500,000	35.64%	-
ASE Test, Inc. ("ASE Test") [3]	2,312,077	13.05%	-
Security ownership of management and directors:			
Chun-Hsien Tsai[1][4]	551,862	3.58%	-
Chung-Yi Tsai[1]	54,400	*	*
Chun-Jung Tsai[1][4]	327,900	2.12%	-
Ting-Chuan Lee[1]	331,432	2.15%	-
Wen-Han Chang[5]	107,733	*	*
Yao-Chung Chiang[6]	56,400	*	*
Pao-Sheng Wei	54,400	*	*
Hsin-Liang Lee	26,376	*	*
All Directors and Executive Officers as a Group (8 persons)	1,510,503	9.79%	1.94% [1][4]

*Represents beneficial ownership of less than 1%

(1) Includes (i) 2,456,319 shares of common stock, $0.01 par value, of Ainos, Inc., a Texas corporation (the "Issuer"), owned directly by Ainos Inc., a Cayman Islands company ("Ainos KY"), (ii) 1,265,594 shares pursuant to a Voting Agreement dated January 26, 2024 (the "2024 Voting Agreement"), by and among the Issuer, Ainos Inc., and Chun-Hsien Tsai, Ting Chuan Lee, Chun-Jung Tsai, and Chung-Yi Tsai (the "Tsai Group"); (iii) 153,856 shares of common stock pursuant to a Voting Agreement dated March 7, 2024 (the "2024 Voting Agreement II") with Chih-Heng Lu; (iv) 2,312,077 shares pursuant to a Voting Agreement dated May 3, 2024 between Ainos KY and ASE Test, Inc. and (v) 5,500,000 shares pursuant to a Voting Agreement dated August 15, 2024 between Ainos KY and Taiwan Carbon Nano Technology Corporation.

(2) 5,500,000 shares pursuant to a Voting Agreement dated August 15, 2024 between Ainos KY and TCNT.

(3) Consisting of the following (i) 29,411 shares owned by ASE Test, (ii) 282,666 shares issuable to ASE Test upon conversion of outstanding convertible notes of the Issuer and (iii) 2,000,000 shares issuable to ASE Test upon conversion of a convertible note of the Issuer issuable within 60 days). All shares beneficially owned by ASE Test are subject to the Voting Agreement dated May 3, 2024 between Ainos KY and ASE Test.

(4) Chun-Hsien Tsai and Chun-Jung Tsai serve as directors of Ainos KY; however, they do not control its board, as the board of directors of Ainos KY includes members who are not executive officers or directors with Ainos.

(5) Includes 54,400 shares of common stock directly held by Wen-Han Chang, and 53,333 shares of common stock indirectly through his spouse, Chien-Hsuan Huang.

(6) Includes 54,400 shares of common stock directly held by Yao-Chung Chiang, and 2,000 shares of common stock indirectly through his spouse, Hsiu-Hwei Tsai Chiang.

Equity Compensation Plan Information

The following table summarizes our equity compensation plan information as of December 31, 2024.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	97,165[1][2]	$ 28.50[3]	60,128
Equity compensation plans not approved by security holders	6,034[4]	$ 19.88	-
Total	103,199		60,128

(1) Includes our 2021 and 2023 Stock Incentive Plans. For a description of these plans, refer to Note 9 to the historical financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2024.

(2) Includes 89,833 shares of RSUs, and 7,332 shares of option.

(3) As RSUs do not have any exercise price, outstanding RSUs are not included in the weighted-average exercise price calculation for options and warrants.

(4) 6,034 shares of warrants were issued to i2China as part of the consulting engagement with Mr. Lin in May 2018. The warrant maturity was then subsequently extended and re-issued in November 2020. The warrants are fully vested and exercisable by November 2025.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

Certain Relationships and Related Party Transactions

In addition to the executive officer and director compensation arrangements discussed above under Item 11 “Executive Compensation”, since January 1, 2024, the following are the only transactions or series of similar transactions to which we were or will be a party in which the amount involved exceeds $120,000 and in which any director, nominee for director, executive officer, beneficial holder of more than 5% of our common stock or any member of their immediate family or any entity affiliated with any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change of control and other arrangements, which are described under “Executive Compensation.”

Purchase of intangible assets and equipment

Patent license agreement

On August 6, 2024, the Company entered into a patent license agreement (the “License Agreement”) with TCNT, as an effort to bolster the Company’s AI Nose and point-of-care testing (POCT) technologies while preserving cash. As of August 5, 2024, prior to TCNT entering into the License Agreement, TCNT controlled, via its majority interest in Ainos KY which is a party to certain voting agreements, approximately 38% of the voting power of the Company. Pursuant to the License Agreement, TCNT has agreed to assign and grant, and the Company has agreed to accept, an exclusive, irrevocable, and perpetual license of certain invention patents and patent applications related to gas sensors and medical devices (the “Licensed Patents”), in exchange for 5,500,000 shares of the Common Stock, at a price per share of 1.05 times the highest closing sale price of the Common Stock during the 30-trading day period preceding the effective date of the License Agreement. The License Agreement shall remain in effect until terminated by mutual written agreement of the parties, or until the expiration of the Licensed Patents, or all claims for alleged infringement of the Licensed Patents are barred by applicable laws. Following the issuance of the 5.5 million shares of stock, TCNT controls the company through its majority interest in Ainos KY, and its direct ownership in the Company.

Working Capital Advances

Ainos KY provided $800,000 in cash in exchange of a promissory note to support working capital of the Company in March 2022 (the “KY Note”). The Company paid off $530,000 of the KY Note during the year ended December 31, 2023. The KY Note bear an interest rate of 1.85% per annum. On August 17, 2023, the Company entered into extension agreements with Ainos KY to extend the maturity of the KY Note to March 31, 2025.

On October 7, 2024, the company paid off the remaining note payable principal amount of $270,000 with accrued interest to Ainos KY, the controlling shareholder of the Company.

On May 3, 2024, The Company entered into Convertible Note and Warrant Purchase Agreement with the ASE, a shareholder of Ainos KY, for the issuance of convertible promissory notes with 6% compound interest in the aggregate principal amount of $9,000,000 (collectively the "Notes") convertible into shares of common stock, par value $0.01 per share, of the Company, payable three (3) years from May 3, 2024 as well as the issuance of warrants for the purchase of up to 500,000 shares of common stock at a price per share of $4.50, exercisable until May 3, 2029. As of December 31, 2024, the Company received the full amount of the payment.

Purchase and Sales

Ainos COVID-19 Test Kits Sales and Marketing Agreement with Ainos KY

On June 14, 2021, the Company entered into an exclusive agreement with Ainos KY to serve as the master sales and marketing agent for the Ainos COVID-19 Antigen Rapid Test Kit and COVID-19 Nucleic Acid Test Kit which were developed and manufactured by TCNT (the "Sales and Marketing Agreement"). On June 7, 2021, the Taiwan Food and Drug Administration (the "TFDA") approved emergency use authorization (the "EUA") to TCNT for the Ainos COVID-19 Antigen Rapid Test Kit sold and marketed under the "Ainos" brand name in Taiwan. On June 21, 2022, the Company began marketing the Ainos SARS-CoV-2 Antigen Rapid Self-Test (together with Ainos COVID-19 Antigen Rapid Test Kit, the "COVID-19 Antigen Rapid Test Kits") under a separate EUA issued by the TFDA to TCNT on June 13, 2022.

The Company incurred costs associated with manufacturing COVID-19 Antigen Rapid Test Kits by TCNT pursuant to the Sales and Marketing Agreement, totaling nil and $46,635 for the years ended December 31, 2024 and 2023, respectively.

Product Development Agreement with TCNT

Pursuant to a five-year Product Development Agreement (the "Product Development Agreement") with TCNT, effective August 1, 2021, the development expenses incurred were $413,324 and $368,372 for the years ended December 31, 2024 and 2023, respectively.

On January 9, 2024, the Company and TCNT entered into an addendum to the Product Development Agreement (the "Addendum Agreement") in connection with the scope of co-development and certain terms. For products defined in the Addendum agreement, TCNT will provide facilities, equipment, mass production process technology, ISO9001 and ISO13485 related management, as well as mass production support. The procurement of parts and raw materials, rental fees, and utility expenses are excluded. The Company will pay a total fee of NT$5 million (USD$162,840) for five-years of development commencing from January 2024. The Company prepaid the full amount of the fee on January 10, 2024 at TCNT's request. In addition, TCNT will provide non-exclusive use of certain patents related to VOC and POCT technologies for a monthly fee of $95,000 (plus 5% indirect tax), with negotiable payment terms for six months from January 2024 to June 2024.

As part of the Second Addendum Agreement entered on July 8, 2024, TCNT provided non-exclusive use of certain patents related to VOC and POCT technologies for a monthly fee of $95,000 (plus 5% indirect tax), with negotiable payment terms for extend another three months from July 2024 to September 2024.

As part of the Third Addendum Agreement entered into on October 16, 2024, TCNT will provide exclusive use of certain patents related to VOC, POCT and nitrogen-oxygen separation machine technologies for a monthly fee of $50,000 (plus 5% indirect tax) for twelve months from October 16, 2024, with negotiable payment terms.

As of December 31, 2024, the Company has paid $1,005,000 (plus 5% indirect tax) of license fee to TCNT.

Controlling Shareholder

Taiwan Carbon Nano Technology Corporation (the "TCNT") holds majority share of Ainos KY, which holds majority voting power of the Company as of December 31, 2024.

Director Independence

We are a "controlled company" as defined in Rule 5615(c)(1) of the Nasdaq Listing Rules because more than 50% of our voting power is held by Ainos KY through direct shareholding and voting agreement dated January 26, 2024 by and among Ainos KY, and Chun-Hsien Tsai, Ting Chuan Lee, Chun-Jung Tsai, and Chung-Yi Tsai. As a "controlled company," we are exempt from the requirements of Rule 5605(b), (d) and (e) of the Nasdaq listing standards that would otherwise require us to have (i) a majority of independent directors on the Board, (ii) compensation and nominating committees composed solely of independent directors, (iii) the compensation of executive officers determined by a majority of the independent directors or a compensation committee composed solely of independent directors, and (iv) director nominees selected or recommended to the Board for selection, either by a majority of the independent directors, or a nominating committee composed solely of independent directors. Consequently, we are exempt from independent director requirements of Rule 5605(b), (d) and (e) of the Nasdaq Listing Rules, except for the requirements under subsection (b)(2) thereof pertaining to executive sessions of independent directors and those under subsection (c) thereof pertaining to the Audit Committee. Currently, we have an Audit Committee and Compensation Committee composed solely of independent directors.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

KCCW Accountancy Corp. (KCCW) was approved and appointed as our principal accounting firm starting Q1 of 2023. The fees billed or will be billed by KCCW is as below:

Audit Fees

The aggregate fees billed and will be billed by our principal auditor for professional services rendered for the audit of annual financial statements, and for the review of quarterly financial statements were $135,000 and $140,000 for the fiscal year ended December 31, 2023 and 2024, respectively, and were pre-approved by the Audit Committee of the Board of Directors.

Audit Related Fees: None.

Tax Fees: None.

All Other Fees: For the fiscal year ended December 31, 2023 and 2024 were nil and $16,250 respectively.

Accountant Approval Policy

Before an accountant is engaged by the Company to perform audit or non-audit services, the accountant must be approved by the Company's Audit Committee. We filed the Charter of the Audit Committee of the Board of Directors in our Form 10-Q with the SEC on November 15, 2021 which describes the committee's pre-approval policies and procedures, attached hereto as Exhibit 99(ii) and is incorporated by this reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

EXHIBIT INDEX

			INCORPORATED BY REFERENCE			
EXHIBIT NUMBER	**DESCRIPTION**	**FILED WITH THIS FORM 10-K**	**FILING DATE WITH SEC**	**FORM**	**EXH #**	**HYPERLINK TO FILINGS**
3.1	Restated Certificate of Formation of the Company, dated April 15, 2021		4/21/2021	8-K	3.1	Restated Certificate of Formation of the Company, dated April 15, 2021
3.2	Certificate of Amendment to the Restated Certificate of Formation, dated August 8, 2022		8/12/2022	8-K	3.1	Certificate of Amendment, dated August 8 2022
3.3	Amended and Restated Bylaws of the Company, effective September 28, 2022		10/4/2022	8-K	3.2	Amended and Restated Bylaws, effective September 28, 2022
3.4	Amended and Restated Bylaws of Ainos, Inc.		06/20/2024	8-K	3.1	Amended and Restated Bylaws
4.1	Form of Common Stock Certificate		4/3/2023	10-K	4.1(a)	Form of Common Stock Certificate
4.2	Form of Warrant		8/2/2022	S-1/A	4.1	Form of Warrant
4.3	Form of Warrant Agency Agreement		8/2/2022	S-1/A	4.2	Form of Warrant Agency Agreement
4.4	Form of Convertible Promissory Note		9/29/2023	8-K	4.2	Form of Convertible Promissory Note
4.5	Form of Common Stock Purchase Warrant		9/29/2023	8-K	4.3	Form of Common Stock Purchase Warrant
4.6	Form of Placement Agent Warrant		9/29/2023	8-K	4.1	Form of Placement Agent Warrant
4.7	Description of securities	X				

EXHIBIT NUMBER	DESCRIPTION	FILED WITH THIS FORM 10-K	INCORPORATED BY REFERENCE			
			FILING DATE WITH SEC	FORM	EXH #	HYPERLINK TO FILINGS
4.8	First Amendment, dated January 23, 2024, to Senior Secured Convertible Promissory Note dated as of September 28, 2023		01/25/2024	8-K	4.1	First Amendment, dated January 23, 2024, to Senior Secured Convertible Promissory Note dated as of September 28, 2023
4.9	Voting Deed, dated as of May 3, 2024, by and among Ainos, Inc., a Cayman Islands company, and ASE Test, Inc.		05/06/2024	8-K	4.1	Voting Deed
4.10	Convertible Promissory Note, dated as of May 3, 2024, issued by Ainos, Inc. in favor of ASE Test, Inc. in the principal amount of US$9,000,000.		05/06/2024	8-K	4.2	Convertible Promissory Note
4.11	Common Stock Warrant, dated as of May 3, 2024, issued by Ainos, Inc. to ASE Test, Inc.		05/06/2024	8-K	4.3	Common Stock Warrant
9.1	Voting Agreement dated September 2, 2022			13D/A	1	Voting Agreement
9.2	Voting Agreement dated on January 26, 2024		1/29/2024	13D/A	1	Voting Agreement
9.3	Termination Agreement dated on January 26, 2024		1/29/2024	13D/A	2	Termination Agreement
9.4	Voting Agreement dated on March 7, 2024		3/8/2024	10-K	9.4	Voting Agreement
10.1	2018 Employee Stock Option Plan*		4/16/2019	10-K	10.72	2018 Employee Stock Option Plan
10.11	Amended and Restated Asset Purchase Agreement, dated as of January 29, 2022, between Ainos Inc. and Ainos, Inc.		2/3/2022	8-K	2.1	Amended and Restated Asset Purchase Agreement, dated as of January 29, 2022, between Ainos Inc. and Ainos, Inc.
10.12	Convertible Promissory Note, dated as of January 30, 2022, issued by the Company to Ainos Inc.		2/3/2022	8-K	10.1	Convertible Promissory Note, dated as of January 30, 2022, issued by the Company to Ainos Inc.

EXHIBIT NUMBER	DESCRIPTION	FILED WITH THIS FORM 10-K	INCORPORATED BY REFERENCE			
			FILING DATE WITH SEC	FORM	EXH #	HYPERLINK TO FILINGS
10.13	Non-Convertible Promissory Note, dated March 4, 2022, issued by the Company to Ainos Inc.		3/17/2022	8-K	10(i)	Non-Convertible Promissory Note, dated March 4, 2022, issued by the Company to Ainos Inc.
10.14	Note Extension Agreement, dated March 17, 2022, between the Company and Ainos Inc.		3/17/2022	8-K	10 (ii)	Note Extension Agreement, dated March 17, 2022, between the Company and Ainos Inc.
10.15	Form of Convertible Note Purchase Agreement, between the Company and the purchasers party thereto		4/4/2022	8-K	2.1	Form of Convertible Note Purchase Agreement, between the Company and the purchasers party thereto
10.16	Form of Convertible Promissory Note		4/4/2022	8-K	10.1	Form of Convertible Promissory Note
10.17	Security Agreement, dated as of September 28, 2023, by and between Lind Global Fund II LP and Ainos, Inc.		9/29/2023	8-K	10.1	Security Agreement, dated as of September 28, 2023, by and between Lind Global Fund II LP and Ainos, Inc.
10.18	Securities Purchase Agreement, dated as of September 25, 2023, by and between Lind Global Fund II LP and Ainos, Inc.		9/29/2023	8-K	10.2	Securities Purchase Agreement, dated as of September 25, 2023, by and between Lind Global Fund II LP and Ainos, Inc.
10.19	Placement Agent Agreement, dated as of September 25, 2023 by and between Maxim Partners LLC and Ainos, Inc.		9/29/2023	8-K	10.3	Placement Agent Agreement, dated as of September 25, 2023 by and between Maxim Partners LLC and Ainos, Inc.
10.20	Employment Agreement by and between Lawrence K. Lin and the Company effective August 1, 2021*		8/16/2021	8-K	10.1(a)	Employment Agreement by and between Lawrence K. Lin and the Company effective August 1, 2021

EXHIBIT NUMBER	DESCRIPTION	FILED WITH THIS FORM 10-K	INCORPORATED BY REFERENCE			
			FILING DATE WITH SEC	FORM	EXH #	HYPERLINK TO FILINGS
10.21	Extension of the consulting agreement and pre-existing warrant certificate between the Company and i2China Management Group, LLC (originally dated April 15, 2018), dated November 30, 2020		3/30/2021	10-K	10.1(J)	Extension of the consulting agreement and pre-existing warrant certificate between the Company and i2China Management Group, LLC (originally dated April 15, 2018), dated November 30, 2020
10.22	Employment Agreement, dated March 17, 2022, by and between the Company and Chun-Hsien Tsai*		3/17/2022	8-K	10(iii)	Employment Agreement, dated March 17, 2022, by and between the Company and Chun-Hsien Tsai
10.23	Employment Agreement, dated March 17, 2022, by and between the Company and Hui-Lan Wu		3/17/2022	8-K	10(iv)	Employment Agreement, dated March 17, 2022, by and between the Company and Hui-Lan Wu
10.24	Employment Agreement, dated March 17, 2022, by and between the Company and Chih-Heng Jack Lu		3/17/2022	8-K	10(v)	Employment Agreement, dated March 17, 2022, by and between the Company and Chih-Heng Jack Lu
10.25	Employment Agreement, dated May 8, 2023, by and between the Company and Meng-Lin Sung*		3/8/2024	10-K	10.25	Employment Agreement, dated May 8, 2023, by and between the Company and Meng-Lin Sung
10.26	English Translation of Product Development Agreement, dated on August 1, 2021		1/12/2024	8-K	10.1	English Translation of Product Development Agreement, dated on August 1, 2021
10.27	English Translation of Addendum to the Product Development Agreement, dated on January 9, 2024		1/12/2024	8-K	10.2	English Translation of Addendum to the Product Development Agreement, dated on January 9, 2024

EXHIBIT NUMBER	DESCRIPTION	FILED WITH THIS FORM 10-K	INCORPORATED BY REFERENCE			
			FILING DATE WITH SEC	FORM	EXH #	HYPERLINK TO FILINGS
10.28	Ainos NISD Inabata Codevelopment Agreement - August 9, 2023, Appendix 1 and 2 redacted		11/9/2023	10-Q	10.1	Ainos NISD Inabata Codevelopment Agreement - August 9, 2023, Appendix 1 and 2 redacted
10.29	Mandate Agreement		03/19/2024	8-K	10.1	Mandate Agreement
10.30	Convertible Note and Warrant Purchase Agreement, dated May 3, 2024, by and between Ainos, Inc. and ASE Test, Inc.		05/06/2024	8-K	10.1	Convertible Note and Warrant Purchase Agreement
10.31	At The Market Offering Agreement between Ainos, Inc. and H.C. Wainwright & Co., LLC		05/31/2024	S-3	1.1	At The Market Offering Agreement
10.32	English Translation of Second Addendum to Product Development Agreement, dated July 8, 2024		07/12/2024	8-K	10.1	English Translation of Second Addendum to Product Development Agreement
10.33	English Translation of Third Addendum to Product Development Agreement, dated October 16, 2024		10/22/2024	8-K	10.1	English Translation of Third Addendum to Product Development Agreement
10.34	Patent License Agreement, dated August 6, 2024, by and between Ainos, Inc. and Taiwan Carbon Nano Technology Corporation.		08/09/2024	8-K	10.1	Patent License Agreement
14.1	Code of Ethics		8/26/2021	8-K	14.1	Code of Ethics
19.1	Insider Trading Policy		11/15/2021	10-Q	99.5	Insider Trading Policy of the Board of Directors, as amended and adopted August 20, 2021
23.1	Consent of KCCW Accountancy Corp., independent registered public accounting firm	X				

EXHIBIT NUMBER	DESCRIPTION	FILED WITH THIS FORM 10-K	INCORPORATED BY REFERENCE			
			FILING DATE WITH SEC	FORM	EXH #	HYPERLINK TO FILINGS
24.1	Power of Attorney	X				
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e)	X				
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-15(e) or Rule 15d-15(e)	X				
32.1	Certification Of Principal Executive Officer Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 Of The Sarbanes-Oxley Act Of 2002	X				
32.2	Certification Of Principal Financial Officer Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 Of The Sarbanes-Oxley Act Of 2002	X				
97.1	Clawback policy		3/8/2024	10-K	97.1	Clawback Policy

The exhibits listed in the Exhibit Index are filed or incorporated by reference as part of this filing.

* Indicates a management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AINOS, INC.

Date: March 7, 2025

By: */s/ Chun-Hsien Tsai*
Chun-Hsien Tsai, Chairman of the Board, President, and Chief Executive Officer

By: /s/ *Hsin-Liang Lee*
Hsin-Liang Lee, Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Chun-Hsien Tsai Chun-Hsien Tsai	Chairman of the Board, President, and Chief Executive Officer	March 7, 2025
/s/ Hsin-Liang Lee Hsin-Liang Lee	Chief Financial Officer	March 7, 2025
/s/ Wen-Han Chang Wen-Han Chang By: Chun-Hsien Tsai, Attorney in fact	Director	March 7, 2025
/s/ Yao-Chung Chiang Yao-Chung Chiang By: Chun-Hsien Tsai, Attorney in fact	Director	March 7, 2025
/s/ Pao-Sheng Wei Pao-Sheng Wei By: Chun-Hsien Tsai, Attorney in fact	Director	March 7, 2025
/s/ Ting-Chuan Lee Ting-Chuan Lee By: Chun-Hsien Tsai, Attorney in fact	Director	March 7, 2025
/s/ Chun-Jung Tsai Chun-Jung Tsai By: Chun-Hsien Tsai, Attorney in fact	Director	March 7, 2025
/s/ Chung-Yi Tsai Chung-Yi Tsai By: Chun-Hsien Tsai, Attorney in fact	Director	March 7, 2025

[This page intentionally left blank]

Ainos, Inc.
Financial Statements

Years ended December 31, 2024 and 2023

Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the board of directors of Ainos, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Ainos, Inc. (the "Company") as of December 31, 2024 and 2023, the related statements of operations, comprehensive loss, shareholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with the U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Assessment of Impairment of Intangible Assets

Critical Audit Matter Description

As discussed in Notes 2 and 4 to the financial statements, the Company acquired certain finite life intellectual properties from a related party. These intellectual properties were capitalized and are amortized over their estimated useful lives. The Company assessed whether events and circumstances indicate the carrying amount of these assets may not be fully recoverable. Given the audit effort in evaluating management's judgements of the indicators of impairment and the required degree of auditor judgment, we determined it was a critical audit matter.

How the Critical Audit Matter Was Addressed in the Audit

Our principal audit procedures related to the Company's assessment of impairment included, amongst others:

- We evaluated management's accounting policy related to intangible assets.
- We evaluated the Company's assumptions used in the estimates of undiscounted cash flow for the asset group and the conclusion reached by management.

/s/ KCCW Accountancy Corp.
We have served as the Company's auditor since 2023.
Diamond Bar, California
March 7, 2025

KCCW Accountancy Corp.
3333 South Brea Canyon Rd. #206, Diamond Bar, CA 91765, USA
Tel: +1 909 348 7228 ● Fax: +1 909 895 4155 ● info@kccwcpa.com

Ainos, Inc.
Balance Sheets

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 3,892,919	$ 1,885,628
Accounts receivable	56	455
Inventory, net	143,756	167,593
Other current assets	301,077	419,521
Total current assets	4,337,808	2,473,197
Intangible assets, net	23,748,328	28,283,208
Property and equipment, net	559,645	876,572
Other assets	174,418	208,827
Total assets	$ 28,820,199	$ 31,841,804
Liabilities and Stockholders' Equity		
Current liabilities:		
Contract liabilities	$ 106,329	$ 112,555
Convertible notes payable (including amounts of related party of $2,000,000 and nil as of December 31, 2024 and 2023, respectively)	3,000,000	-
Other notes payable, related party	-	42,000
Accrued expenses and other current liabilities	848,615	1,182,283
Total current liabilities	3,954,944	1,336,838
Senior secured convertible notes measured at fair value	-	2,651,556
Convertible notes payable - noncurrent (including amounts of related party of $9,000,000 and $2,000,000 as of December 31, 2024 and 2023, respectively)	9,000,000	3,000,000
Other notes payable, related party - noncurrent	-	270,000
Other long-term liabilities	348,945	135,829
Total liabilities	13,303,889	7,394,223
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 50,000,000 shares authorized as of December 31, 2024 and 2023, respectively; none issued and outstanding	-	-
Common stock, $0.01 par value; 300,000,000 shares authorized as of December 31, 2024 and 2023; 15,427,385 shares and 4,677,787 shares issued and outstanding as of December 31, 2024 and 2023, respectively	154,274	46,778
Common stock to be issued, nil and 162,337 shares as of December 31, 2024 and 2023, respectively	-	1,623
Additional paid-in capital	68,520,881	62,555,808
Accumulated deficit	(52,749,316)	(37,886,155)
Accumulated other comprehensive loss - translation adjustment	(409,529)	(270,473)
Total stockholders' equity	15,516,310	24,447,581
Total liabilities and stockholders' equity	$ 28,820,199	$ 31,841,804

See accompanying notes to financial statements.

Ainos, Inc.
Statements of Operations

	Years ended December 31,	
	2024	2023
Revenues (including amounts of related party of nil and $33,388 for the years ended December 31, 2024 and 2023, respectively)	$ 20,729	$ 122,112
Cost of revenues (including amounts of related party of nil and $118,497 for the years ended December 31, 2024 and 2023, respectively)	(52,595)	(375,845)
Gross losses	(31,866)	(253,733)
Operating expenses:		
Research and development expenses (including amounts of related party of $1,418,887 and $368,372 for the years ended December 31, 2024 and 2023, respectively)	8,413,923	7,317,388
Selling, general and administrative expenses	5,395,415	5,635,275
Total operating expenses	13,809,338	12,952,663
Loss from operations	(13,841,204)	(13,206,396)
Non-operating (expenses) income		
Interest expense	(616,467)	(144,193)
Issuance cost of senior secured convertible note measured at fair value	(308,336)	(525,643)
Fair value change of senior secured convertible note	(275,624)	94,207
Other income, net	179,270	12,276
Total non-operating expenses, net	(1,021,157)	(563,353)
Net loss before income taxes	(14,862,361)	(13,769,749)
Provision for income taxes	800	800
Net loss	$ (14,863,161)	$ (13,770,549)
Net loss per common share - basic and diluted	$ (1.56)	$ (3.36)
Weighted-average shares used in computing net loss per common share-basic and diluted	9,503,618	4,098,109

See accompanying notes to financial statements.

Ainos, Inc.
Statements of Comprehensive Loss

	Years ended December 31,	
	2024	**2023**
Net loss	$ (14,863,161)	$ (13,770,549)
Other comprehensive loss:		
Translation adjustment	(139,056)	(68,820)
Comprehensive loss	$ (15,002,217)	$ (13,839,369)

See accompanying notes to financial statements.

Ainos, Inc.
Statements of Stockholders' Equity
Years Ended December 31, 2024 and 2023

	Preferred Stock		Common Stock		Common Stock - to be issued		Additional Paid-in	Accumulated	Accumulated Other Comprehensive Loss - Translation	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Adjustment	Equity
Balance at December 31, 2023	-	$ -	4,677,787	$ 46,778	162,337	$ 1,623	$62,555,808	$(37,886,155)	$ (270,473)	$ 24,447,581
Conversion of convertible notes payable to common stock	-	-	3,233,655	32,336	(162,337)	(1,623)	2,410,978	-	-	2,441,691
Issuance of stock to settle vested RSUs	-	-	1,768,443	17,685	-	-	(17,685)	-	-	-
Issuance of common stock for special stock bonus	-	-	247,500	2,475	-	-	86,521	-	-	88,996
Related party used computer equipment	-	-	-	-	-	-	(4,428)	-	-	(4,428)
Warrants issued in connection with senior secured convertible note payable	-	-	-	-	-	-	1,586	-	-	1,586
Issue common stock for patent license agreement	-	-	5,500,000	55,000	-	-	(55,000)	-	-	-
Share-based compensation	-	-	-	-	-	-	3,543,101	-	-	3,543,101
Net loss	-	-	-	-	-	-	-	(14,863,161)	-	(14,863,161)
Translation adjustment	-	-	-	-	-	-	-	-	(139,056)	(139,056)
Balance at December 31, 2024	-	$ -	15,427,385	$154,274	-	$ -	$68,520,881	$(52,749,316)	$ (409,529)	$ 15,516,310
Balance at December 31, 2022	-	$ -	4,002,320	$ 40,023	-	$ -	$58,905,242	$(24,115,606)	$ (201,653)	$ 34,628,006
Issuance of stock in exchange of vehicle	-	-	12,231	122	-	-	48,437	-	-	48,559
Conversion of convertible notes payable to common stock	-	-	18,666	187	-	-	274,602	-	-	274,789
Issuance of stock to settle vested RSUs	-	-	44,680	447	-	-	(447)	-	-	-
Issuance of common stock for special stock bonus	-	-	600,000	6,000	-	-	1,941,000	-	-	1,947,000
Fractional shares paid out in cash for the reverse stock split	-	-	(110)	(1)	-	-	(300)	-	-	(301)
Warrants issued in connection with senior secured convertible note payable	-	-	-	-	-	-	19,893	-	-	19,893
Conversion of senior secured convertible notes to common stock	-	-	-	-	162,337	1,623	252,614	-	-	254,237
Share-based compensation	-	-	-	-	-	-	1,114,767	-	-	1,114,767
Net loss	-	-	-	-	-	-	-	(13,770,549)	-	(13,770,549)
Translation adjustment	-	-	-	-	-	-	-	-	(68,820)	(68,820)
Balance at December 31, 2023	-	$ -	4,677,787	$ 46,778	162,337	$ 1,623	$62,555,808	$(37,886,155)	$ (270,473)	$ 24,447,581

See accompanying notes to financial statements.

Ainos, Inc.
Statements of Cash Flows

	Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (14,863,161)	$ (13,770,549)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,801,716	4,871,057
Impairment loss of property and equipment	-	286,777
Loss on inventory write-downs	-	235,047
Share-based compensation expense	3,543,101	1,114,767
Stock issued for special stock bonus	88,996	1,947,000
Issuance cost of senior secured convertible note measured at fair value	308,336	525,643
Changes in fair value of senior secured convertible note	275,624	(94,207)
Changes in operating assets and liabilities:		
Accounts receivable	399	201,091
Inventory	23,837	221,767
Other current assets	118,444	(223,734)
Accrued expenses and other current and long-term liabilities	(105,559)	(9,327)
Net cash used in operating activities	(5,808,267)	(4,694,668)
Cash flows from investing activities:		
Purchase of property and equipment	(21,331)	(92,984)
Increase in refundable deposits and other assets	(103,961)	(8,541)
Net cash used in investing activities	(125,292)	(101,525)
Cash flows from financing activities:		
Proceeds from convertible notes payable- noncurrent	-	1,000,000
Proceeds from convertible notes payable- noncurrent, related party	9,000,000	2,000,000
Proceeds from senior secured convertible notes payable	875,000	3,000,000
Repayment of convertible notes payable, related party	-	(114,026)
Repayment of senior secured convertible notes payable	(1,439,754)	-
Repayment of other notes payable, related party	(312,000)	(572,000)
Payment of issuance cost of senior secured convertible note measured at fair value	(97,500)	(390,000)
Fractional shares paid out in cash for the reverse stock split	-	(301)
Net cash provided by financing activities	8,025,746	4,923,673
Effect from foreign currency exchange	(84,896)	(95,214)
Net increase in cash and cash equivalents	2,007,291	32,266
Cash and cash equivalents at beginning of year	1,885,628	1,853,362
Cash and cash equivalents at end of year	$ 3,892,919	$ 1,885,628
Supplemental Cash Flow Information		
Cash paid for interest	$ 21,671	$ 16,897
Cash paid for income taxes	$ 800	$ 800
Noncash financing and investing activities		
Conversion of convertible notes payable to common stock and accrued interest waived or converted by convertible note holders	$ -	$ 274,789
Conversion of senior secured convertible notes to common stock	$ 2,441,691	$ 254,237
Issuance of common stock in exchange of vehicle	$ -	$ 48,559
Payable for purchase of equipment	$ -	$ 5,848

See accompanying notes to financial statements.

Ainos, Inc.
Notes to Financial Statements
December 31, 2024 and 2023

1. Description of Business

Organization and Business

Ainos, Inc. (the "Company"), incorporated in the State of Texas, is a diversified healthcare company focused on the development of novel point-of-care testing (the "POCT"), therapeutics based on very low-dose interferon alpha (the "VELDONA"), and synthetic RNA-driven preventative medicine. The Company's products include VELDONA clinical-stage human therapeutics, VELDONA Pet supplements, and telehealth-friendly POCTs powered by its AI Nose technology platform.

The Company's POCT platforms aim to provide connected, rapid and convenient testing of a broad range of health conditions. Building on its extensive research and development of VELDONA, the Company is focused on commercializing a suite of VELDONA-based products including VELDONA Pet supplements and human related VELDONA therapeutics.

In 2021 and 2022, the Company acquired intellectual property from its immediate controlling shareholder, Ainos Inc., a Cayman Islands company ("Ainos KY"), and continues to expand its product portfolio into POCTs. Pivoting from the sales of its COVID-19 POCT, the Company is commercializing POCTs that detect volatile organic compounds (the "VOC") emitted by the body, powered by the Company's AI Nose technology platform. The Company's lead VOC POCT candidate, Ainos Flora, aims to quickly and easily test female vaginal health and certain common sexually transmitted infections (the "STIs").

During the year ended December 31,2024 and 2023, the Company generated revenues from sales of COVID-19 POCT and VELDONA Pet supplements.

Public Offering and Uplisting

The Company's registration statement related to its underwritten public offering (the "Offering") was declared effective on August 8, 2022, and the Company's common stock and warrants began trading on the Nasdaq Capital Market (the "Nasdaq") on August 9, 2022 under the trading symbols "AIMD" and "AIMDW", respectively.

Reverse Stock Splits

In connection with the Offering, the Company's board of directors on April 29, 2022 and its shareholders on May 16, 2022 approved a 1-for-15 reverse stock split of the Company's common stock that became effective on August 9, 2022. Further, to comply with Nasdaq's minimum $1.00 per share continued listing rules, the Company filed a Certificate of Amendment to its Restated Certificate of Formation on November 27, 2023, to apply for another reverse stock split of the Company's common stock at a ratio of 1-for-5 which was effectuated on December 14, 2023 after receiving required approvals.

The par value of $0.01 and authorized shares of the Company's common stock remain the same and were not adjusted as a result of the reverse stock splits. All issued and outstanding common stock, restricted stock units (RSUs), outstanding convertible notes, warrants and options to purchase common stock and per share amounts contained in the financial statements have been retroactively adjusted to give effect to the reverse stock splits for all periods presented.

Additional information regarding the Offering and the reverse stock splits can be found in Note 7 to the financial statements.

At The Market

On May 31, 2024, the Company entered into an At The Market Offering Agreement, or sales agreement, with H.C. Wainwright & Co., LLC or Wainwright, pursuant to which the Company may issue and sell, from time to time, shares of its common stock (the "Shares"), depending on market demand, with the Sales Agent acting as the sales agent or principal (the "Offering"). Sales of the Shares may be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the "Securities Act"), including, without limitation, sales made directly on or through the Nasdaq Capital Market. The Agent will use its commercially reasonable efforts to sell the Shares requested by the Company to be sold on its behalf, consistent with the Agent's normal trading and sales practices, under the terms and subject to the conditions set forth in the ATM Agreement. The Company has no obligation to sell any of the Shares. The Company may instruct the Agent not to sell the Shares if the sales cannot be effected at or above the price designated by the Company from time to time and the Company may at any time suspend sales pursuant to the ATM Agreement.

The Company will pay the Agent placement fee of 3.0% of the gross sales price of the Shares sold by the Agent under the ATM Agreement. The Company has also agreed to reimburse the Agent for the fees and disbursements of its counsel, payable upon execution of the Sales Agreement, in an amount not to exceed $35,000 in addition to certain ongoing disbursements of its legal counsel up to $2,500 per calendar quarter. In addition, the Company has agreed to provide customary indemnification rights to the Sales Agent.

The aggregate market value of Shares eligible for sale in the Offering and under the ATM Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3, to the extent required under such instruction. The prospectus supplement filed with the SEC on July 11, 2024, is offering Shares having an aggregate offering price of $1,840,350.

The Company intends to use the net proceeds from the offering to fund the continued development of its product candidate and for general corporate purposes and working capital. The precise amount and timing of the application of these proceeds will depend upon a number of factors, such as the timing and progress of our research and development efforts, our funding requirements and the availability and costs of other funds. As of December 31, 2024 there have been no shares sold under the ATM Agreement.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (the "GAAP") and rules and regulations of the U.S. Securities and Exchange Commission (the "SEC").

Liquidity

As of December 31, 2024, the Company had cash and cash equivalents of $3,892,919. The Company plans to finance its operations and development needs with its existing cash and cash equivalents, additional equity and/or debt financing arrangements, and expected revenue primarily from the sale of VELDONA Pet supplements to support the Company's clinical trial activities, largely in connection with Ainos Flora and human related VELDONA therapeutics. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company, on a timely basis, or at all. If the Company is not able to obtain sufficient funds on acceptable terms when needed, the Company's business, results of operations, and financial condition could be materially adversely impacted.

On May 31, 2024, the Company entered into an At The Market Offering Agreement, or sales agreement, with H.C. Wainwright & Co., LLC or Wainwright, pursuant to which the Company may issue and sell, from time to time, shares of its common stock, the aggregate market value of Shares eligible for sale in the Offering and under the ATM Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3, to the extent required under such instruction. The prospectus supplement filed with the SEC on July 11, 2024, is offering Shares having an aggregate offering price of $1,840,350.

For the year ended December 31, 2024, the Company generated a net loss of $14,863,161. The Company expects to continue incurring development expenses for the next twelve months as the Company advances Ainos Flora and VELDONA therapeutics for humans through clinical development until regulatory approval is received and the sales and marketing of the products is authorized.

The financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net operating losses and has an accumulated deficit as of December 31, 2024 of $52,749,316 and expects to incur additional losses and negative operating cash flows for at least the next twelve months. The Company's ability to meet its obligations is dependent upon its ability to generate sufficient cash flows from operations and future financing transactions. Because a large portion of our future expenditures will be to fund our growth, the Company expects that if needed the Company will be able to adjust their capital and operating expenditures by operating segment.

Accordingly, the Company's management believes that the measures described in the above liquidity plan will be adequate to satisfy its liquidity requirements for the twelve months after the date that the financial statements are issued.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make certain estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosures as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company bases its estimates on various factors, including historical experience, and on various other assumptions that are believed to be reasonable under the circumstances, when these carrying values are not readily available from other sources. Significant items subject to estimates and assumptions include useful lives of property and equipment, valuation of stock option, warrants and senior secured convertible notes measured at fair value, undiscounted cash flows used for an impairment testing of intangible assets, inventory losses and sales return. Actual results may differ from these estimates.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker (the "CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's Chief Executive Officer is the Company's CODM. The CODM reviews financial information prepared on the basis of accounting policy disclosed in its annual financial statement for purposes of making operating decisions, allocating resources, and evaluating financial performance of the Company. As such, the Company has determined that it operates as one operating segment.

The revenues from external customers or long-term assets are based or located in Taiwan.

Cash and Cash Equivalents

As of December 31, 2024 and 2023, cash and cash equivalents consist of cash on hand and cash in bank which is potentially subject to concentration of credit risk. Such balance is maintained at financial institutions that management determines to be of high-credit quality. Cash accounts at each institution are insured by the Federal Deposit Insurance Corporation in the U.S.A or Central Deposit Insurance Corporation in Taiwan up to certain limits. At times, such deposits may be in excess of the insurance limit. Accounts are guaranteed by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. As of December 31, 2024 and December 31, 2023, the Company had approximately $212,400 and $1,557,487 in excess of FDIC insured limits, respectively. The Company maintains cash in state-owned banks in Taiwan. In Taiwan, the insurance coverage of each bank is NTD$3,000,000 (approximately USD$91,505). As of December 31, 2024 and December 31, 2023, the Company had approximately $3,311,000 and $0 cash in excess of the insured amount, respectively. The Company has not experienced any losses in such accounts.

Allowances for Doubtful Accounts

The allowances for doubtful accounts represent management's best estimate of the expected future credit losses from the Company's accounts receivable. Determination of the allowances requires management to exercise judgment about the timing, frequency and severity of credit losses that could materially affect the provision for credit losses and, therefore, net loss. The Company regularly performs detailed reviews of its portfolios to determine if an impairment has occurred and evaluates the collectability of receivables based on a combination of various financial and qualitative factors that may affect customers' ability to pay. In circumstances where the Company is aware of a specific customer's inability to meet its financial obligations, a specific reserve is recorded against amounts due to reduce the recognized receivable to the amount reasonably expected to be collected. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional reserves would be required. The Company has not experienced significant customer payment defaults, or identified other significant collectability concerns at December 31, 2024 and 2023.

Inventory

Inventories are stated at the lower of cost or net realizable value. Cost including amounts related to materials, labor and overhead is determined on a weighted-average basis. Net realizable value is the estimated selling price in the ordinary course of business less reasonably predictable costs of completion, disposal, and transportation. The valuation of inventory requires management to estimate excess and obsolete inventory. Reserves for excess and obsolete inventory are primarily based on management's estimates of forecasted sales, usage levels and expiration dates. The Company records inventory loss for excess and obsolete inventory within cost of revenues.

Intangible Assets

Intangible assets, mainly consisting of patents are initially recorded at fair value and stated net of accumulated amortization and, if applicable, impairments. The Company amortizes its intangible assets that have finite lives using the straight-line method. Amortization is recorded over the estimated useful lives ranging from 5 to 19 years.

The Company evaluates the recoverability of its definite lived intangible assets together with property and equipment whenever events or changes in circumstances or business conditions indicate that the carrying value of these assets may not be recoverable based on expectations of future undiscounted cash flows for each asset group in accordance with ASC 360-10, *Property, Plant and Equipment—Impairment or Disposal of Long-Lived Assets* (ASC 360-10). If the carrying value of an asset or asset group exceeds its undiscounted cash flows, the Company estimates the fair value of the assets using market participant assumptions pursuant to ASC 820, *Fair Value Measurements*.

During the year end of 2024, the Company reassessed its short-term and long-term commercial plans for its VOC POCT related products which is identified as an asset group being assigned the major intangible assets and identified that an impairment testing is warranted for the intangible assets. As a result, the Company performed an undiscounted cash flow analysis pursuant to ASC 360-10 to determine if the cash flows expected to be generated by the VOC POCT products over the estimated remaining useful life of its primary assets were sufficient to recover the carrying value of the asset group. Based on this analysis, the undiscounted cash flows were sufficient to recover the carrying value of the long-lived assets. Thus, no impairment loss is needed.

To estimate the undiscounted cash flow of the asset group, the Company used assumptions requiring significant judgment, including judgment about when the in-development product can be commercialized, estimated selling price and sales volume of the in-development product and the amount and timing of other cash outflows required to complete the development, commercialization and sales of the product. The forecasted cash flows were based on the Company's most recent strategic plan and for periods beyond the strategic plan, the Company's estimates were based on assumed growth rates expected as of the measurement date. The Company believes its assumptions were consistent with the strategic plans and business goals.

Property and Equipment

Property and equipment are stated on the basis of historical cost less accumulated depreciation and impairment. Expenditures which materially increase value or extend useful lives of assets are capitalized, while maintenance and repairs which do not improve or extend the lives of the respective assets are charged to operations when incurred. Gains and losses on the retirement or disposal of individual assets are included in the results of operations. Depreciation is provided using the straight-line method over estimated useful lives of assets including 3 to 6 years for machinery and equipment and 2 to 5 years for furniture and fixture.

Fair Value Option

ASC 825-10, *Financial Instruments*, provides a fair value option (the "FVO") election that allows companies an irrevocable election to use fair value as the initial and subsequent accounting measurement attribute for certain financial assets and liabilities. ASC 825-10 permits entities to elect to measure eligible financial assets and liabilities at fair value on an ongoing basis. Unrealized gains and losses on items for which the FVO has been elected are reported in earnings, except for the effect of changes in own credit, which are recognized in other comprehensive income/loss. The decision to elect the FVO is determined on an instrument-by-instrument basis, must be applied to an entire instrument and is irrevocable once elected. Assets and liabilities measured at fair value pursuant to ASC 825-10 are required to be reported separately from those instruments measured using another accounting method.

The Company elected to account for the senior secured convertible notes issued to Lind Global Fund II LP (the "Lind Note") using FVO, which allows for valuing the Lind Note at fair value in its entirety versus bifurcation of the embedded derivatives (see Note 6). The fair value of the Lind Note is determined using a binomial lattice valuation model, which is widely used for valuing convertible notes. The significant assumption used in the model is volatility of the Company's common stock. If different assumptions are used, the fair value of the convertible notes and the change in estimated fair value could be materially different. A significant increase in the volatility of the market price of the Company's common stock, in isolation, would result in a significantly higher fair value; and a significant decrease in volatility would result in a significantly lower fair value.

Foreign Currency Translation

Assets and liabilities of a foreign entity whose functional currency is the local currency are translated to U.S. dollar at the exchange rate in effect at each balance sheet date. Before translation, the Company re-measures foreign currency denominated assets and liabilities into the functional currency of the respective entity, resulting in unrealized gains or losses recorded in the Statements of Operations. Revenues and expenses are translated using average exchange rates during the respective period. Foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income (loss), which is a separate component of stockholders' equity.

Revenue Recognition

The Company accounts for revenue pursuant to ASC 606, *Revenue from Contracts with Customer* (ASC 606) and generates revenue from the sale of its products, primarily VELDONA Pet supplements in Taiwan.

The Company considers revenue to be earned when all of the following criteria are met: the Company has a contract with a customer that creates enforceable rights and obligations; promised products or services are identified; the transaction price, or the amount the Company expects to receive, including an estimate of uncertain amounts subject to a constraint to ensure revenue is not recognized in an amount that would result in a significant reversal upon resolution of the uncertainty, is determinable; and the Company has transferred control of the promised items to the customer. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in the contract. The transaction price for the contract is measured as the amount of consideration the Company expects to receive in exchange for the goods and services expected to be transferred. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, control of the distinct good or service is transferred. Transfer of control for the Company's products is generally at shipment or delivery, depending on contractual terms. As such, the Company has one performance obligation related to product sales which is satisfied at a point in time.

The Company recognizes a receivable when it has an unconditional right to payment. Payment terms are typically 30 to 60 days based on the contractual term.

Shipping and Handling Costs

Shipping and handling costs represent those costs incurred in operating and staffing fulfillment, including costs attributable to receiving, inspecting, picking, packaging, and preparing customer orders for shipment, and outbound freight costs associated with shipping orders to customers. Shipping generally occurs prior to the transfer of control to the customer and is therefore accounted for as a fulfillment expense. Shipping and handling fees billed to the customers are recorded as revenue.

Research and Development

Costs incurred for the research and development (the "R&D") of the Company's products are expensed as incurred. Clinical trial costs incurred by third parties are expensed as the contracted work is performed. Nonrefundable advance payments for goods or services to be received in the future by the Company for use in R&D activities are deferred. The deferred costs are expensed as the related goods are delivered or the services are performed.

Advertising Costs

Costs associated with the Company's advertising is expensed as incurred and are included in selling, general and administrative expenses in the Statements of Operations, which is comprised primarily of print and internet advertising fees.

General and Administrative

General and administrative expenses mainly include compensation costs, share-based compensation expense and professional service fees.

Share-Based Compensation

Share-based compensation expense is recorded in accordance with ASC 718, *Compensation – Stock Compensation*, for stock, RSUs and stock options awarded in return for services rendered. The expense is measured at the grant-date fair value of the award and recognized as compensation expense on a straight-line basis over the service period, which is the vesting period.

The Company has adopted the simplified method to account for forfeitures of employee awards as they occur and as a result, the Company records compensation cost assuming all grantees will complete the requisite service period. If an employee forfeits an award because they fail to complete the requisite service period, the Company will reverse compensation cost previously recognized in the period the award is forfeited.

Fair Value of Financial Instruments

The fair value of financial instruments is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company measures financial instruments at fair value at each reporting period using a fair value hierarchy that requires to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's classification within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Three levels of inputs may be used to measure fair value:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
Level 2 - Other inputs that are directly or indirectly observable in the marketplace.
Level 3 - Unobservable inputs that are supported by little or no market activity.

The carrying value of cash and cash equivalents, accounts receivable, accounts payable, convertible notes payable, current, and other notes payable, current, approximate their fair value because of their short-term nature. The carrying value of long-term debt related to noncurrent convertible notes payable, other notes payable and accrued interest expense approximates its fair value after calculating present value at observable market interest rate.

In addition, the Company elected FVO to measure the senior secured convertible notes using Level 3 inputs on issuance and at each reporting date. Significant unobservable inputs used in the binominal lattice valuation model is the expected volatility of the Company's common stock. The use of different assumptions and/or estimation methodologies could have a material effect on the estimated fair values. The following table sets forth a reconciliation of senior secured convertible notes measured as Level 3 financial instrument:

	December 31, 2024	December 31, 2023
Beginning of year	$ 2,651,556	$ -
Issue	875,000	3,000,000
Conversion into common stock	(2,441,691)	(254,237)
Change in fair value	275,624	(94,207)
Retirement in fair value	(1,360,489)	-
End of year	$ -	$ 2,651,556

Interest Expense

The company recorded interest expense based upon interest rates and maturities of current and noncurrent debt (see Note 6).

Interest Income

The company recorded interest income based on interest earned on the cash and cash equivalents.

Income Taxes

The asset and liability approach is used to account for income taxes by recognizing deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized.

The Company recognizes a tax benefit from uncertain tax positions only if it is more likely than not that the position is sustainable, based solely on its technical merits and consideration of the relevant taxing authorities' administrative practices and precedents. The tax benefits recognized from such positions are measured based on the largest benefit that has a greater than 50% likelihood of being recognized upon settlement. The Company did not recognize any tax benefits from uncertain tax positions during the years ended December 31, 2024 and 2023. The Company recognizes tax-related interest and penalties, if any, as a component of income tax expense.

Net Loss Per Common Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since the effect of potentially dilutive securities is anti-dilutive given the net loss of the Company.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. ASU 2023-07, which is applicable to entities with a single reportable segment, will primarily require enhanced disclosures about significant segment expenses and enhanced disclosures in interim periods. The guidance in ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023 and interim reporting periods in fiscal years beginning after December 31, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-07 will have on its financial statements and disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. ASU 2023-09 is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The guidance in ASU 2023-09 will be effective for annual reporting periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating the impact that the adoption of ASU 2023-09 will have on its financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented on the statement of operations. The guidance in this ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its financial statements and disclosures.

3. Inventory, net

Inventory stated at cost, net of reserve, consisted of the following:

	December 31,	
	2024	2023
Raw materials	$ 74,875	$ 92,708
Work in process	1,131	1,208
Finished goods	67,750	73,677
Total	$ 143,756	$ 167,593

Inventory related to COVID-19 POCT write-downs to estimated net realizable values and excess and obsolete inventory loss were nil and $235,047 for the years ended December 31, 2024, and 2023, respectively.

As of December 31, 2024 and 2023, the inventory consisted of $143,756 and $167,593, related to the Company's product VELDONA Pet supplements.

4. Intangible assets, net

Intangible assets are stated at cost less accumulated amortization, and consist of the following at December 31, 2024 and 2023:

	December 31,	
	2024	2023
Patents acquired	$ 39,143,975	$ 39,143,975
Others	227,013	227,009
Total cost	39,370,988	39,370,984
Less: accumulated amortization	(15,622,660)	(11,087,776)
Intangible assets, net	$ 23,748,328	$ 28,283,208

Amortization expense for the years ended December 31, 2024 and 2023 was $4,534,729 and $4,523,516, respectively. No impairment loss was recorded in 2024 and 2023.

Estimated future amortization expense is as follows:

2025	$ 4,522,377
2026	4,522,232
2027	4,521,505
2028	4,533,858
2029	1,926,411
Thereafter	3,721,945
Total expense	$ 23,748,328

5. Property and Equipment, net

Property and equipment are stated at cost less accumulated depreciation and impairment, and consist of the following at December 31, 2024 and 2023:

	December 31,	
	2024	2023
Machinery and equipment	$ 1,046,534	$ 1,137,352
Furniture and fixture	636,939	669,502
Total cost	1,683,473	1,806,854
Less: accumulated depreciation and impairment	(1,123,828)	(930,282)
Property and equipment, net	$ 559,645	$ 876,572

Depreciation expense for the years ended December 31, 2024 and 2023 was $252,548 and $328,938, respectively.

The Company charged nil and $286,777 of impairment loss to the equipment related to COVID-19 POCT and classified it to the research and development expenses for the years ended December 31, 2024 and 2023, respectively.

6. Debts

The Company issued promissory notes to creditors for funding. As of December 31, 2024 and 2023, the details of the notes are as follows:

	December 31,	
	2024	2023
Other notes payable, related party – current	$ -	$ 42,000
Other notes payable, related party – noncurrent (KY Note)	-	270,000
March 2025 Convertible Notes, related party – noncurrent (ASE Note)	-	2,000,000
March 2025 Convertible Notes, related party – current (ASE Note)	2,000,000	-
March 2025 Convertible Notes – noncurrent (Lee Note)	-	1,000,000
March 2025 Convertible Notes –current (Lee Note)	1,000,000	-
May 2027 Convertible Notes, related party – noncurrent (ASE Note)	9,000,000	-
Senior secured convertible notes payable (Lind Note) – at fair value	-	2,651,556
	$ 12,000,000	$ 5,963,556

The other notes payable was issued to Ainos KY in exchange for $800,000 in cash to support working capital of the Company in March 2022 (the "KY Note"). The Company paid off $530,000 of the KY Note during the year ended December 31, 2023 and $270,000 with accrued interest of the KY Note during the year ended December 31, 2024.

Another note payable was issued to i2China Management Group, LLC ("i2China") in exchange for consulting services in 2020 (the "i2China Note"). The Company paid off $42,000 with accrued interest of the i2China Note during the year ended December 31, 2024.

Both the KY Note and the i2China Note bear an interest rate of 1.85% per annum.

May 2027 Convertible Notes and Warrant Purchase Agreement

On May 3, 2024, The Company entered into Convertible Note and Warrant Purchase Agreement with the ASE Test, Inc. ("ASE"), a shareholder of Ainos KY, for the issuance of convertible promissory notes with 6% compound interest in the aggregate principal amount of $9,000,000 (collectively the "Notes") convertible into shares of common stock, par value $0.01 per share, of the Company, payable three (3) years from May 3, 2024 as well as the issuance of warrants for the purchase of up to 500,000 shares of common stock at a price per share of $4.50, exercisable until May 3, 2029. As of December 31, 2024, the Company received the full amount of the payment

March 2025 Convertible Notes

On March 13, 2023, the Company entered into two convertible promissory note purchase agreements pursuant to Regulation S of the Securities Act of 1933, as amended, in the total principal amount of $3,000,000 with the following investors (the "March 2025 Convertible Notes" or "Notes").

Convertible Note Issued to ASE Test, Inc. (the "ASE Note")

Pursuant to the one of the aforementioned agreements, ASE Test, Inc. (the "ASE"), a shareholder of Ainos KY, committed to pay a total aggregate amount of $2,000,000 to the Company in exchange for convertible promissory note(s) in three tranches in the amounts of $1,000,000 (the "First Tranche"), $500,000 (the "Second Tranche"), and $500,000 (the "Third Tranche") conditioned, among other things, on the Company achieving certain business milestones. As of December 31, 2024, the Company received the full amount of the payment.

Convertible Note Issued to Li-Kuo Lee (the "Lee Note")

The Company issued a convertible note in the principal amount of $1,000,000 to an unrelated party, Li-Kuo Lee, in exchange of $1,000,000 in cash. As of December 31, 2024, the full amount of the payment was received.

The March 2025 Convertible Notes will mature in two years from the issuance dates, bearing interest at the rate of 6% compounded interest per annum. At any time after the issuance and before the maturity date, the Notes are convertible into the common stock of the Company at the conversion price of $7.50 per share, subject to anti-dilutive adjustment as set forth in the Notes. Unless previously converted, the Company shall repay the outstanding principal amount plus all accrued and unpaid interest on the maturity date. The Notes shall be an unsecured general obligation of the Company.

The total interest expense of convertible notes payable, other notes payable and March 2025 Convertible Notes for the years ended December 31, 2024 and 2023, were $533,405 and $132,843, respectively, among which were with related party for amounts of $470,373 and $83,622, respectively. As of December 31, 2024 and 2023, the unpaid accrued interest expense was $651,268 and $138,939, respectively, among which $341,753 and $135,829 was long-term liabilities, respectively. Among the unpaid accrued interest expense, $540,039 and $90,743, respectively, was with related party as of December 31, 2024 and 2023.

Senior Secured Convertible Notes Payable

On September 25, 2023, the Company entered into a securities purchase agreement (the "SPA") with Lind Global Fund II LP (the "Lind"). The SPA provides for loans in an aggregate amount of up to $10,000,000 under various tranches to fund clinical trials, commercial product launch and working capital of the Company. On September 28, 2023, the initial closing date, the Company issued and sold to Lind, in a private placement, (a) a senior secured convertible promissory note in the aggregate principal amount of $2,360,000 (the "Lind Note") and (b) warrants to purchase 460,829 shares of common stock at an exercise price of $4.50 per share of common stock (the "Lind Warrant") for a cash amount of $2,000,000.

On December 21, 2023, an additional $1,000,000 was drawn down after certain conditions were met. The aggregate principal amount of the Lind Note was increased to $3,540,000 and the shares of common stock Lind Warrant can purchase was increased to 691,244 shares.

On January 23, 2024, the Company received an Increased Funding Amount of up to $1.75 million, with $875,000 funded at closing and $875,000 to be funded subject to an effective registration statement and other conditions specified in the Securities Purchase Agreement, and amended the Initial Note to, among other amendments, increase the principal amount to $4,235,000 (the Initial Note as so amended, the "Note"). In connection with additional funding, the Company issued Lind a warrant to purchase 1,021,400 shares at an exercise price of $2.16 per share (the "Second Lind Warrants and together with the First Lind Warrants, the "Lind Warrants").

The Lind Note does not bear any interest and matures on March 28, 2025.

Following the earlier to occur of (i) 90 days from the date of the SPA or (ii) the date the resale Registration Statement is declared effective by the SEC, the Lind Note is convertible into shares of the Company's common stock at the option of Lind at any time with the conversion price at lower of $7.50 per share, subject to adjustment, or 90% of stock price as defined in the SPA. Under certain conditions as defined in the SPA, the Company can prepay the note at 105% of the outstanding principal amount or Lind can put back the note at 105%, when there is a change of control, or 120%, when there is an event of default, of the outstanding principal amount, etc.

On August 2, 2024, the Company retired its remaining senior secured convertible debt (the "Note") with Lind Global Fund II LP, an institutional investment fund managed by The Lind Partners (together the "Investor"), as a result of conversions by the Investor and payments by the Company, which aggregates at a total of approximately US$1.67 million. The repayment was made with $1,439,754 in cash and $224,842 through the issuance of 382,384 shares of Common Stock, valued at $0.588 per share.

During the year ended December 31, 2024, the Company issued an aggregate of 3,233,655 shares of its common stock upon the conversions of senior secured convertible notes payable at the conversion price from $0.588 to $1.848 per share.

From an accounting perspective, the Lind Note is considered a debt host instrument embedded with an issuer's call and investor's contingent puts, and is issued at substantial discount. The Company elects the fair value option (the "FVO") to account for the Lind Note at fair value and mark to market each quarter. For the year ended December 31, 2024, the change in the fair value of the Lind Note was recorded in the Statements of Operations in the amount $275,624. No portion of the change in fair value was related to changes in credit risk of the Company which would be charged to other comprehensive loss if any. The Company has granted to Lind a senior security interest in all of the Company's right, title, and interest in, to and under all of the Company's property, subject to certain exceptions as set forth in the SPA. The issuance cost including a commitment fee charged by Lind, placement agent fee and warrants, and legal fees is $308,336, which is expensed off due to FVO election.

7. Stockholders' Equity

Preferred Stock

The Company increased authorized shares of preferred stock from 10,000,000 shares to 50,000,000 shares upon the filing of an amendment to the Company's Certificate of Formation with the Secretary of State of Texas on November 27, 2023. No shares of preferred stock were issued and outstanding as of December 31, 2024 and 2023.

Common Stock

Holders of common stock are entitled to one vote per share, and to receive dividends and, upon liquidation or dissolution, are entitled to receive all assets available for distribution to stockholders.

The Company has 300,000,000 shares of common stock authorized for issuance at par value of $0.01. As of December 31, 2024, 15,427,385 shares of common stock were issued and a total of 8,130,609 shares were reserved for conversion of convertible notes (2,831,472 shares), warrants issued to investors or in connection with funding's (1,909,810 shares), share-based compensation awards (1,855,697 shares) and ATM reserved (1,533,630 shares).

The Company issued 247,500 shares of common stock to officers, and employees for achieving non-financial milestones or for on-boarding bonuses. The fair value of the special stock bonus was $88,996 based on the closing price of the common stock at the date of major shareholder approval was obtained and was recorded immediately as selling, general and administrative and research and development expenses in the Statements of Operations as no future service is required.

Public Offering of Common Stock and Warrants

The Company completed its public offering (the "Offering") of an aggregated 780,000 units at a price of $4.25 per unit on August 9, 2022. Each unit issued in the Offering consisted of 0.2 share of common stock and one unit of warrant to purchase 0.2 share of common stock of the Company at a price of $21.25 per share (the "Public Warrants"). In addition, the Company issued its underwriters a 45-day over-allotments option to purchase up to an additional 23,400 shares of common stock and/or up to an additional 117,000 units of Public Warrants at the public offering price. The underwriters exercised its option to purchase an additional 117,000 units of Public Warrants at $0.01 per unit for a total cash proceeds of $1,170. The Company received aggregate net proceeds of approximately $1.78 million after deducting direct offering cost of approximately $1.54 million including underwriting commissions and legal fees.

The Public Warrants may be exercised from February 5, 2023 (181 days from the effective date of the Company's S-1 Registration Statement made effective August 8, 2022, hereafter "Registration Date") to August 8, 2027 (5 years from the Registration Date). The fair value of the Public Warrants was around $3.28 million and was determined using the Black-Scholes option pricing model with the assumptions: $18.30 of stock price, $21.25 of strike price, 5-year expected term, 277% of expected volatility, 0% of expected dividend rate and 2.97% of risk-free interest rate.

On August 11, 2022, the Company agreed to issue to the representative of the underwriters warrants to purchase up to a total of 7,800 shares of common stock (the "Representative's Warrants") pursuant to an underwriting agreement. The Representative's Warrants are exercisable at $23.375 per share, are initially exercisable 180 days after the effective date of the Offering and have a term of five years from their initial exercise date. The fair value of the Representative's Warrants was around $107 thousands which was recorded in the additional paid-in capital and was determined using the Black-Scholes option pricing model with the assumptions: $13.75 of stock price, $23.375 of strike price, 5-year expected term, 304% of expected volatility, 0% of expected dividend rate and 2.91% of risk-free interest rate.

The direct issue cost paid in cash of $1.54 million together with the cost of the Representative's Warrants was allocated based on the relative fair value of common stocks issued for the Offering and the Public Warrants, and was recorded as a reduction to the additional paid-in capital.

Upon completion of the Offering, convertible notes outstanding in the principal amount of $30.4 million and accrued interest of $42,959 were automatically converted into 1,814,627 shares of common stock in 2022 August.

Warrants

As of December 31, 2024 and 2023, warrants issued and outstanding in connection with financing are summarized as below:

	December 31,	
(In number of shares of common stock to purchase when warrants exercised)	**2024**	**2023**
Lind Warrant with exercise price of from $2.16 to $4.50	1,201,944	691,244
Public Warrants with exercise price of $21.25	179,400	179,400
Representative's Warrants with exercise price of $23.375	7,800	7,800
Placement agent warrant with exercise price of $8.25	20,666	16,000
ASE Warrant with exercise price of $4.50	500,000	-
Total	1,909,810	894,444

As discussed in Note 6, the Company issued the Lind Warrant on September 28, 2023, December 21, 2023, and January 23, 2024 in connection with the private placement of the Lind Note. The Company total issued 20,666 shares of warrants with an exercise price of $8.25 per share to the placement agent as the agent fee. Each warrant has a contractual term of 5 years and can be exercised for the purchase of one share of common stock of the Company. The carrying amount of the Lind Warrant is nil after allocating proceeds to the Lind Note measured at fair value. The fair value of the placement agent warrant is estimated as $21,479 using the Black-Scholes Model.

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the instruments' specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*. The assessment considers whether the instruments are free standing financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the instruments meet all of the requirements for equity classification under ASC 815, including whether the instruments are indexed to the Company's own common shares and whether the instrument holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of

professional judgment, is conducted at the time of warrant issuance and as of each subsequent period end date while the instruments are outstanding. Management has concluded that the warrants issued in connection with the underwritten public offering and the private placement of Lind Note qualify for equity accounting treatment and are recorded as additional paid-in capital.

As of December 31, 2024, none of the warrants have been exercised nor have expired. The remaining contractual life of the warrants was 2.78 years as of December 31, 2024.

Dividends

The Company has never declared or paid, and does not anticipate declaring or paying, any cash dividends on any of its capital stock. The Company does not anticipate paying any dividends in the foreseeable future, and currently intends to retain all available funds and any future earnings for use in the operation of the business, to finance the growth and development and for future repayment of debt. Future determinations as to the declaration and payment of dividends, if any, will be at the discretion of the Company's board of directors and will depend on then-existing conditions, including operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors of the Company that the board of directors may deem relevant.

8. Revenue

The Company started to manufacture and deliver VELDONA Pet supplements to on-line and off-line distribution channels beginning the third quarter of 2023. Revenue from sales through on-line platform were recognized after the expiration of right of return which was offered for a limited time. Revenue from sales through off-line distribution channels was recognized only to the extent that the product sold was not expected to be returned.

$106,329 and $112,555 of contract liabilities were recorded for the cash received in advance from distribution channels as of December 31, 2024 and 2023, respectively.

Revenue recognized during the year ended December 31, 2024 and 2023 that was included in the contract liability balance at the beginning of each year were nil.

9. Share-Based Compensation

2023 Stock Incentive Plan

The Company effectuated an amendment to its 2021 Stock Incentive Plan, now restated as the Company 2023 Stock Incentive Plan (the "2023 SIP" or "Plan") which includes, among other things, a change in the number of reserved shares under the Plan. Under the 2023 SIP, subject to a change in capital structure or a change in control, the aggregate number of shares which may be issued or transferred pursuant to awards under the Plan will be equal to up to twenty percent (20%) of shares of outstanding common stock of the Company existing as of December 31st of the previous calendar year (the "Plan Share Reserve"). Upon the effectiveness of the 2023 SIP on February 16, 2023, the aggregate number of shares which may be issued pursuant to awards under the Plan is 871,075 shares of common stock, including shares that remained available for grant under the 2021 Stock Incentive Plan. On July 19, 2024, the Company filed Form S-8 to increase the aggregate number of shares may be issued to 946,432 shares of common stock including shares that remained available for grant under the 2021 Stock Incentive Plan. As of December 31, 2024, 1,816,632 shares have been granted under the 2023 SIP.

2021 Stock Incentive Plan

On June 20, 2022, the Company's 2021 Stock Incentive Plan (the "2021 SIP") was effective following an approval by its shareholders. The 2021 SIP seeks to attract and retain key personnel, and to strengthen the commitment of the Company's directors, officers, employees, consultants and advisors by making available equity interests in the Company or compensation measured by reference to the value of Company's common stock. The 2021 SIP provides for the issuance of up to 266,666 shares of the Company's common stock pursuant to equity awards, including options, stock appreciation rights and restricted stock units. No shares were granted or issued under the 2021 SIP.

2021 Employee Stock Purchase Plan

On June 20, 2022, the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP") was effective following an approval by its shareholders. The 2021 ESPP provides eligible employees (as such term is defined in the ESPP) with an opportunity to purchase common stocks of the Company at a discount through voluntary contributions and is intended to qualify as an employee stock purchase plan under Section 423 of the U.S. Internal Revenue Code of 1986, as amended. A total of 10,000 shares of common stock have made available for issuance under the ESPP. As of December 31, 2024, the total remain 10,000 shares were issued under the 2023 SIP.

Based on the aforementioned plans, the Company will issue new shares upon option exercise or shares vested.

Restricted Stock Units ("RSUs")

RSUs entitle the recipient to be paid out an equal number of common stock shares upon vesting which is generally 3 years. The fair value of RSUs is based on the closing price of the underlying stock on the date of grant. A summary of the Company's RSUs activity and related information for the years ended December 31, 2024 and 2023 is as follows:

	For the Year Ended December 31,			
	2024		2023	
	Number of Shares	Weighted-Average Grant Date Fair Value Per Share	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Unvested balance at January 1	954,306	$ 4.39	160,000	$ 12.08
RSUs granted	946,432	$ 0.53	870,200	$ 3.46
RSUs vested	(1,768,443)	$ 2.31	(44,680)	$ 13.11
RSUs forfeited	(42,464)	$ 2.75	(31,214)	$ 5.28
Unvested balance at December 31	89,831	$ 5.51	954,306	$ 4.39

Stock Options and Warrants

A summary of option activity for the years ended December 31, 2024 and 2023 is presented below.

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2022	7,332	$ 28.50	8.3	-
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited or expired	-	-	-	-
Outstanding at December 31, 2023	7,332	$ 28.50	7.3	-
Granted	-	-	-	-
Exercised	-	-	-	-
Forfeited or expired	-	-	-	-
Outstanding at December 31, 2024	7,332	$ 28.50	6.3	-
Vested or expected to vest at December 31, 2024	7,332	$ 28.50	6.3	-
Exercisable at December 31, 2024	7,332	$ 28.50	6.3	-

As of December 31, 2024, 6,034 shares of warrants which were granted to i2China Management Group, LLC in November 2020 were outstanding and remained unexercised. The warrants were fully vested and exercisable as of December 31, 2024. The exercise price of the warrant is $19.88 with remaining contractual term in 0.9 years.

The Company used the Black-Scholes option pricing model to value the above option and warrant awards to determine the grant date fair value. The contractual term of the option and warrant is 10 years and 5 years, respectively.

Share-Based Compensation

The RSUs, options and warrants (the "Awards") were granted to employees and consultants with service conditions. The share-based compensation expense of the Awards for the years ended December 31, 2024 and 2023 were $3,543,101 and $1,114,767, respectively.

	For the Year Ended December 31,	
	2024	2023
Selling, general and administrative expenses	$ 2,728,852	$ 875,509
Research and development expenses	805,217	220,723
Cost of revenues	9,032	18,535
Total	$ 3,543,101	$ 1,114,767

The total income tax benefit recognized in the Statements of Operations for the share-based compensation arrangements were nil for the years ended December 31, 2024 and 2023. Compensation cost capitalized as part of inventory has been minimal.

As of December 31, 2024, the total unrecognized compensation cost related to the Awards was $188,741, which is expected to be recognized over a weighted-average period of 1.42 years. The total fair value of shares vested during the years ended December 31, 2024 and 2023 was $4,242,956 and $745,706, respectively.

10. Income Taxes

The components of the provision (benefit) for income taxes consist of the following:

	For the Year Ended December 31,	
	2024	2023
Current federal taxes	$ -	$ -
Current state taxes	800	800
Current tax provision	800	800
Deferred tax provision	129,000	1,573,000
Change in valuation allowance	(129,000)	(1,573,000)
Total income tax expense provision	$ 800	$ 800

A reconciliation of the statutory tax rates to the effective tax rates applicable to the Company is as follows:

	For the Year Ended December 31,	
	2024	2023
Statutory federal income tax rate	21%	21%
Permanent differences	(1)%	0%
Deferred adjustment	(4)%	(5)%
State income tax expense	0%	0%
Change in valuation allowance	(16)%	(16)%
Effective income tax rate	0%	0%

The components of the Company's deferred tax asset and liabilities are as follows:

	December 31,	
	2024	2023
Deferred tax assets (liabilities)		
Net operating loss carry forwards	$ 6,911,000	$ 7,394,000
Amortization	1,426,000	1,025,000
Depreciation	23,000	28,000
Capitalized research and development	611,000	290,000
Share-based compensation	119,000	232,000
Other temporary differences	54,000	46,000
Total deferred tax assets	9,144,000	9,015,000
Depreciation	-	-
Total deferred tax liabilities	-	-
Valuation allowance	(9,144,000)	(9,015,000)
Net deferred tax assets	$ -	$ -

The asset and liability approach is used to account for income taxes by recognizing deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. The Company has a valuation allowance against the full amount of its net deferred tax assets due to the operating loss history of the Company. The effect of a change in tax rates or laws on deferred tax assets and liabilities is recognized in operations in the period that includes the enactment date of the rate change.

As of December 31, 2024, the Company had U.S. federal net operating loss carryforwards of approximately $32,910,800. The federal net operating loss carryforwards generated through December 31, 2018 of $12,402,700 will expire in 2025 through 2038, while $20,508,100 of federal net operating loss carryforwards generated in post December 31, 2017 or later do not expire due to the provisions in the Tax Cuts and Jobs Act, but may only offset 80% of taxable income in periods of future utilization. The state net operating loss carryovers has been immaterial.

The Company files returns with the U.S. federal government, and various state jurisdictions. The Company's returns have been, and could in the future, subject to examination which may, or may not, have an impact to the financial statements.

11. Net Loss per Common Share

The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders:

	For the Year Ended December 31,	
	2024	2023
Net loss attributable to common stockholders, basic and diluted	$ (14,863,161)	$ (13,770,549)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted	9,503,618	4,098,109
Net loss per share attributable to common stockholders, basic and diluted	$ (1.56)	$ (3.36)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding because they would be anti-dilutive:

	For the Year Ended December 31,	
	2024	2023
Option and RSUs to purchase common stock	97,163	961,638
Special Stock Award	1,752,500	-
Warrants to purchase common stock	1,915,844	900,478
Convertible notes to purchase common stock	2,517,211	2,197,573
Total potential shares	6,282,718	4,059,689

12. Related Party Transactions

During the years ended December 31, 2024 and 2023, other than disclosed elsewhere, the Company had the following material related party and related party transactions:

Related Party

Controlling shareholders

Taiwan Carbon Nano Technology Corporation (the "TCNT") is the controlling shareholder of the Company through its controlling interests in Ainos KY who is an immediate controlling shareholder of the Company as of December 31, 2024. The Company acquired the POCT intellectual properties from Ainos KY. TCNT manufactures COVID-19 antigen test kits sold by the Company and has a product development agreement with the Company. The Company relies on TCNT to manufacture or develop POCT products and has a concentration risk on the sole supplier.

Entity under common control

AI Nose Corporation, a wholly owned subsidiary of Ainos KY is under common control with the Company.

Related Party Transactions

Purchase

Ainos COVID-19 Test Kits Sales and Marketing Agreement with Ainos KY

On June 14, 2021, the Company entered into an exclusive agreement with Ainos KY to serve as the master sales and marketing agent for the Ainos COVID-19 Antigen Rapid Test Kit and COVID-19 Nucleic Acid Test Kit which were developed and manufactured by TCNT, a controlling shareholder of Ainos KY (the "Sales and Marketing Agreement"). On June 7, 2021, the Taiwan Food and Drug Administration (the "TFDA") approved emergency use authorization (the "EUA") to TCNT for the Ainos COVID-19 Antigen Rapid Test Kit sold and marketed under the "Ainos" brand name in Taiwan. On June 21, 2022, the Company began marketing the Ainos SARS-CoV-2 Antigen Rapid Self-Test (together with Ainos COVID-19 Antigen Rapid Test Kit, the "COVID-19 Antigen Rapid Test Kits") under a separate EUA issued by the TFDA to TCNT on June 13, 2022.

The Company incurred costs associated with manufacturing COVID-19 Antigen Rapid Test Kits by TCNT pursuant to the Sales and Marketing Agreement, totaling nil and $46,635 for the years ended December 31, 2024 and 2023, respectively.

Due to the expiration of EUA to TCNT, excess materials, supplies and mode purchased by TCNT were sold back to the Company. As a result, the Company absorbed $33,002 of losses which was recorded in the cost of revenues of 2023.

Manufacturing Service Agreement with TCNT for the VELDONA Pet Supplements

On August 28, 2023, the Company entered into a manufacturing service agreement with TCNT, together with another third-party vendor, to manufacture pet supplement products. The Company incurred costs totaling nil and $38,860 for the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024 and 2023, the accounts payable to TCNT for the above two products were nil and $323, respectively.

Product Development Agreement with TCNT

Pursuant to a five-year Product Development Agreement (the "Product Development Agreement") with TCNT, effective August 1, 2021, the development expenses incurred were $413,324 and $368,372 for the years ended December 31, 2024 and 2023, respectively.

On January 9, 2024, the Company and TCNT entered into an addendum to the Product Development Agreement (the "Addendum Agreement") in connection with the scope of co-development and certain terms. For products defined in the Addendum agreement, TCNT will provide facilities, equipment, mass production process technology, ISO9001 and ISO13485 related management, as well as mass production support. The procurement of parts and raw materials, rental fees, and utility expenses are excluded. The Company paid a total fee of NT$5 million (approximately USD$162,840) for a five-years development commencing from January 2024. The Company prepaid the full amount of the fee on January 10, 2024 at TCNT's request.

As part of the Second Addendum Agreement entered on July 8, 2024, TCNT provided non-exclusive use of certain patents related to VOC and POCT technologies for a monthly fee of $95,000 (plus 5% indirect tax), with negotiable payment terms for extend another three months from July 2024 to September 2024.

As part of the Third Addendum Agreement entered into on October 16, 2024 the Company entered an Addendum Agreement with TCNT. TCNT will provide exclusive use of certain patents related to VOC, POCT and nitrogen-oxygen separation machine technologies for a monthly fee of $50,000 (plus 5% indirect tax) for twelve months from October 16, 2024, with negotiable payment terms.

As of December 31, 2024, the Company has paid $1,005,000 (plus 5% indirect tax) of license fee to TCNT.

Patent license agreement

On August 6, 2024, the Company entered into a patent license agreement (the "License Agreement") with TCNT, as an effort to bolster the Company's AI Nose and point-of-care testing (POCT) technologies while preserving cash. As of August 5, 2024, prior to TCNT entering into the License Agreement, TCNT controlled, via its majority interest in Ainos Inc., a Cayman Islands corporation ("Ainos KY") which is a party to certain previously disclosed Voting Agreements, approximately 38% of the voting power of the Company. Pursuant to the License Agreement, TCNT has agreed to assign and grant, and the Company

has agreed to accept, an exclusive, irrevocable, and perpetual license of certain invention patents and patent applications related to gas sensors and medical devices (the "Licensed Patents"), in exchange for 5,500,000 shares of the Company's common stock (the "Common Stock"), at a price per share of 1.05 times the highest closing sale price of the Common Stock during the 30-trading day period preceding the effective date of the License Agreement. The License Agreement shall remain in effect until terminated by mutual written agreement of the parties, or until the expiration of the Licensed Patents, or all claims for alleged infringement of the Licensed Patents are barred by applicable laws. Following the issuance of the 5.5 million shares of stock, TCNT controls the company through its majority interest in Ainos KY, and its direct ownership in the Company.

Product sales

COVID-19 Antigen Rapid Test Kits Sales

The Company sold COVID-19 Antigen Rapid Test Kits to ASE's affiliates, totaling nil and $33,388 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, the accounts receivable was nil.

Miscellaneous

On April 26, 2023, the Company issued a total of 12,231 shares of common stock to Ting-Chuan Lee, a director of the Company, pursuant to a purchase and sale agreement relating to the Company's acquisition of a vehicle. The purchase price was in the amount of $48,559.

The Company engaged Ms. Chien-Hsuan Huang as a medical device development consultant in September 2022 for one year. Ms. Huang is the spouse of one of the members of the board of directors of the Company. The R&D expense was nil and $51,143 for the years ended December 31, 2024 and 2023, respectively.

13. Commitments and Contingencies

The Company operates in an industry characterized by extensive patent litigation. Competitors may claim that the Company's products infringe upon their intellectual property. Resolution of patent litigation or other intellectual property claims is typically time consuming and costly and can result in significant damage awards and injunctions that could prevent the manufacture and sale of the affected products or require the Company to make significant royalty payments in order to continue selling the affected products. As of December 31, 2024, there were no such commitments or contingencies.

The Company has entered into agreements to purchase goods or services that are enforceable and legally binding on the Company and that specify all significant terms, including fixed or minimum quantities to be purchased, fixed, minimum or variable price provisions and the approximate timing of the transaction. As of December 31, 2024, there is no purchase obligations exclude agreements that are cancellable at any time without penalty.

The company record for the cash received in advance $106,329 as contract liabilities from distribution channels, the company will expect to realize the revenue in the first quarter of year 2025, however, there can be adjusted due to the company's strategy.

14. Subsequent Events

Nasdaq Deficiency Notice

On January 17, 2025 the company received written notification (the "Written Notification") from the Listing Qualifications Department of the Nasdaq Stock Market LLC ("Nasdaq") that the Company is eligible for a 180-day extension to regain compliance with the $1.00 minimum bid price requirement under Nasdaq Listing Rule 5550(a)(2) (the "Rule").

As previously reported, on July 15, 2024, the Company received a deficiency letter from the 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 the Rule and the Company had been given 180 calendar days, or until January 13, 2025, to regain compliance with the Rule. Pursuant to the Written Notification, the Company now has until July 14, 2025 to meet the minimum bid price requirement.

The Written Notification has no immediate effect on the listing or trading of the Company's shares, which will continue to trade on the Nasdaq Capital Market.

EXHIBIT 4.7

DESCRIPTION OF SECURITIES

Ainos, Inc. (the "Company," "we," "us" or "our") has two classes of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock, par value $0.01 per share, and warrants to purchase common stock (the "Warrants").

General

Our authorized capital stock consists of 300,000,000 shares of common stock, par value $0.01 per share, and 50,000,000 shares of preferred stock, par value $0.01 per share. As of March 7, 2025, there were 15,433,257 shares of our common stock issued and outstanding. No shares of preferred stock have been issued or are outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by the Board out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. In the event of our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all of our debts and other liabilities, subject to the liquidation preferences of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. All outstanding shares of our common stock are fully paid and non-assessable.

Warrants

The Warrants entitle the registered holders to purchase common stock at a price of $21.25 per share after giving effect to the 1:5 Reverse Stock Splits, subject to adjustment as discussed below, immediately following the issuance of such Warrants and terminating at 5:00 p.m., New York City time.

The exercise price and number of shares of common stock issuable upon exercise of the Warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation. However, the Warrants will not be adjusted for issuances of shares of common stock at prices below its exercise price.

Exercisability. The Warrants are exercisable immediately upon issuance and at any time up to the date that is five years from the date of issuance. The Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of common stock purchased upon such exercise. Each Warrant entitles the holder thereof to purchase one share of common stock. Warrants are not exercisable for a fraction of a share and may only be exercised into whole numbers of shares. In lieu of fractional shares, we will, pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price and round down to the nearest whole share. Unless otherwise specified in the Warrant, the holder will not have the right to exercise the Warrants, in whole or in part, if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or 9.99% at the holder's election) of the number of our shares of common stock outstanding immediately after giving effect to the exercise, as such percentage is determined in accordance with the terms of the Warrant. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon at least 61 days' prior notice from the holder to us.

Exercise Price. The initial exercise price per share of common stock purchasable upon exercise of the Warrants is $4.25 per share, which has been adjusted to $21.25 per share after giving effect to the 1:5 Reverse Stock Splits, and is subject to adjustments for stock splits, reclassifications, subdivisions, and other similar transactions. In addition to the exercise price per share of common stock, and other applicable charges and taxes are due and payable upon exercise.A

Cashless Exercise. If we fail to maintain the effectiveness of the registration statement and current prospectus relating to the common shares issuable upon exercise of the Warrants the holders of the Warrants shall have the right to exercise the Warrants solely via a cashless exercise feature provided for in the Warrants, until such time as there is an effective registration statement and current prospectus. Upon a cashless exercise, the holder would be entitled to receive a number of shares of common stock in accordance with certain formula set forth in the Warrant.

No Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the Warrants, and the number of Warrants will be rounded to the nearest whole number.

Authorized Shares. During the period the Warrants are outstanding, we will reserve from our authorized and unissued common stock a sufficient number of shares to provide for the issuance of common stock underlying the warrants upon the exercise of the Warrants.

Warrant Agent; Global Certificate**.** The warrant agent for the Warrants is American Stock Transfer & Trust Company LLC. The Warrants were issued in registered form under a warrant agency agreement between a warrant agent and us. The Warrants will initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company ("DTC"), and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Transferability**.** Subject to applicable laws, the Warrants may be transferred at the option of the holders upon surrender of the Warrants to the warrant agent, together with the appropriate instruments of transfer.

Adjustments; Fundamental Transaction. The exercise price and the number of shares underlying the Warrants are subject to appropriate adjustment in the event of stock splits, stock dividends on our common shares, stock combinations or similar events affecting our common shares. In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding common shares (each, a Fundamental Transaction), then following such Fundamental Transaction the holders of the Warrants will be entitled to receive upon exercise of the Warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the Warrants immediately prior to such Fundamental Transaction. Any successor to us or surviving entity will assume the obligations under the warrants. Additionally, as more fully described in the Warrant, in the event of certain Fundamental Transactions, the holders of the Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the Warrants on the date of consummation of such transaction.

Rights as a Shareholder. Except by virtue of such holder's ownership of our common stock, the holder of a Warrant does not have rights or privileges of a shareholder, including any voting rights, until the holder exercises such Warrant.

EXHIBIT 23.1

Audit ● **T**ax ● **C**onsulting ● **F**inancial **A**dvisory
Registered with Public Company Accounting Oversight Board (PCAOB)

Consent of Independent Registered Public Accounting Firm

We hereby consent to the inclusion in this Annual Report on Form 10-K of Ainos, Inc. (the "Company") for the years ended December 31, 2024 and 2023, of our report dated March 7, 2025, with respect to our audits of the financial statements of the Company as of and for the years ended December 31, 2024 and 2023.

/s/ KCCW Accountancy Corp.

Diamond Bar, California
March 7, 2025

EXHIBIT 24.1

AINOS, INC.

POWER OF ATTORNEY

WHEREAS, AINOS, INC., a Texas corporation (hereinafter referred to as the "Company"), proposes to file with the Securities and Exchange Commission under the provisions of the Securities Exchange Act of 1934, as amended, an annual report on Form 10-K for the period ending December 31, 2024 (the "Form 10-K").

NOW, THEREFORE, the undersigned members of the Board of Directors do hereby appoint Chun-Hsien Tsai and Hsin-Liang, Lee and each of them, his true and lawful attorneys-in-fact and agents with full power of substitution, for him and in his name, place and stead, in any and all capacities, to sign the Form 10-K and any and all amendments to the Form 10-K, and to file the same, with all exhibits thereto and all documents in connection therewith, making such changes in the Form 10-K as such person or persons so acting deems appropriate, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

IN WITNESS WHEREOF, the undersigned has executed this Power of Attorney this 5th day of March 2025.

/S/ Chun-Hsien Tsai
Chun-Hsien Tsai

/S/ Wen-Han Chang
Wen-Han Chang

/S/ Chung-Yi Tsai
Chung-Yi Tsai

/S/ Pao-Sheng Wei
Pao-Sheng Wei

/S/ Chung-Jung Tsai
Chung-Jung Tsai

/S/ Yao-Chung Chiang
Yao-Chung Chiang

/S/ Ting-Chuan Lee
Ting-Chuan Lee

AINOS INC BOARD OF DIRECTORS POWER OF ATTORNEY
Form 10-K for the quarter ended December 31, 2024

SEEN AND ACCEPTED:

/S/ Chun-Hsien Tsai
Chun-Hsien Tsai — President, Chairman of the Board, President and Chief Executive Officer

/S/ Hsin-Liang, Lee
Hsin-Liang, Lee — Chief Financial Officer

AINOS INC BOARD OF DIRECTORS POWER OF ATTORNEY
Form 10-K for the quarter ended December 31, 2024

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13A- 14(A) / 15D – 14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Chun-Hsien Tsai, certify that:

1. I have reviewed this annual report on Form 10-K of Ainos, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2025

/s/ Chun-Hsien Tsai
Chun-Hsien Tsai
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13A- 14(A) / 15D – 14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002

I, Hsin-Liang, Lee, certify that:

1. I have reviewed this annual report on Form 10-K of Ainos, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements and other financial information included in this report, fairly present, in all material respects, the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 7, 2025

/s/ Hsin-Liang, Lee
Hsin-Liang, Lee
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Ainos, Inc. on Form 10-K for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 7, 2025 */s/ Chun-Hsien Tsai* — Chief Executive Officer
Chun-Hsien Tsai — (Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Ainos, Inc. and will be retained by Ainos, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CERTIFICATION OF
PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Ainos, Inc. on Form 10-K for the period ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

March 7, 2025 /s/ Hsin-Liang, Lee Chief Financial Officer (Principal Financial Officer)
Hsin-Liang, Lee

BR00902F-0925-10K