

UNITED STATES
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 PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-42545

Apimeds Pharmaceuticals US, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

85-1099700

(IRS Employer
Identification No.)

2 East Broad Street 2nd Floor
Hopewell, NJ

(Address of principal executive offices)

08425

(Zip Code)

808-209-7887

(Registrant's telephone number, including area code)

Not applicable

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01	N/A	N/A

Securities registered pursuant to Section 12(g) of the Act: None.

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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 Securities Exchange Act of 1934 during the preceding 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 (Section 232.405 of this chapter) during the preceding 12 months (or 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 June 28, 2024, the last business day of the registrant's last completed second quarter, there was no established public market for the registrant's common stock.

As of April 15, 2025, there were 8,193,398 shares of the registrant's common stock, par value \$0.01 per share, issued and outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this Annual Report on Form 10-K (the “Annual Report”) of Apimeds Pharmaceuticals US, Inc. are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this report, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. These statements are subject to risks and uncertainties (some of which are beyond our control) and are based on information currently available to our management. Words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “contemplates,” “predict,” “project,” “target,” “likely,” “potential,” “continue,” “ongoing,” “will,” “would,” “should,” “could,” or the negative of these terms and similar expressions or words, identify forward-looking statements. The events and circumstances reflected in our forward-looking statements may not occur and actual results could differ materially from those projected in our forward-looking statements. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including risks and uncertainties that could delay, divert or change these expectations, and could cause actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described under Part I, Item 1A: “Risk Factors.” Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements.

This Annual Report contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this report is generally reliable, such information is inherently imprecise and subject to change.

All written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We caution investors not to rely on the forward-looking statements we make or that are made on our behalf as predictions of future events. We undertake no obligation and specifically decline any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

We encourage you to read the management’s discussion and analysis of our financial condition and results of operations and our financial statements contained in this Annual Report. There can be no assurance that we will in fact achieve the actual results or developments we anticipate or, even if we do substantially realize them, that they will have the expected consequences to, or effects on, us. Therefore, we can give no assurances that we will achieve the outcomes stated in those forward-looking statements, projections and estimates.

PART I

Item 1. Business

We are a clinical stage biopharmaceutical company in the process of developing Apitox, an intradermally administered bee venom-based toxin. Our focus is primarily on developing innovative therapies that address inflammation and pain management symptoms associated with knee OA and, to a lesser extent, MS. Apitox is currently marketed and sold by Apimedex Inc. (“Apimedex Korea”) in South Korea as “Apitoxin” for the treatment of OA. Apimedex US is not associated with the market, sale and revenues generated from Apitoxin in South Korea, and Apitoxin has not yet been approved by the FDA for any indication.

Apitox is a purified, pharmaceutical grade venom (bee venom), of the *Apis mellifera*, or western honeybee, which is classified by the FDA as an active pharmaceutical ingredient (“API”). Bee venom has been used in Asia and Europe to treat pain for hundreds of years. While not FDA approved in a controlled, prescription based biologic environment for defined indications, the use of bee venom has been FDA approved as a “under the skin injection” to reduce the allergic reactions to bee stings. Apimedex Korea has developed a proprietary method and process for turning extracted bee venom into a lyophilized powder for reconstitution prior to intradermal dose injections, which they sell in South Korea as Apitoxin. We intend to use a similar process with respect to Apitox, pursuant to the Business Agreement, which gives us a license to utilize all prior clinical development data associated with Apitoxin. The advancement of extracted bee venom for treatment of inflammatory conditions, including but not limited to knee OA and MS is speculative but based on direction provided by prior clinical data.

Apimedex Korea successfully completed Phase I, Phase II, and Phase III trials in OA in 2003, at which point Apitoxin was approved by the Korean Ministry of Food and Drug Safety (“MFDA”) to treat pain and mobility in patients with OA. Since 2003, a post-marketing/approval safety study in South Korea followed 3,194 patients from 2003 through 2009, with no serious adverse events. The purpose of a Phase I trial is to test to determine whether a new treatment is safe and look for the best way to give the treatment. Phase II trials test to determine whether a condition or disease responds to the new treatment. Phase III trials test to determine whether a new treatment is better than a standard treatment.

In 2013, the first of two required U.S. Phase III clinical trials was authorized to enroll patients to study the use of Apitoxin to study the same indication as approved in South Korea in 2003 — treatment of pain and lack of mobility in patients with OA (the “Apimedex Korea Phase III OA Trial”). The Apimedex Korea Phase III OA Trial (330 patients) was completed in 2018, and displayed no serious adverse events.

Based on the results from the Apimedex Korea Phase III OA Trial, which demonstrated therapeutic (statistical and clinically significant improvements in all outcome measures of pain, physical function, and disease assessment) effect compared to the placebo group, but in combination with prior development by Apimedex Korea, did not meet the FDA’s standards for approval, as the study population was too small and the methods for handling missing data were inadequate, resulting in a study that did not demonstrate a significant treatment effect. We will be pursuing a second Phase III trial to meet agreed upon FDA standards. Based on results from the Apimedex Korea Phase III OA Trial, we have evaluated the most appropriate population, defined as advanced knee OA patients, which will range from defined grade 2, 3 and 4 within this treatment group, to continue to progress our own Phase III trial. Pursuant to our previous correspondence with the FDA, we have designed and will implement our Phase III trial to best address our patient population, appropriate dosing, and the most effective way to evaluate Apitox in meeting the patient population’s needs.

We believe the progress we are making in clinical trials provides us support in our belief in the potential of Apitox to be an innovative therapy. We aim to treat the inflammation and pain management symptoms associated with knee OA and to help manage the devastating symptoms of this disease. In the future, we also aim to leverage our research in knee OA to investigate how Apitox may be used to treat similar symptoms associated with MS.

Treatment of OA

OA is typically treated with painkillers known as non-steroidal anti-inflammatory drugs (NSAIDs). These medications have an anti-inflammatory and pain-relieving effect. These medications include ibuprofen (Motrin, Advil) naproxen (Aleve) and diclofenac (Voltaren and others). All of these medications work by blocking enzymes that cause pain and swelling. The problem is that some of those enzymes also help blood to clot and protect the lining of your stomach. Without them, you can bruise easily, develop ulcers and may even bleed in your intestines. NSAIDs also increase your chance of heart attack, stroke and heart failure. The risk increases the longer you use them and the more you take. We believe Apitox could be a successful alternative to NSAIDs in the treatment of the inflammation and pain management symptoms associated with OA without the harmful side effects.

According to MedicalNewsToday, OA is the most common form of arthritis, affecting around 500 million people worldwide, or around 7% of the global population. Currently, in the United States, over 32 million people suffer from OA. As the 15th highest cause of years lived with disability (YLDs) worldwide, the burden OA poses to individuals is substantial, characterized by pain, activity limitations, and reduced quality of life. The economic impact of OA, which includes direct and indirect (time) costs, is also substantial, ranging from 1 to 2.5% of gross national product (GNP) in countries with established market economies, like the United States. Though trends in OA prevalence vary by geography, the prevalence of OA is projected to rise in regions with established market economies such as North America and Europe, where populations are aging and the prevalence of obesity is rising.

While OA can occur in any joint, it occurs most frequently in the knee, which, according to ScienceDirect, currently accounts for 365 million cases worldwide and 61% of YLDs lost due to OA, followed by the hand.

Our current efforts are focused on the development of Apitox in the United States for the treatment of inflammation and pain management relating to OA in the knee.

Treatment of MS

Additionally, we believe the previous clinical trial success of Apimedex Korea with respect to the use of Apitoxin to treat symptoms associated with knee OA, and pending the success of our anticipated Phase III trial in knee OA, we will be in a position to further explore the use of Apitox as a potential treatment for the symptoms of MS. MS is a chronic disease of the central nervous system. It is an autoimmune condition that is characterized by the body's own immune cells (macrophages and lymphocytes) attacking the myelin that coats nerve cells, which can lead to inflammation throughout the central nervous system. MS is an unpredictable disease that affects people differently. Some people with MS may have only mild symptoms. Others may lose their ability to see clearly, write, speak, or walk when communication between the brain and other parts of the body becomes disrupted.

MS is the most common progressive neurologic disease of young adults worldwide. A study funded by the National MS Society estimates that nearly one million individuals are currently affected by this disease in the United States. The total economic burden of MS in the United States is estimated to be \$85.4 billion, with \$63.3 billion in direct medical costs and \$22.1 billion in indirect and nonmedical costs. MS typically affects patients at a young age, resulting in a greater loss of productivity and quality of life.

Beta interferon drugs are among the most common medications used to treat MS. Interferons are signaling molecules that regulate immune cells. Potential side effects of these drugs include flu-like symptoms (which usually fade with continued therapy), depression, or elevation of liver enzymes.

Pain from MS can be felt in different parts of the body. Trigeminal neuralgia (facial pain) is treated with anticonvulsant or antispasmodic drugs, or less commonly, painkillers. Central pain, a syndrome caused by damage to the brain and/or spinal cord, can be treated with gabapentin and nortriptyline. Treatments for chronic back or other musculoskeletal pain may include heat, massage, ultrasound, and physical therapy.

OA and the Current Standard of Care

OA is a degenerative joint disease in which the tissues in the joint break down over time. It is the most common type of arthritis and is more common in older people. People with osteoarthritis usually have joint pain and, after rest or inactivity, stiffness for a short period of time.

There are four stages of OA: (1) Minor — minor wear-and-tear in the joints and little to no pain in the affected area, (2) Mild — more noticeable bone spurs, the affected area feels stiff after sedentary periods and patients may need a brace, (3) Moderate — cartilage in the affected area begins to erode, the joint becomes inflamed and causes discomfort during normal activities, and (4) Severe — the patient is in a lot of pain, the cartilage is almost completely gone leading to an inflammatory response from the joint, and overgrowth of bony spurs may cause severe pain.

With the progression of OA of the knee, there is obvious joint inflammation which causes frequent pain when walking, running, squatting, extending or kneeling. Along with joint stiffness after sitting for long or when waking up in the morning, there may be popping or snapping sounds when walking.

The data from the Apimeds Korea Phase III OA Trial suggest that Apitox would have the most potential in treating OA in stages 3 and 4.

MS and the Current Standard of Care

MS is increasingly recognized as a neurodegenerative disease triggered by an inflammatory attack of the central nervous system. There is no cure for multiple sclerosis. Treatment typically focuses on speeding recovery from attacks, reducing new radiographic and clinical relapses, slowing the progression of the disease, and managing MS symptoms.

MS is unpredictable and can vary substantially from person to person. MS is divided into four types: clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS).

CIS refers to a first episode of neurologic symptoms caused by inflammation and demyelination in the central nervous system.

RRMS, the most common disease course, shows clearly defined attacks of new or increasing neurologic symptoms. These attacks are also called relapses or exacerbations. They are followed by periods of partial or complete recovery, or remission. In remissions, all symptoms may disappear or some symptoms may continue and become permanent. However, during those periods, the disease does not seem to progress.

SPMS follows the initial relapsing-remitting course. Some people diagnosed with RRMS eventually go on to have a secondary progressive course, in which neurologic function worsens progressively or disability accumulates over time.

With PPMS, neurologic function worsens or disability accumulates as soon as symptoms appear, without early relapses or remissions. PPMS can be further characterized as either active (with an occasional relapse and/or evidence of new MRI activity over a specified period of time) or not active, as well as with progression (evidence of disability accrual over time, with or without relapse or new MRI activity) or without progression.

Patients with MS tend to be more educated about their disease and better organized than patients with other diseases, resulting in patients that are aggressive in their approach to treatment. This is due to MS impacting otherwise healthy people in the prime of their lives.

MS treatment has undergone significant evolution in the last ten years with the development and approval of certain new drugs, including several oral agents such as Ocrevus, in the United States. These new agents not only give patients additional treatment options, but also have improved the efficacy and safety of treatment for MS overall. In general, these drugs are “disease modifying agents,” intended to slow down the immune mediated damage to the myelin sheaths that underlie symptoms in MS. However, they often do not adequately address the symptoms that MS patients experience such as walking problems, bladder control, dizziness, and especially pain. A 2022 study estimated that the average cost of treatment for patients with MS is approximately \$88,000 annually. The out-of-pocket expense for patients can be significantly reduced through certain insurance plans. However, we believe there is the ability for Apitox to be positioned as an important and cost-effective therapy.

We believe the data from the Apimeds Korea Phase III OA Trial suggest that Apitox may have the potential as an adjunctive therapy for all four types of MS. We intend to Apitox as a potential adjunctive therapy through non-registered corporate sponsorship studies to begin determining the appropriate MS patient populations.

Market Opportunity

We believe there is a significant market opportunity in the United States for Apitox in the treatment of certain symptoms of knee OA and eventually MS. According to Precedence Research the osteoarthritis therapeutics market size accounted for \$8.28 billion in 2022 and it is expected to hit around \$20.24 billion by 2032, expanding at a CAGR of 9.4% from 2023 to 2032. Although OA can damage any joint, the disorder most commonly affects joints in your hands, knees, hips and spine. OA symptoms can usually be managed, although the damage to joints can’t be reversed. Apitox has certain anti-inflammatory properties, which we believe give it significant potential to help treat the symptoms of certain chronic diseases that involve difficult to control pain and inflammation.

According to Pharmaceutical Technology the MS market size in the United States accounted for \$10.73 billion in 2022 and is expected to hit \$24.4 billion by 2030, expanding at a CAGR of 10.32%. Starting in the first quarter of 2025, we intend to begin the early prosecution of appropriate MS patient populations through non-registered corporate sponsorship studies. Subject to FDA approval, our development of Apitox in the United States will in the near term, have two distinct focuses (i) the treatment of the certain symptoms of knee OA and (ii) the quality of life issues surrounding knee OA, such as pain and lack of mobility.

Living with a chronic disease is challenging, as it interferes with physical, mental, and social functions and thus greatly affects a person's quality of life. Indeed, chronically ill patients are facing major struggles such as higher expenditures, social isolation and loneliness, disabilities, fatigue, pain/discomfort, feelings of distress, anger, hopelessness, frustration, anxiety, and depression. There is the general assumption that symptom reduction increases a patient's quality of life. Our approach with Apitox centers around this concept — effectively treating certain symptoms of the patient's disease, thus improving their overall quality of life. Bee venom has been shown to have anti-inflammatory effects. At low doses, bee venom can suppress inflammatory cytokines such as interleukin-6 (IL-6), IL-8, interferon- γ (IFN- γ), and tumor necrosis factor- α (TNF- α). A decrease in the signaling pathways responsible for the activation of inflammatory cytokines, such as nuclear factor-kappa B (NF- κ B), extracellular signal-regulated kinases (ERK1/2) and protein kinase Akt, and porphyromonas gingivalis lipopolysaccharide (PgLPS)-treated human keratinocytes has been associated with treatments involving bee venom. We believe the driver of pain in the highest category of OA is correlated to the key inflammatory elements treated by bee venom, meaning the evaluation of our Phase III data may lead to a small indication for narcotic use reduction in the treatment of stage 4 OA.

Our Product Candidate

Apitox is purified honeybee (*Apis mellifera*) venom manufactured as a lyophilized powder for reconstitution in 0.5% preservative-free lidocaine (1mg/mg) prior to intradermal dose injections that are administered up to 1,500 micrograms per weekly visit. The biologically active components include melittin (40-50%), apamin (2-3%), mast cell degranulating ("MCD") peptide (Peptide 401, 2-3%), phospholipase A2 (10-15%), hyaluronidase (1.5-2%) and other components in small amounts, including dopamine and norepinephrine. According to a publication entitled "*Pharmacological effects and mechanisms of bee venom and its main components: Recent progress and perspective*" by Shi et al., certain components of honeybee venom have been found to have both anti-inflammatory and analgesic effects. The anti-inflammatory and analgesic effects are attributed to the presence of Peptide 401, adolapin and other components that inhibit prostaglandin synthesis. The hormone-stimulating effects are attributed to the presence of melittin, cardiopep and other components that stimulate the pituitary-adrenal axis to produce cortisol. Results from an animal study entitled "*Effect of bee venom and melittin on plasma cortisol in the unanesthetized monkey*" published by Vick et al., indicate that melittin appears to stimulate the production of cortisol from the adrenal gland. The immune-modulating effects, especially as it pertains to MS, are suggested to be mediated by CD4+CD2S+Foxp3+ regulatory T cells (Tregs) that are influenced by phospholipase A2. While the exact mechanism of action of Apitox is not fully understood, research such as the publication entitled "*Therapeutic Use of Bee Venom and Potential Applications in Veterinary Medicine*" by Bava et al., suggests that certain components in Apitox may ameliorate immune-inflammatory responses associated with MS. Such studies suggested that treatments with melittin prevent inflammatory cytokine expression and produces anti-inflammatory effects. The proposed indication for Apitox is to provide add-on therapy for the signs and symptoms of MS in patients whose condition is relapsing-remitting (RRMS), primary-progressive (PPMS) or secondary progressive (SPMS).

Clinical Development History

Founded in 1989, Apimeds Korea pursued a traditional drug development process in South Korea for *Apis mellifera*, the bee venom API for Apitoxin. Apimeds Korea completed a formal preclinical study to validate dosing and safety for human administration with a focus on antigenicity and toxicology in 1993.

A Phase I trial was completed in 1994, studying the toxicity and safety of Apitoxin in 20 healthy subjects. The purpose of the Phase I trial was to determine if therapeutic doses of Apitoxin was safe and to identify possible side-effects, if any. Injections of Apitoxin were given two to three times a week, for a total of 12 sessions spanning over four to six weeks. Laboratory and physical examination of the subjects included (i) serum cortisol levels (to see if Apitoxin stimulated the release of cortisol), (ii) serum ionized calcium level (to determine if Apitoxin decreased the serum calcium level), (iii) urinalysis, (iv) hematology and blood chemistry, and (v) vital signs. The Phase I trial demonstrated that there were no significant changes pre- and post-testing of the serum cortisol levels, serum ionized calcium levels, hematology, blood chemistry, urinalysis, and vital signs after the subjects were injected with Apitoxin according to the protocol. There were no significant physiological changes in the clinical evaluations of the subjects and localized itching was the most frequent side effect and was managed with ice packs or external anti-itching gels. No severe side effects or aftereffects were observed. The Phase I trial indicated that Apitoxin is safe for humans when applied in therapeutic doses.

The Phase I trial was followed by a Phase II trial in 101 subjects to determine the efficacy of Apitoxin at various dose levels. This was a randomized active-controlled clinical trial with three groups receiving the study drug at various dose levels and one group receiving the control drug (nabumetone) for a six-week period. Patients received twice weekly injections of Apitoxin intradermally at dosages titrated to a maximum of 0.7 mg (Group A), 1.5 mg (Group B), and 2.0 mg (Group C) for a period of six weeks. Control group patients (Group D) received 1,000 mg of nabumetone orally each day for the same six-week period. There were 25, 26, 25 and 25 patients assigned to Groups A, B, C and D, respectively. Efficacy of treatment was evaluated by the physician investigators using a 4-point Likert-like symptom severity rating scale developed by the authors to assess Pain, Disability and Physical Signs. A similar 5-point scale was used for patient self-evaluation. Safety of the Apitoxin injection was evaluated by patient reaction, hematologic examination, and laboratory chemistry analysis of blood and urine. Efficacy data was reported for the 81 patients who completed the study. While there were no significant differences in symptom severity scores among the four groups at baseline, symptom scores were significantly better in the bee venom injection groups than in the control group at six weeks and 10 weeks after the start of treatment ($p < 0.01$). A treatment was considered effective if there was a 20% improvement from baseline in symptom scores after 6 weeks of treatment. Based on this definition, therapy demonstrated overall efficacy in 70.0% of patients in Group A, 85.7% in Group B, 90.0% in Group C, and 61.9% in Group D (drug control). Overall efficacy was significantly greater in treatment Groups B and C combined than in the nabumetone-treated control group D ($p < 0.0177$). Importantly, efficacy of treatment among all patients treated with Apitoxin injection was greater than among nabumetone-treated patients for each category assessed: Pain: 85.2% versus 76.2%; Disability: 77.0% versus 71.4%; and Physical Signs: 62.3% vs. 23.8%. It is also noteworthy that, unlike the drug control group, the Apitoxin injection groups continued to demonstrate improved symptom scores at four weeks after the last treatment (10 weeks). There were no significant changes in vital signs or results of laboratory examinations of any patient in this clinical trial. Localized itching was experienced by all patients who received Apitoxin injections. Itching at the injection site generally lasted for two to three weeks; several patients had this reaction for a longer period. This Phase II study showed that Apitoxin was significantly more effective than the control drug, nabumetone, in the treatment of knee and spinal osteoarthritis patients. It clearly showed that improvement in pain, disability and physical signs was greater in the bee venom injection groups than in the nabumetone control group. No significant side effects developed at the therapeutic doses studied. However, research should be continued to minimize itching and pain at bee venom injection sites, and possible allergic reaction should always be considered with treatment at high doses.

In 2002, a formal Phase III double-blind, placebo-controlled trial was completed with 407 subjects (311 of which obeyed the trial protocol and completed the clinical study). The purpose of the Phase III trial was conducted to verify the efficacy and safety of the medicine resulting from the prior Phase I and Phase II trials. The therapeutic course treatment included a total of 12 injections over a period of 6 weeks. Final evaluations were completed in the 8th week, following two weeks of no injections. During the trial period, laboratory tests were carried out three times (before injection, in the second week, in the sixth week), and the efficacy evaluation was performed four times (before injection, in the second week, in the sixth week, and in the eighth week). Safety of the Apitoxin injection was evaluated by, hematologic examination, measurement of cortisol and calcium levels, and laboratory chemistry analysis of blood and urine. The primary efficacy variable for the trial was the ratio of the subjects who showed more than 20% improvement in the total points of test items for efficacy evaluation 6 weeks after injection, compared with the total points before injection of the medicine (the “improvement rate”). Data obtained from subjects of the clinical test were analyzed by two methods, ITT (Intention to Treat) analysis and PP (Per Protocol) Among 310 subjects who participated in the efficacy evaluation, 153 and 157 patients belonged to the Apitoxin group and the nabumetone group, respectively. For the Apitoxin group, the ratio of the subjects who showed more than 20% improvement in the total points was 48.70% (75/154 subjects, 95% confidence interval (“CI”): 40.8–56.6%), while for the nabumetone group, it was 46.15% (72/156 subjects, 95% CI: 38.3–54.0%), indicating that the improvement rate in the Apitoxin group was greater than in the nabumetone group; however, there was no statistical significance. (p=0.6533). Among a total of 407 subjects (Apitoxin group: 204; Nabumetone group: 203), 38.24% (78/204) of the Apitoxin group showed more than 20% improvement during the 6th week of injection, while 38.42% of the Nabumetone group improved by more than 20%, indicating that the two groups showed similar improvement rate (p=0.9688). The second efficacy variable was the improvement rate during the 8th week (2 weeks after the completion of the final injection). According to results from comparing the total points of efficacy evaluation items during the second week after completion of injection (during the 8th week after injection) with the total points before injection, 58.44% (90/154) of the Apitoxin group showed a higher improvement rate than during the 6th week (48.70%), while 42.95% (67/156) of the Nabumetone group showed lower improvement rate than during the 6th week (46.15%). There was statistical difference in total point of efficacy evaluation items between the two groups (p=0.0064). These results suggest that even after treatment stops, the efficacy of Apitoxin continues. With respect to safety, among a total of 407 subjects who participated in the safety evaluation, 69 (33.82%) of the Apitoxin group showed an adverse event, while 59 (29.06%) of the Nabumetone indicated adverse event. These results indicate that the Apitoxin group had an elevated adverse event rate than the Nabumetone group, but there was no statistically significant difference between the two groups (p=0.3526).

In May 2003, MFDA granted approval for the use of Apitoxin in the treatment of pain and mobility in patients with OA. A post-marketing/approval safety study in South Korea followed 3,194 patients from 2003 through 2009, with no serious adverse events or negative safety signals.

In 2013, preliminary Phase III clinical trials were authorized to enroll patients by the FDA to study the same indication approved in South Korea — treatment of pain and lack of mobility in patients with OA. The results of the preliminary Phase III clinical trial indicated statistical and clinically significant improvements in all outcome measures of pain, physical function, and disease assessment in the study group. The study group included 330 patients with diagnosed osteoarthritis of the knee. The subjects were evaluated for relief of pain using Western Ontario and McMaster Osteoarthritis Index (WOMAC) and physician and patient global assessments. The primary efficacy measure was relief of pain and inflammation over a 12-week treatment period after randomization into the trial. The secondary efficacy measure was improvement of mobility. Treatment effect will be compared in a 2-1 Apitox vs active control. Compared with the placebo group (histamine), subjects in the Apitox group who received a maximum dose (1500 micrograms) at each weekly visit over 12 weeks showed a significantly more improvement in all outcome measures (WOMAC pain, WOMAC physical function, visual analog scale (“VAS”) pain, patient and physician global assessments of OA). Further, post hoc analyses showed that a statistically significant greater percentage of Apitox-treated subjects had at least a 40% and 60% reduction in WOMAC pain as compared to placebo-treated subjects. Sensitivity analyses confirmed the validity of the statistical methods and population definitions. The improvements in pain endpoints were highly significant for both the modified intention to treat and per protocol populations and the improvement was sustained during the four weeks following Apitox treatment.

Except for an expected higher incidence of injection site reactions (<5%) in the Apitox group, the overall safety profiles were comparable between the treatment groups. A serious adverse event of the anaphylactic reaction occurred in an Apitox-treated subject because of a quick injection rate. However, the subject was treated, and the event was resolved within one day. The incidence of adverse events overall was similar between the Apitox and Placebo groups (49.0% and 46.3%, respectively), and there were no clinically meaningful changes, within and between groups, in laboratory parameters, vital signs, physical examination, or electrocardiogram results.

During Apimed Korea meetings with the FDA, the FDA highlighted concerns regarding the opioid crisis. As Apitoxin has been previously approved in South Korea, we believe Apitox could be a viable treatment option within the United States after additional clinical investigation, including our anticipated Phase III trial. Initially, Apimed Korea elected not to pursue the OA indication in the United States based on its evaluation of potential market adoption and the existing competitive environment for OA. Based on results from the Apimed Korea Phase III OA Trial and correspondence with the FDA, we believe we are now in a position to continue to advance our Phase III trial for knee OA.

We intend to conduct an additional Phase III trial in knee OA. Based on our previous correspondence with the FDA, we have started to design and will implement our Phase III trial to best address our patient population of patients with grade 2, 3 and 4 knee OA, appropriate dosing, and the most effective way to evaluate Apitox in meeting a patient’s needs. This trial will be an update to the plan of execution based on review of data, discussions with former principal investigators from Apimed Korea. Upon successful completion and FDA clearance of our Phase III trial in knee OA, we will be positioned to submit a BLA.

We intend that the purpose of this trial will be to evaluate the effectiveness of Apitox in the treatment of grade 2, 3 and 4 OA of the knee. The trial will be designed with a specific focus on the identified subgroup from which we see the highest degree of benefit.

The following table summarizes the preliminary clinical trial activity by Apimed Korea with respect to Apitoxin:

	Phase I	Phase II	Phase III	Phase I	NDA (KFDA)	Phase IV*	MS Society Sponsored Study	Phase II	FDA/Phase III Osteoarthritis
Company/ Investigator	Brando Pharma/ Chris Kim, MD	Brando Pharma/Guju Pharma	Guju Pharma Apimed Korea	Hauser et al 2001, Altem Comp Ther.	Guju Pharma Apimed Korea	Guju Pharma Apimed Korea	Wessellus et al 2005 Neurology	Apimed Korea	Apimed Korea
Indication	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Multiple Sclerosis	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Multiple Sclerosis	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain
Year	1994	1996	2002	2001	2003	2003-2009	2005	2011	2016
Subjects	20	161	407	51	N/A	3,194	26	40	330
Design	Toxicity and Safety	Efficacy and Safety	Efficacy and Safety	Safety and Efficacy	Regulatory Submission	Post Marketing Safety	Safety and Efficacy	Efficacy and Safety	Efficacy and Safety
Results	No Neg Safety Signals	Improvement in mobility and pain reduction	Improvement in OA mobility and reduction in pain	Improvement in MS fatigue, endurance, balance, bladder control, coordination No Serious Adverse Events	Approved	No Serious Adverse Events No negative safety signals	Mean Improvement in MS Functional Composite symptoms No Serious Adverse Events	No Serious Adverse Event Improvement of OA Symptoms	Improvement in OA mobility and reduction in pain
Statistical and Clinical Significance	No Negative Safety signals	Significant reduction in pain and disability (p = 0.0177)	Significant reduction in pain and disability (p = 0.0019)	MS Outcome Improved: 35 patients No improvement 16 Patients	N/A	No Serious Adverse Events	MS Functional Composite Baseline -0.85 ± 1.41 Venom -1.12 ± 1.95	Significant pain reduction (p = 0.0355) Apitox vs Control	Significant pain reduction (p = 0.0057) with Apitox dose vs Placebo

Preliminary Clinical Data in MS Patients

The United States data from the literature on bee venom studies in MS patients, Table A (Hauser et al. 2001) below, showed clinically significant improvements in disability symptoms following treatment.

In Table A, results were categorized into the following groups: dramatic disability improvement (>12 points on the Related Observable Symptom Scale (“ROSS”), good improvement (7-12 points on ROSS), minimal improvement (<7 points on ROSS), no improvement (<2 points on ROSS), and negative (any total negative response on ROSS). Descriptive analysis of the ROSS clinical outcomes showed that more than 68% of MS patients showed some kind of positive improvement in disability (dramatic, good or minimal) and 58% demonstrated a marked improvement (dramatic or good).

Table A. Summary of Patient Disability Improvement to Bee Venom Treatment Using ROSS

	N	% of Participants	Follow-up Survey (% improvement)	Related Observable Symptoms Scale (points improvement)
Dramatic	15	29.4%	>30%, or	>12 points
Good	15	29.4%	10 – 29%, or	7 – 12 points
Minimal	5	9.8%	<10%, or	<7 points
None	15	29.4%	<2%, or	<2 points
Negative	1	2.0%	Any total negative response	Any total negative response

After 1 year of bee-venom injections, 68.6 percent of participants showed improvement. N = number of participants.

Apimeds Korea used data from its first Phase III clinical trial for OA and peer reviewed publications, including those referenced in Table A above and formal Phase I (the “Castro Phase I Trial”) and Phase II (the “Wesseliuss Phase II Trial”) publications specific to MS, to support its submission in 2014 of its Investigational New Drug Application (“IND”) 122804 (A Phase III, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of Apitox Add-on Therapy for Improving Disability and Quality of Life in Patients with Multiple Sclerosis).

Castro Phase I Trial

The Castro Phase I Trial involved a total of nine bee venom nonallergic patients with progressive forms of MS, who were 21–55 years of age with no other illnesses. The subjects distributed across four groups (A, B, C, and D) and followed a structured 1-year immunization schedule. Hyperreactivity to bee venom was evaluated by questionnaire, physical examination, and a battery of hematologic, metabolic, and immunologic tests. Responses to therapy were evaluated by questionnaire, functional neurological tests, and changes in measurement of somatosensory-evoked potentials. While no serious adverse allergic reactions were observed in any of the subjects, four experienced worsening of neurological symptoms, requiring their discontinuation in the study. The observed negative effects could not be conclusively attributed to adverse reactions arising from the administered therapy. Of the remaining five subjects, three reported subjective amelioration of symptoms and two exhibited objective improvement. Despite suggesting safety in this preliminary study, the small sample size precluded definitive conclusions regarding the efficacy of the treatment for MS. Larger and more carefully conducted multicenter studies were required to establish efficacy.

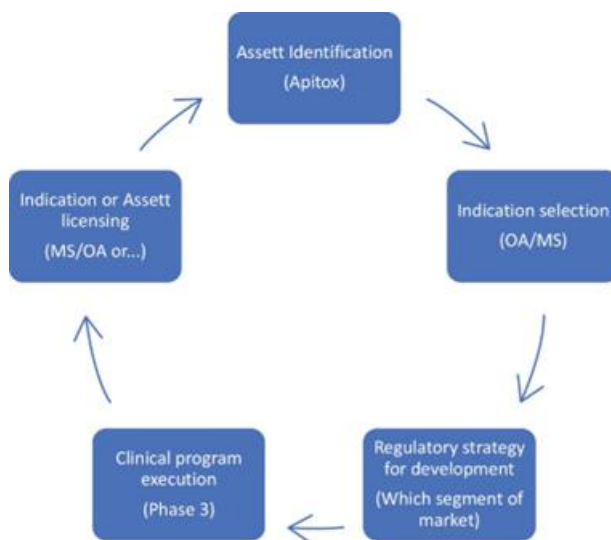
Wesseliuss Phase II Trial

The Wesseliuss Phase II Trial involved a randomized crossover study of 26 patients diagnosed with relapsing-remitting or relapsing secondary progressive MS. Participants were assigned to 24 weeks of medically supervised bee sting therapy, or a control period of 24 weeks of no treatment. Live bees (up to a maximum of 20) were used to administer bee venom three times per week. The primary outcome was the cumulative number of new gadolinium-enhancing lesions on T1-weighted MRI of the brain. Secondary outcomes were lesion load on T2*-weighted MRI, relapse rate, disability (Expanded Disability Status Scale, Multiple Sclerosis Functional Composite, Guy’s Neurologic Disability Scale), fatigue (Abbreviated Fatigue Questionnaire, Fatigue Impact Scale), and health-related quality of life (Medical Outcomes Study 36-Item Short Form General Health Survey). The results of the Wesseliuss Phase II Trial indicated that during bee sting therapy, there was no significant reduction in the cumulative number of new gadolinium-enhancing lesions. The T2*-weighted lesion load further progressed, and there was no significant reduction in relapse rate. There was no improvement of disability, fatigue, and quality of life. Bee sting therapy was well tolerated, and there were no serious adverse events. In this trial, treatment with bee venom in patients with relapsing multiple sclerosis did not reduce disease activity, disability, or fatigue and did not improve quality of life measured using gadolinium-enhancing MRI.

From June 2014 to June 2018, Apimeds Korea corresponded with the FDA and there were no clinical holds at that time. Sponsorship of IND 122804 was transferred from Apimeds Korea to us in October 2020. On September 21, 2021, we responded to customary non-clinical hold comments from the FDA. In November 2021, we received a customary clinical hold from the FDA due to the retirement of the former principal investigator. We have subsequently updated the FDA with a new principal investigator via our Chief Medical Officer, Dr. Christopher Kim. In February 2023, the FDA removed the clinical hold and concluded it may be initiated. We have subsequently made the strategic decision to focus our efforts and capital on our Phase III trial in knee OA, and instead focus our MS efforts on the early prosecution of appropriate MS patient populations through non-registered corporate sponsorship studies.

Our Commercialization Strategy

We are dedicated to the effective implementation of regulatory, clinical and legal strategies to create value in Apitox. The effective execution of this strategy will provide us the opportunity to evaluate and potentially acquire other assets that fit within our space for development.



Manufacturing

We intend to continue to engage a third-party manufacturer, Piramal Pharma Solutions, in Lexington, Kentucky to support our Phase III trial and, if Apitox is approved by the FDA, commercial manufacturing. This manufacturer has dedicated experience in development and technology transfer of sterile dose formulations, including liquid and lyophilized formulations.

Research and Development

We are currently engaged exclusively in the clinical development of Apitox for continued use in knee OA through a Phase III trial in knee OA and potential use for MS through the early prosecution of appropriate patient populations through non-registered corporate sponsorship studies.

Sales and Marketing

The healthcare providers associated with the treatment of inflammation and pain management symptoms associated with OA and MS are not limited to one specialist but involve a comprehensive team of providers focused on slowing the progression of the disease along with the physical, emotional and day-to-day management of the condition. Each of these providers represents a potential customer for Apitox.

Apitoxin, which will be known as Apitox in the United States, has established technological credibility through its preclinical testing, Phase I, Phase II and preliminary Phase III clinical studies completed by Apimed Korea. Apimed Korea received regulatory approval for Apitoxin by the MFDA in South Korea, as well as long-term safety data from treatment of patients in Korea from 2003 to 2009. There were no serious adverse events from over 3,000 patients monitored, and Apitoxin has been approved and marketed in South Korea for OA since 2003. We update the FDA annually on safety data generated by Apimed Korea from South Korea.

We aim to obtain FDA approval for Apitox in the United States market for treatment of inflammation and pain management symptoms associated with knee OA, and eventually MS, and expand the indication portfolio in the autoimmune market with a strategic marketing partner. The marketing partner strategy is common in the pharmaceutical marketplace, as the infrastructure, overhead, and barriers to entry dilute the focus and can rapidly erode the financial well-being of small, product development-based companies such as us. By identifying the strategic marketing partner at an early stage, the companies can deliver a final product, or family of products, in a form factor or variety of form factors over time, that specifically suit the target market. We believe that Apitox represents a significant opportunity as a platform technology, with numerous product-line extensions, and the potential for new, ancillary products such as delivery devices.

Reimbursement Strategy

Apimeds expects to apply to the Centers for Medicare and Medicaid Studies (“CMS”) for temporary generic reimbursement codes 12 to 18 months prior to a BLA approval. Temporary codes are used until manufacturers apply for, and receive, permanent codes, which identify the drug and its therapeutic class. Permanent codes are issued by CMS on a rolling quarterly basis.

We will engage third party contractors to assist the us with reimbursement, coding and policy development prior to, during and at the time of approval of Apitox. We will look for a contractor to provide the following services to us:

- *Coding Assessment and Strategy/Execution — CPT Review of Apitox Administration by Multiple Intradermal Injections.* Assess the landscape to ensure a clear understanding of the key dynamics and analyze relevant proxies and precedent. Further assess relevant drug administration codes and whether appropriate codes exist.
- *Medical Coverage Policy Analysis —* Provide a framework and set expectations for Medicare’s anticipated coverage approach to Apitox, specifically in the context of intra articular hyaluronic acid use agent coverage policies and implications of their efficacy uncertainty.
- *Medicare Local Coverage Analysis and Implications —* Given the significance of Medicare policy standards, local and national Medicare policies often shape payer and provider perceptions and decisions. As complex statutory and regulatory guidance shape Medicare decision-making, ADVI analyzes, investigates, and synthesize Medicare policies that could affect access (coverage, coding and reimbursement) for Apitox.
- *Medicaid and Commercial Coverage Analysis and Implications —* Analyze available medical policies for five large state Medicaid agencies (based on population and geographic variation) and major commercial payers (where publicly available).
- *Payer Policy Internal Expert Interviews —* Conduct payer interviews with relevant Medicare, Medicaid and commercial policy advisors.
- *HCPCS Coding and Payment Assessment —* Assess the coding and reimbursement landscape to ensure Apimeds has a clear understanding of the key dynamics with the HCPCS application process and the Medicare Hospital Outpatient Prospective Payment System (OPPS) pass-through status application process. Through this assessment, identify the areas of concern, expectations, timing, timelines, and processes associated. This is especially relevant given the 2020 implementation of a new HCPCS review process.
- Address key Part B/medical benefit implications to Apitox in the following fields:
 - HCPCS and OPPS application timelines (and potential evolution leading to launch).
 - Coding/access implications prior to code assignment (e.g., NOC/miscellaneous codes), review the merits/risks of Q-code.
 - further review the application processes, expectations, case examples, timelines, and hurdles that APUS may face across settings of care, payers, and with CMS,
 - Case examples, timelines, and hurdles across settings of care with payers and CMS,
 - Review of reimbursement implications; and
 - Methodologies (ASP, WAC, AWP), role of sequestration, 340B, patient financial burden
- *Develop Payer (with Emphasis on Medicare) Launch Recommendations —* Based on the above primary and secondary research, synthesize the discussions and summarize the overall findings of the payer survey, highlighting themes, and provide recommendations and considerations for optimizing market access, given the current and evolving reimbursement landscape. This section will include payer (emphasis on Medicare) launch strategy recommendations (including timeline) and a local/national Medicare engagement strategy.

Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition, a changing regulatory and legislative landscape and a strong emphasis on the benefits of intellectual property protection and regulatory exclusivities.

Like any biopharmaceutical company, we face competition from multiple sources, including large or established pharmaceutical, biotechnology, and wellness companies, academic research institutions, government agencies, and private institutions. We believe our drug candidate will prevail amid the competitive landscape through its efficacy, safety, administration methods, cost, public and institutional demand, intellectual property portfolio, and treatment of the root cause of many age-associated diseases.

Many of our competitors, either alone or with strategic partners, have substantially greater financial, technical, and human resources than we do. Accordingly, our competitors may be more successful in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites, patient registration for clinical studies, and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, more tolerable, more convenient, or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our products' entry. We believe the factors determining the success of our programs will be the efficacy, safety, and convenience of our drug candidates.

Additionally, consumer preference for branded, generic or private label products sold by competitors could adversely impact our financial performance. Our competitors, which differ within individual geographic markets, include large-scale retailers, smaller high-growth companies (which often operate on a regional basis and offer aggressive competition), multinational corporations moving into or expanding their presence in the consumer healthcare market, and "private-label" products sold by retailers.

Our aim is to reduce the use of NSAIDs and opioid use as it relates to the pain management associated with OA. We believe that if approved by the FDA, Apitox may be a non-addictive option to patients experiencing debilitating pain.

Business Agreement

On August 2, 2021, we entered into an agreement with Apimeds Korea, a principal stockholder of the Company (the "Business Agreement"). Pursuant to the Business Agreement, Apimeds Korea granted to the Company a sublicensable, royalty-bearing license to utilize all prior clinical development data associated with Apitoxin, Apitox, and all related names, advance clinical research, develop, manufacture and commercialize and sell Apitox in the United States. In exchange for this license, the Company will pay Apimeds Korea a perpetual royalty of 5% of the Company's earnings before interest and taxes (as determined consistent with GAAP, derived from the sale or license of Apitox, less any shipping, handling, and insurance charges, credits (arising from returns or other adjustments), discounts, rebates, or allowances of any kind (if any)). The Business Agreement can be terminated by mutual written agreement by the parties and will automatically terminate upon the bankruptcy or dissolution of the Company.

Assignment Agreement

On October 12, 2021, we entered into an intellectual property assignment agreement (the "Assignment Agreement"), which was effective as of May 12, 2020, with Apimeds Korea and Dr. Christopher Kim, the Company's Chairman and Chief Medical Officer and the founder of Apimeds Korea. During Dr. Kim's engagement with Apimeds Korea, he contributed to the development of the intellectual property as it relates to Apitoxin, which will be marketed in the United States as Apitox (the "Assigned IP").

Pursuant to the Assignment Agreement, Dr. Kim sold, transferred, and conveyed all his rights, title and interest in the Assigned IP to Apimeds Korea. Dr. Kim retained no right to use the Assigned IP. Additionally, the Assignment Agreement acknowledged that the Assigned IP was licensed to us to use via the Business Agreement.

Intellectual Property

Apitox's API is bee venom, a natural, non-synthetic compound that is not patentable, so we rely principally on trade secrets to protect our rights to Apitox, particularly the method and process of manufacturing Apitox.

Supplier

We purchase venom from our United States supplier, Apico, Inc. ("Apico"), via a letter agreement. Pursuant to the letter agreement, Apico agreed that for a period of ten years, or until November 3, 2031 it would not supply *Apis Mellifera venom* for pharmaceutical use for any buyer other than us; *provided that* Apico may also supply Apimeds Korea for its use outside of the United States. The letter agreement excludes customers using venom for immunology, cosmetic or any other "non-pharmaceutical" use. The letter agreement may be terminated upon mutual written consent of both Apico and the Company.

Apico has developed and practices a proprietary method of harvesting venom. It operates under and is certified in current good manufacturing practice regulations enforced by the FDA and has an active and current Drug Master File ("DMF") with the FDA. DMF's are submissions to the FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products. We have an exclusive relationship with our supplier for pharmaceutical use in the United States and they are not permitted to sell to any other party for pharmaceutical use.

Apimeds Korea has a number of proprietary analytical methods for the classification and identification of specific pharmacologically active fractions of its venom, along with numerous manufacturing processes from filtration, vial filing and lyophilization required to produce Apitoxin. Apitoxin is the only approved and commercially available therapeutic product containing purified and sterile bee venom that is registered as an API in South Korea. The proprietary methods developed and practiced for the commercial manufacturing of Apitoxin include dilution, filtering, vial staging and lyophilization parameters and cycles.

We plan to file Apitox as a BLA with the Centers for Biologics and Research of the FDA following the successful completion of our Phase III trial for knee OA. The FDA provides 12-year market exclusivity at the time of approval of a BLA, with the potential for a six-month extension upon approval for pediatric use. If the BLA is approved, the 12-year period would be retroactive to the date of the application.

We intend to file a U.S. trademark application for "Apitox".

Regulatory Environment

Government Regulation and Product Approval

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and the Public Health Service Act (the "PHSA"), and other federal, state, and local statutes and regulations. Both the FDCA and PHSA and their corresponding regulations govern, among other things, the research, development, clinical trials, testing, manufacturing, quality control, safety, purity and potency (efficacy), labeling, packaging, storage, record keeping, distribution, reporting, marketing, promotion, advertising, post-approval monitoring, and post-approval reporting involving biological products. Along with third-party contractors, we will be required to navigate the various preclinical and clinical regulatory obligations and the commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidate. The processes for obtaining regulatory approvals in the United States, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Government policies may change, and additional government regulations may be enacted that could prevent or delay further development or regulatory approval of any product candidates, product or manufacturing changes, additional disease indications or label changes. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action.

Review and Approval for Licensing Biologics in the United States

In the United States, FDA regulates our current product candidate as a biological product, or biologics, under the FDCA, the PHSA, and associated implementing regulations. Biologics, like other drugs, are used for the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. In contrast to low molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biologics are generally derived from living material (human, animal, or microorganism), are complex in structure, and thus are usually not fully characterized.

Biologics are also subject to other federal, state, and local statutes and regulations. The failure to comply with applicable statutory and regulatory requirements at any time during the product development process, approval process, or after approval may subject a sponsor or applicant to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by FDA, FDA's refusal to approve pending applications or supplemental applications, withdrawal of an approval, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA, the Department of Justice ("DOJ"), and other governmental entities.

An applicant seeking approval to market and distribute a biologic in the United States must typically undertake the following:

- completion of non-clinical laboratory tests and studies performed in accordance with FDA's good laboratory practice ("GLP") regulations;
- manufacture, labeling and distribution of investigational drugs in compliance with FDA's current good manufacturing practice ("cGMP") requirements;
- submission to FDA of an investigational new drug application ("IND"), which must become effective before clinical trials may begin and must be updated annually and when significant changes are made;
- approval by an independent institutional review board ("IRB") for each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with FDA's Good Clinical Practices ("GCP") to establish the safety, purity, and potency of the proposed biological product candidate for its intended purpose;
- after completion of all pivotal clinical trials, preparation of and submission to FDA of a BLA requesting marketing approval, which includes providing sufficient evidence to establish the efficacy, safety, purity, and potency of the proposed biological product for its intended use, including from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA advisory committee review, when appropriate, as may be requested by FDA to assist with its review;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the proposed product, or certain components thereof, are produced to assess compliance with cGMP and data integrity requirements to assure that the facilities, methods, and controls are adequate to preserve the biological product's identity, strength, quality, and purity and, if applicable, FDA's good tissue practice ("GTP") requirements for human cellular and tissue products;
- satisfactory completion of FDA inspections of selected clinical investigation sites to assure compliance with GCP requirements and the integrity of the clinical data;
- satisfactory completion of an FDA sponsor GCP inspection, often conducted at the applicant's headquarters facility;

- payment of user fees (unless there is a waiver, exemption, or reduction) under the Prescription Drug User Fee Act (“PDUFA”) for the relevant year;
- FDA’s review and approval of the BLA to permit commercial marketing of the licensed biologic for particular indications for use in the United States;
- compliance with post-approval requirements, including the potential requirements to implement a risk evaluation and mitigation strategy (“REMS”), to report adverse events and biological product deviations, and to complete any post-approval studies; and
- completion of any post-approval clinical studies required by FDA, such as confirmatory trials or pediatric studies.

From time to time, legislation is drafted, introduced, and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing, and marketing of biological products regulated by FDA. In addition to new legislation, FDA regulations, guidance documents, and policies are often revised or interpreted by the agency in ways that may significantly affect the regulation of biological products in the United States. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies, or interpretations will change, and the effects of any such changes.

Preclinical and Clinical Development

Before an applicant can begin testing the potential product candidate in human subjects, the applicant must first conduct preclinical studies. Preclinical studies may include laboratory evaluations of product chemistry, toxicity, and formulation, as well as in vitro and animal studies to assess the potential safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. Preclinical studies are subject to federal regulations and requirements, including GLP regulations, which govern the conduct of animal studies designed to test a product’s safety. None of our preclinical studies to date have been animal studies. The results of an applicant’s preclinical studies are submitted to FDA as part of an IND.

An IND is a request for authorization from FDA to administer an investigational new drug product to humans. An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in a clinical trial. Such authorization must be secured prior to interstate shipment and administration of a biological drug that is not subject of an approved BLA. In support of an IND, applicants must submit a protocol for each clinical trial, which details, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

Human clinical trials may not begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by FDA, unless FDA raises safety concerns or questions about the proposed clinical trial within the 30-day time period. In such a case, FDA may place the IND on clinical hold and the IND sponsor must resolve any of FDA’s outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in regulatory authorization to begin a clinical trial.

FDA may also place a clinical hold or partial clinical hold on a clinical trial following commencement of the trial under an IND. A clinical hold is an order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, under a partial clinical hold, FDA may instruct a sponsor not to enroll any new patients into a study but permit the previously enrolled patients to continue in the study. No more than 30 days after imposition of a clinical hold or partial clinical hold, FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. FDA will base that determination on information provided by the sponsor addressing the deficiencies previously cited or otherwise satisfying FDA that the investigation can proceed.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP regulations, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. If a sponsor chooses to conduct a foreign clinical study under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with GCP regulations in order to use the study as support for an IND or application for marketing approval, including review and approval by an IRB and informed consent from subjects.

Furthermore, an independent IRB for all sites participating in a clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at each site and must monitor the trial until completed. Regulatory authorities, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives.

Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board (“DSMB”). DSMBs review unblinded study data at pre-specified times during the course of the study. If the DSMB determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy, the DSMB can make a recommendation to the sponsor to modify or stop the trial.

Other grounds for a sponsor’s decision to suspend or terminate a study may be made based on evolving business objectives or the competitive climate.

For purposes of BLA approval, clinical trials are typically conducted in the following sequential phases:

- *Phase 1:* The investigational product is initially introduced into a small group of healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These trials may also yield early evidence of effectiveness.
- *Phase 2:* The investigational product is administered to a slightly larger patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase III clinical trials.
- *Phase 3:* The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to generate sufficient data to statistically demonstrate the efficacy and safety of the product, to establish the overall risk/benefit ratio of the investigational product, and to provide an adequate basis for product approval by FDA.

These phases may overlap or be combined. In some cases, FDA may require, or companies may voluntarily pursue, additional clinical trials after a product are approved to gain more information about the product, referred to as Phase 4 trials. Post-approval trials are conducted following initial approval, often to develop additional data and information relating to the use of the product in new indications.

Progress reports detailing the results of the clinical trials must be submitted at least annually to FDA. In addition, IND safety reports must be submitted to FDA for any of the following: serious and unexpected suspected adverse reactions in study subjects; findings from epidemiological studies, pooled analysis of multiple studies, animal or in vitro testing, or other clinical studies, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure.

A sponsor’s planned clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the drug has been associated with unexpected serious harm to patients. FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

During clinical development, the sponsor often refines the indication and endpoints on which the BLA will be based. For endpoints based on patient-reported outcomes (“PROs”), the process typically is an iterative one. FDA has issued guidance on the framework it uses to evaluate PRO instruments. Although the agency may offer advice on optimizing PRO instruments during the clinical development process, FDA usually reserves final judgment until it reviews the BLA.

Concurrent with clinical trials, companies often complete additional animal studies, and develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity and potency of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required clinical testing in accordance with all applicable regulatory requirements, an applicant may submit a BLA requesting licensing to market the biologic for one or more indications in the United States. The BLA must include the results of nonclinical studies and clinical trials; detailed information on the product’s chemistry, manufacture, controls; and proposed labeling. Under the PDUFA, a BLA submission is subject to an application user fee, unless a waiver, reduction, or exemption applies.

FDA will initially review the BLA for completeness before accepting it for filing. Under FDA’s procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing and substantive review. If the agency determines that the application does not meet this initial threshold standard, FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the requested information and review of the application delayed.

After the BLA is accepted for filing, FDA reviews the BLA to determine, among other things, whether a product is safe, pure, and potent and if the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product’s continued identity, strength, quality, safety, purity, and potency. To ensure cGMP, GLP, GCP, GTP, and other regulatory compliance, an applicant must incur significant expenditure of time, money, and effort in the areas of training, record keeping, production and quality control. In addition, FDA expects that all data be reliable and accurate, and requires sponsors to implement meaningful and effective strategies to manage data integrity risks. Data integrity is an important component of the sponsor’s responsibility to ensure the safety, efficacy and quality of its product or products.

For cellular products, FDA will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. GTPs are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and cellular and tissue-based products (“HCT/Ps”), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also specify how HCT/P establishments must register and list their HCT/Ps with FDA and how they must evaluate donors through screening and testing, where applicable.

If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The performance goals and policies implemented by FDA under the PDUFA generally provide for FDA action on an original BLA within 10 months of filing, which (as discussed above) typically occurs within 60 days of submission, but that deadline is extended in certain circumstances. Furthermore, the review process is often significantly extended by FDA’s requests for additional information or clarification.

FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate, and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually has followed such recommendations.

After FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its components will be produced, FDA may issue an approval letter or a Complete Response Letter (“CRL”). An approval letter authorizes commercial marketing of the biological with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that FDA has identified in the BLA, except that where FDA determines that the data supporting the application are inadequate to support approval, FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. If and when the deficiencies have been addressed to FDA’s satisfaction in a resubmission of the BLA, FDA will issue an approval letter. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional data, information, or clarification. FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied and may require additional testing or information and/or require new clinical trials. Even with submission of this additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

During the approval process, FDA will determine whether a REMS is necessary to help ensure the benefits outweigh the risks of the biologic. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

If the FDA approves a product, it may limit the approved indications for use for the product, or require that contraindications, warnings, or precautions be included in the product labeling. FDA may also require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug’s safety after approval. FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

FDA may also require testing and surveillance programs to monitor the product after commercialization. For biologics, such testing may include official lot release, which requires the manufacturer to perform certain tests on each lot of the product before it is released for distribution. The manufacturer then typically must submit samples of each lot of products to the FDA, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer’s tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products itself, before releasing the lots for distribution by the manufacturer.

In general, an approved BLA only allows the sponsor to market the biologic as approved, without modification. If, for example, a sponsor modifies an approved T cell product to target different peptides or in our case to target another HLA type, the sponsor would be required to either file a supplemental BLA with FDA or receive FDA approval for a comparability protocol in order to implement this change into the final product.

The FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, reporting of certain deviations and adverse experiences, product sampling and distribution, and advertising and promotion of the product. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are often subject to further testing requirements and FDA review and approval, depending on the nature of the post-approval change. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their third-party contractors are required to register their facilities with the FDA and certain state agencies. These facilities are subject to routine and periodic unannounced inspections by FDA and certain state agencies for compliance with cGMP, post-marketing safety reporting and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of manufacturing and product. FDA has increasingly observed cGMP violations involving data integrity during site inspections and is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls ensuring complete and secure data; activities documented at the time of performance; audit trail functionality; authorized access and limitations; validated computer systems; and review of records for accuracy, completeness, and compliance with established standards.

Post-approval changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon the sponsor and any third-party manufacturers that the sponsor may use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP, data integrity, pharmacovigilance, and other aspects of regulatory compliance.

The FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-approval studies to assess new safety risks; or imposition of distribution or other restrictions under a REMS. Other potential consequences include, for example:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market, or product recalls;
- fines, warning or untitled letters, or holds on post-approval clinical studies;
- refusal of FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of FDA to permit the import or export of products; or
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties.

FDA strictly regulates the marketing, labeling, advertising, and promotion of prescription drug products placed on the market. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved labeling. FDA's regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims relating to a product's safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications and prohibit the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services ("HHS"), as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil, administrative, and criminal fines, penalties, and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil, administrative, and criminal fines and penalties against companies for alleged improper promotion and has also requested that companies enter into Corporate Integrity Agreements and Consent Decrees of Permanent Injunction under which specified promotional conduct is changed or curtailed.

The distribution of prescription drugs and biologics are subject to the Drug Supply Chain Security Act (“DSCSA”), which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification, and licensing requirements. In addition, the Prescription Drug Marketing Act and its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market.

Expedited Development and Review Programs

FDA offers a number of expedited development and review programs for qualifying product candidates. The fast-track program is intended to expedite or facilitate the process of reviewing new products that meet certain criteria. Specifically, new products are eligible for fast-track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. Any marketing application for a biologic submitted to FDA for approval, including a product with a fast-track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite FDA review and approval process, such as priority review and accelerated approval. FDA also may grant accelerated approval to certain products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions.

The RMAT designation, which we are currently planning to seek for some of our therapies, is intended to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) the drug is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites (including through expansion to additional sites) so as to remove any likelihood of site-specific or investigator-specific bias on the evidence of effectiveness. Once approved, when appropriate, FDA can permit fulfillment of post-approval requirements for RMATs receiving accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five year term patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a drug or biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between the effective date of an IND and initial BLA submission, and all of the approval phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval, even if the product cannot be commercially marketed at that time. The USPTO, in consultation with FDA, reviews and approves the application for patent term restoration.

For patents that might expire during the BLA application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the product candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a product candidate for which a BLA has not been submitted.

Biosimilars and Marketing Exclusivities

The Biologics Price Competition and Innovation Act (“BPCIA”) created an abbreviated approval pathway for biological product candidates shown to be highly similar to or interchangeable with an FDA licensed biological product. A biological product on which another biological product candidate’s BLA relies to establish bio similarity is known as a reference product. Bio similarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form and strength, and no clinically meaningful differences between the biological product candidate and the reference product in terms of safety, purity, and potency. Bio similarity must be shown through analytical trials, animal trials and at least one clinical trial, unless the Secretary of HHS waives a required element. A biosimilar product candidate may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biological product candidate and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biologics, as well as the process by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being resolved by FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biological product candidate submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar’s application has been approved if a patent lawsuit is ongoing within the 42 month period. At this time, it is unclear whether products deemed “interchangeable” by FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy laws and regulations.

Healthcare Regulation

Coverage, Pricing, and Reimbursement

Our ability to successfully commercialize any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products, and significant uncertainty exists as to the coverage and reimbursement status of any products for which may we obtain regulatory approval. In the United States, third-party payors include federal and state health care programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies, and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

Although we currently do not have any commercialized products, our current and future business operations may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician sunshine laws. Some of our pre-commercial activities are subject to some of these laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration in cash or in kind that is intended to induce or reward the referral of business, including the purchase, order, or lease of any item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers and beneficiaries on the other.

Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have found that the Anti-Kickback Statute may be violated if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare program business. In addition, liability may be established without actual knowledge of the statute or specific intent to violate it. Violations of this law are punishable by up to ten years in prison, and can also result in criminal fines, civil money penalties and exclusion from participation in federal healthcare programs.

Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including: providing free product to customers with the expectation that the customers would bill federal programs for the product; providing sham consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company’s products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between \$13,508 and \$27,018 for each separate false claim, and the potential for exclusion from participation in federal healthcare programs. In addition, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

The healthcare fraud provisions of the Health Insurance Portability and Accountability Act (“HIPAA”) prohibit 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 knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many states have analogous laws and regulations, such as: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to certain healthcare providers; laws that require drug manufacturers to report information related to clinical trials or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and laws and local ordinances that require identification or licensing of sales representatives.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

The U.S. federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners as of 2022), as well as ownership and investment interests held in the company by physicians and their immediate family members.

Because we intend to commercialize products that could be reimbursed under a federal health care program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal control to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal control and facilitate compliance can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results

Health Care Reform

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. 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 and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act (“ACA”) substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies’ share of sales to federal health care programs. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers’ rebate liability by raising the minimum basic Medicaid rebate. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

There have been judicial challenges to certain aspects of the ACA, as well as efforts by Congress to modify, and by agencies to alter the implementation of, certain aspects of the ACA. For example, Congress eliminated the tax penalty for failure to comply with the ACA’s individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D to close the coverage gap in most Medicare drug plans, commonly referred to as the donut hole.

It is possible that the ACA, as currently enacted or as may be amended in the future, as well as other healthcare reform measures, including those that may be adopted in the future, may result in more rigorous coverage criteria, and less favorable payment methodologies, or other downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement or restriction on coverage under Medicare or other federal health care programs may result in a similar reduction or restriction by private payors.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. For example, the Inflation Reduction Act introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program which could negatively affect the profitability of our product candidates. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs with respect to the government health benefit programs and otherwise. The IRA or other legislative changes could impact the market conditions for our product candidates.

In general, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Drug Pedigree Laws

State and federal governments have proposed or enacted various drug pedigree laws which can require the tracking of all transactions involving prescription drugs from the manufacturer to the pharmacy (or other dispensing) level. Companies are required to maintain records documenting the chain of custody of prescription drug products beginning with the purchase of such products from the manufacturer. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with customers and manufacturers. While we fully intend to comply with these laws, there is uncertainty about future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our financial results.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, companies are required to file with the U.S. Federal Trade Commission (“FTC”) and the U.S. Department of Justice certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities.

Other

The U.S. federal government, various states and localities have laws regulating the manufacture and distribution of pharmaceuticals, as well as regulations dealing with the substitution of generic drugs for branded drugs. Our operations are also subject to regulation, licensing requirements and inspection by the states and localities in which our operations are located or in which we conduct business.

Certain of our activities are also subject to FTC enforcement actions. The FTC enforces a variety of antitrust and consumer protection laws designed to ensure that the nation’s markets function competitively, are vigorous, efficient and free of undue restrictions. Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us.

In addition, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances, the discharge of pollutants into the air and water and the cleanup of contamination. We are required to maintain and comply with environmental permits and controls for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could incur significant costs or liabilities as a result of any failure to comply with environmental laws, including fines, penalties, third-party claims and the costs of undertaking a clean-up at a current or former site or at a site to which our wastes were transported. In addition, we have grown in part by acquisition, and our diligence may not have identified environmental impacts from historical operations at sites we have acquired in the past or may acquire in the future.

Employees

As of the date of this Annual Report, we have two full time employees. We have no part-time employees and we engage one consultant. We believe that we maintain good relations with our employees.

Item 1A. Risk Factors

As a smaller reporting company, as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information required by this Item.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

Managing Material Risks & Integrated Overall Risk Management

In the normal course of business, we may collect and store certain sensitive company information, including proprietary and confidential business information. We maintain various protections designed to safeguard against cyberattacks, including firewalls, key-based authentication, and virtual private networks. We protect against business interruption by backing up our major systems. We consider these cybersecurity risk management efforts as part of our broader risk management framework. This integration helps ensure that cybersecurity considerations are a fundamental part of our decision-making processes. Our management team works with our audit committee and board of directors (the “Board”) to evaluate and address cybersecurity risks in alignment with our business objectives and operational needs.

Engage Third Parties on Risk Management

To date, we have not engaged independent third parties to assess the risks associated with our information technology resources and information assets. In the future, we may engage third parties to analyze data on the interactions of users of our information technology resources, including our employees, and evaluate the performance of our cybersecurity systems and processes.

Oversee Third Party Risk

We utilize various third-party software applications in the functioning of our core business. We consider the cybersecurity practices of our third-party service providers, including through a general security assessment and contractual requirements, as appropriate, before engaging them in order to help protect us from any related vulnerabilities. Our assessment of risks associated with the use of third-party providers is part of our overall risk management framework.

Risks from Cybersecurity Threats

We face risk from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation.

To date, we have not experienced any previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition.

Governance

Board of Directors Oversight

Our Board is aware of the critical nature of managing risks associated with cybersecurity threats, and recognizes the significance of these threats to our operational integrity and stockholder confidence.

Risk Management Personnel

The audit committee is central to the Board's oversight of cybersecurity risks and bears the primary responsibility for this domain as part of its broader responsibility for risk assessment and management. The audit committee is responsible for escalating significant cybersecurity matters and strategic risk management decisions to the Board, granting the Board comprehensive oversight and the ability to provide guidance on critical cybersecurity issues. We intend for the audit committee to review the Company's cybersecurity posture and the effectiveness of its risk management strategies annually and brief the full Board with respect to the Company's cybersecurity posture and potential risks on a regular basis, with a minimum frequency of once per year.

Management's Role Managing Risk and Reporting to the Board

We do not currently have an employee who has significant and demonstrated professional IT management experience and possesses the requisite education, skills and experience needed to develop and execute our cybersecurity strategies. Presently, our senior management is responsible for monitoring our cybersecurity risks and maintaining an ongoing dialogue with the audit committee regarding emerging or potential cybersecurity risks as needed. The relationship between senior management and the audit committee regarding current and emerging cybersecurity concerns helps to integrate cybersecurity consideration into the Company's broader strategic objectives.

Item 2. Properties

We are located at 2 East Broad Street, 2nd Floor, Hopewell, NJ 08525. This space is donated to us by one of our officers and we do not pay a monthly fee. We believe our current facilities are suitable for our current operations.

Item 3. Legal Proceedings

We are not currently subject to any legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities Market Information

There is no established public trading market for our common stock currently, nor can we give any assurance that one will develop. The Company intends to seek to list its shares of common stock on a national securities exchange (an "Exchange Listing"). Any Exchange Listing is subject to future market conditions and there can be no assurance that any Exchange Listing will occur. Until any Exchange Listing, our common stock is not registered under the Securities Act of 1933, as amended (the "Securities Act"), or any state securities law, and will be restricted as to transfer by law.

Holders

As of the date of this Annual Report, there were 9 holders of record of our common stock.

Dividends

We have not paid any cash dividends on our common stock to date. It is the present intention of our Board to retain all earnings, if any, for use in our business operations and, accordingly, our Board does not anticipate declaring any dividends in the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Unregistered Sales of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and related notes and other financial information included elsewhere in this Annual Report. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under the section entitled "Risk Factors" and elsewhere in this Annual Report. Please also see the section entitled "Special Note Regarding Forward-Looking Statements."

Overview

Apimeds Pharmaceuticals US, Inc. is a clinical stage biopharmaceutical company that is in the process of developing Apitox, a proprietary intradermally administered bee venom-based toxin. Our primary focus is to advance Apitox in the treatment of inflammatory conditions in the United States, specifically osteoarthritis ("OA") and, eventually, multiple sclerosis ("MS").

Apitox, is currently marketed and sold by Apimeds, Inc. in South Korea ("Apimeds Korea") as "Apitoxin" for the treatment of inflammation and pain management symptoms associated with OA. There is an extensive history of use of bee venom, both in the United States and around the world, to assist with pain management. We believe that, in addition to knee OA and MS, Apitox has the potential to help manage difficult to control pain and inflammation issues, which we will explore in the future.

Our Product Candidate

Our product candidate Apitox is a purified, pharmaceutical grade venom of the *Apis mellifera*, or honeybee, which is classified by the U.S Food and Drug Administration (“FDA”) as an active pharmaceutical ingredient (“API”). Apimeds Korea has developed a proprietary method and process of turning extracted bee venom into a lyophilized powder for reconstitution prior to intradermal dose injections, which they sell in Korea as South Apitoxin. Apimeds Korea has exclusively licensed to us all rights to develop, commercialize, market and sell Apitoxin as “Apitox” in the United States in exchange for a sales royalty. See “*Item 13. Certain Relationships and Related Transactions, and Director Independence — Certain Relationships and Related Transactions — Business Agreement.*”

The success of the Company is dependent on obtaining the necessary regulatory approvals of its product candidates, marketing its products and achieving profitable operations. The continuation of the research and development activities and the commercialization of its products, if approved, are dependent on the Company’s ability to successfully complete these activities and to obtain additional financing through a combination of financing activities and operations. It is not possible to predict either the outcome of future research and development or commercialization programs, or the Company’s ability to fund these programs.

Financial Results

Since inception, Apimeds has incurred significant operating losses. For the years ended December 31, 2024 and 2023, Apimeds Pharmaceuticals US, Inc. net loss was \$1,389,990 and \$777,694, respectively. As of December 31, 2024, Apimeds Pharmaceuticals US, Inc. had an accumulated deficit of \$4,391,924, a stockholders’ deficit of \$1,358,121 and a working capital deficit of \$1,011,277.

Going Concern

The Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the issuance date of these financial statements. As of December 31, 2024, the Company had accumulated deficit amount to \$4,391,924. The Company incurred net losses of \$1,389,990 for the year ended December 31, 2024, and expects to continue to incur substantial losses in the future. Based on such conditions and the Company’s current plans, which are subject to change, management believes that the Company’s existing cash as of December 31, 2024, is not sufficient to satisfy its operating cash needs for 12 months from the issuance date of the report.

The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

The success of the Company is dependent on obtaining the necessary regulatory approvals of its product candidates, marketing its products and achieving profitable operations. The continuation of the research and development activities and the commercialization of its products, if approved, are dependent on the Company’s ability to successfully complete these activities and to obtain additional financing through a combination of financing activities and operations. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all.

Results of operations for the years ended December 31, 2024 and 2023

Operating Expense

The following table sets forth the Company's selected statements of operations data for the following periods:

	Years Ended December 31,		
	2024	2023	Change
Operating expenses			
Research and development expenses	\$ -	\$ 98,544	\$ (98,544)
General and administrative expenses	1,275,095	648,892	626,203
Loss from operations	(1,275,095)	(747,436)	(527,659)
Other expenses			
Interest income	2,824	7,811	(4,987)
Interest expense	(117,719)	(38,069)	(79,650)
Net loss	\$ (1,389,990)	\$ (777,694)	\$ (612,296)

Revenues

For the years ended December 31, 2024 and 2023, the Company had no revenue.

Research and Development Expenses

The following table summarizes the year-over-year changes in research and development expenses for the periods presented:

	Years Ended December 31,		
	2024	2023	Change
Research and development expenses	\$ -	\$ 98,544	\$ (98,544)
Total research and development expenses	\$ -	\$ 98,544	\$ (98,544)

Research and development expenses were \$0 for the year ended December 31, 2024, compared to \$98,544 for the same period in 2023, representing a decrease of \$98,544. The decrease in research and development expenses was primarily attributed to a decrease as the Company was not performing any R&D activities currently in 2024.

General and administrative expenses

The following table summarizes the year-over-year changes in general and administrative expenses for the years presented:

	Years Ended December 31,		
	2024	2023	Change
Payroll expenses	\$ 413,404	\$ 114,000	\$ 299,404
Professional services	815,271	485,949	329,322
Office expenses	16,257	33,539	(17,282)
General administrative	30,163	15,404	14,759
	\$ 1,275,095	\$ 648,892	\$ 626,203

General and administrative expenses were \$1,275,095 for the year ended December 31, 2024, compared to \$648,892 for the same period in 2023, representing an increase of \$626,203. The increase was mostly attributable to an increase in professional expenses for a total of approximately \$329,000 and an increase in payroll expenses for the officers of the Company for a total of approximately \$299,000.

Other Expense

The following table summarizes the year-over-year changes in general and administrative expenses for the years presented:

	Years Ended December 31,		Change
	2024	2023	
Interest income	\$ 2,824	\$ 7,811	\$ (4,987)
Interest expense	(117,719)	(38,069)	(79,650)
	<u>\$ (114,895)</u>	<u>\$ (30,258)</u>	<u>\$ (84,637)</u>

Other expense was \$114,895 for the year ended December 31, 2024, compared to \$30,258 for the same period in 2023. Representing an increase of \$84,637. The increase was mainly due to an increase in interest expense for a total of approximately \$80,000.

Net Loss

Net loss was \$1,389,990 for the year ended December 31, 2024, compared to \$777,694 in the same period of 2023, representing an increase of \$612,296. The increase was mainly due to the increase in general and administrative expenses, specifically professional fees associated with the filing of the registration statement on Form S-1 with the U.S. Securities and Exchange Commission (the "SEC") and pre-IPO expenses as well as an increase in payroll expenses.

Liquidity and Capital Resources

The Company has generated no revenue, has incurred operating losses since inception, expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. Until such time as the Company is able to establish a revenue stream, it is dependent upon obtaining necessary equity and/or debt financing to continue operations. The Company cannot make any assurances that sales will commence in the near term or that additional financing will be available to it on acceptable terms or at all. This could negatively impact our business and operations and could also lead to the reduction of our operations.

Cash Flows

The following table presents selected financial information and statistics for each of the periods shown below:

	2024	2023	Change
Net cash used in operating activities	\$ (733,526)	\$ (627,790)	\$ (105,736)
Net cash used in investing activities	-	-	-
Net cash provided by financing activities	326,500	1,032,100	(705,600)
Net (decrease) increase in cash	<u>\$ (407,026)</u>	<u>\$ 404,310</u>	<u>\$ (811,336)</u>

During the year ended December 31, 2024, operating activities used approximately \$734,000 of cash, primarily resulting from a net loss of \$1,389,990, partially offset by non-cash interest expense-related parties of \$37,766, accretion expense of \$79,953, and changes in operating assets and liabilities of \$538,745.

During the year ended December 31, 2023, operating activities used approximately \$628,000 of cash, primarily resulting from a net loss of \$777,694, partially offset by stock compensation expense of \$69,993, non-cash interest expense-related parties of \$33,000, accretion expense of \$5,069, and changes in operating assets and liabilities of \$41,842.

Investing activities

During the years ended December 31, 2024 and 2023 investing activities used \$0.

Financing activities

During the year ended December 31, 2024, financing activities provided \$326,500 of cash resulting from \$250,000 in proceeds from notes payable from related parties and cash advances from related parties of \$76,500.

During the year ended December 31, 2023, financing activities provided \$1,032,100 of cash resulting from \$1,055,000 in proceeds from issuance of shares, cash advances from related parties of \$9,000, offset by repayments to cash advances from related parties of \$31,900.

Contractual Obligations and Commitments

See Note 4 – Debt, and Note 6 – Commitments and Contingencies, of the notes to the Company’s financial statements as of and for the year ended December 31, 2024 included elsewhere in this Annual Report for further discussion of the Company’s commitments and contingencies.

Off-Balance Sheet Arrangements

The Company is not party to any off-balance sheet transactions. The Company has no guarantees or obligations other than those which arise out of normal business operations.

Critical Accounting Policies and Significant Judgments and Estimates

The Company’s management’s discussion and analysis of its financial condition and results of operations is based on its financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”). The preparation of these financial statements requires Apimeds Pharmaceuticals US, Inc. to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. In accordance with GAAP, Apimeds Pharmaceuticals US, Inc. evaluates its estimates and judgments on an ongoing basis. The most significant estimates relate to convertible instruments. Apimeds Pharmaceuticals US, Inc. bases its estimates and assumptions on current facts, historical experiences, and various other factors that Apimeds Pharmaceuticals US, Inc. believes 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.

The Company defines its critical accounting policies as those accounting principles that require it to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on its financial condition and results of operations, as well as the specific manner in which the Company applies those principles. While its significant accounting policies are more fully described in Note 2 to its financial statements, the Company believes the following are the critical accounting policies used in the preparation of its financial statements that require significant estimates and judgments.

Convertible Instruments

The Company evaluates and accounts for conversion options embedded in convertible instruments in accordance with ASC 815 “Derivatives and Hedging Activities”.

The Company accounts for convertible instruments (when we have determined that the embedded conversion options should not be bifurcated from their host instruments) as follows: The Company records when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

As a smaller reporting company, we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data

The financial statements required pursuant to this item are included in Part IV, Item 15 of this Annual Report, beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures**(a) Evaluation of Disclosure Controls and Procedures**

We maintain “disclosure controls and procedures,” as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act, designed to ensure that information required to be disclosed in our reports filed pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

In designing and evaluating the disclosure controls and procedures, we recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and we were required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures. We have carried out an evaluation as of December 31, 2024 under the supervision, and with the participation, of our management, including our Chief Executive Officer (who serves as our principal executive officer) and our Chief Financial Officer (who serves as our principal financial officer), of the effectiveness of the design and operation of our disclosure controls and procedures.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2024 in providing reasonable assurance of achieving the desired control objectives.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our Board, management and other personnel, 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, and includes those policies and procedures that:

- (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

We have conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the framework established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO Framework). This assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls. Based on that evaluation, as a result of the material weaknesses described below, management has concluded that our internal control over financial reporting was not effective as of December 31, 2024.

A material weakness in internal controls is a deficiency in internal control, or combination of control deficiencies, that adversely affects our ability to initiate, authorize, record, process, or report external financial data reliably in accordance with GAAP such that there is more than a remote likelihood that a material misstatement of our annual or interim financial statements that is more than inconsequential will not be prevented or detected. In the course of making our assessment of the effectiveness of internal controls over financial reporting, we identified material weaknesses in our internal control over financial reporting. Specifically, we do not have sufficiently documented procedures or control activities in place to support a reliable financial reporting process. This includes an absence of controls over the review and approval of journal entries, segregation of duties, reconciliations, and other fundamental accounting processes.

Based on our assessment under the criteria described above, we have concluded that our internal control over financial reporting was not effective as of December 31, 2024.

(b) Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal controls over financial reporting that occurred during the year ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The Company continues to review its disclosure controls and procedures, including its internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that the Company's systems evolve with its business.

Item 9B. Other Information

None of our officers or directors, as defined in Rule 16a-1(f) of the Exchange Act, adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Regulation S-K Item 408, during the last fiscal quarter.

Item 9C. Disclosure Regarding Foreign Jurisdiction that Prevents Inspections

Not applicable.

PART III - OTHER INFORMATION

Item 10. Directors, Executive Officers and Corporate Governance

Information Regarding Directors and Executive Officers

The following table sets forth information regarding our executive officers and non-employee directors.

Name	Age	Position
Dr. Christopher Kim, MD	74	Chairman and Chief Medical Officer
Erik Emerson	54	Chief Executive Officer and Director
Mark Corrao	67	Chief Financial Officer
Jakap Koo	64	Director
Dr. Bennett Weintraub, PhD.	56	Director
Hankil Yoon	62	Director
Carol O'Donnell	67	Director
Elona Kogan	55	Director

Christopher Kim, MD. — Chairman and Chief Medical Officer

Dr. Christopher Kim has been our Chairman and Chief Medical Officer since our inception and served as our interim Chief Executive Officer from July 2022 to September 2023. Dr. Kim is the inventor and developer of Apitox and the founder of Apimeds Korea, where he has served as a director since its inception. Mr. Kim served as the Chief Executive Officer of Apimeds Korea from May 2003 to August 2011. Prior to founding Apimeds Korea, Dr. Kim lead with the support of Guju Pharmaceuticals, clinical trials for Apitoxin in Korea, which was approved by the Korea Food and Drug Administration in 2003 for relief of pain and inflammation for patients with Osteoarthritis. In 2005, he began focusing on the clinical development of Apitox in the United States, including the first of two-Phase III clinical studies for Osteoarthritis. Prior to his time with Apimeds Korea, Dr. Kim served as the President of the International Pain Institute of New Jersey from January 1983 to May 2003, a center for chronic pain and other disabling diseases that conducted clinical research and provided treatment. He served as a professor at Biomedical Center, CHA Graduate School of Medicine in Korea from March 2005 to February 2017. Dr. Kim is a licensed physician in New Jersey, New York and Korea and a Pain Medicine Specialist (American Board). Over the past twenty years, Dr. Kim has treated thousands of chronically disabled patients with autoimmune diseases, including MS. Dr. Kim received his medical degree from the School of Medicine, CN University in Korea.

We believe Dr. Kim's extensive experience in pharmaceutical development and the biopharmaceutical industry, as well as his research and treatment of autoimmune diseases, and institutional knowledge of our product candidate, qualifies him to serve on our Board.

Erik Emerson — Chief Executive Officer

Erik Emerson has been our Chief Executive Officer since September 2023. Mr. Emerson is a 25-year veteran of the biopharmaceutical industry. He also serves as an advisor to Odyssey Neuropharma, Inc. where he has served since August 2022. In this role, Mr. Emerson leads business development and positioning efforts for a Phase II asset in evaluation for the treatment of mild traumatic brain injury (concussion). Mr. Emerson was the Chief Commercial Officer for Mezzion Pharmaceuticals, a Korean company establishing operations in the United States, for treatment of Single Ventricle Heart Disease post Fontan surgery, from February 2017 to January 2020. At Adhera Therapeutics, previously known as Marina Biotech, Mr. Emerson served as the Chief Commercial Officer and board member from February 2018 to November 2019. Prior to that Mr. Emerson served as the Executive Chairman and Chief Executive Officer of BioMaris LLC from July 2017 to November 2019. He also served as the President and Chief Executive Officer of Symplmed Pharmaceuticals & Technologies from July 2013 to May 2018. From May 2010 to July 2013, he served as the Senior Director of Commercial Development, Xoma Ltd. He was the director of marketing at Gilead Sciences from May 2007 to May 2010. Mr. Emerson has served as an advisory board member to NuGen Medical Devices since August 2022. Mr. Emerson began his career in sales, sales training and marketing with King Pharmaceuticals from September 2001 to May 2007. Mr. Emerson received a Bachelor's in Arts in Political Science from the University of Oregon.

We believe Mr. Erikson's extensive experience in the biopharmaceutical industry, as well as his prior executive-level experience at similarly situated companies, qualifies him to serve on our Board.

Mark Corrao — Chief Financial Officer

Mr. Mark Corrao has served as our Chief Financial Officer since October 2024. Mr. Corrao is currently serving as the chief financial officer for Ealixir, Inc. (OTC:EAXR), a publicly traded software company specializing in the management and protection of digital identities. He began serving in this role in January 2024. Previously, Mr. Corrao was the chief financial officer for Amesite, Inc. (OTC:AMST), a publicly traded software company from December 2021 through December 2022. Since February 2012, Mr. Corrao has served as the chief financial officer of Neuropathix, Inc., a private biopharmaceutical company. From June 2012 to July 2020 Mr. Corrao was a Managing Director of The CFO Squad LLC, where he is currently an advisor. From January 2017 to June 2021 Mr. Corrao was the chief financial officer for Generex Biotechnology Corp (OTC:GNBT) and its subsidiaries. From December 2018 to October 2021, Mr. Corrao was the chief financial officer for Brain Scientific, Inc., a medical device company. Mr. Corrao served as the chairman of the audit committee for Success Holdings Group International from January 2015 through December 2017. In February 2003, Mr. Corrao founded Strikeforce Technology, Inc. (OTC:SFOR), a publicly traded software development and services company and served as the chief financial officer until June 2010, and he remained a board member until August 2013. Prior to starting Strikeforce, Mr. Corrao was a director at Applied Digital Solutions from December 2000 through December 2001. Mr. Corrao was one of the founders and a Vice President at Advanced Communication Sciences from June 1997 through December 2000, when the company was sold. Mr. Corrao has spent numerous years in the public accounting arena specializing in certified auditing, SEC accounting, corporate taxation and financial planning. Mr. Corrao's background also includes numerous years on Wall Street with Merrill Lynch, Spear Leeds & Kellogg and Greenfield Arbitrage Partners. While on Wall Street, Mr. Corrao was involved in several initial public offerings and has been a guiding influence in several startup companies. Mr. Corrao has a B.S. in Accounting from The City University of New York.

Jakap Koo — Director

Mr. Jakap Koo has served as a director since October 2023. Mr. Koo is also the Chief Executive Officer and President of both Apimeds Korea and its parent company, Inscobee Inc. (KRX: 006490), where he has served since March 2020. Before joining Apimeds Korea and Inscobee, from March 2015 to December 2019 he served as the Chief Executive Officer at Lotte Auto Lease Co. Ltd., where he grew company revenue through various financial services of car rental, installment payment, automobile leasing and investment banking to both B2B and B2C clients. Mr. Koo has spent more than 35 years mostly as C-level executives in various financial institutions and IT companies. His management and operational experiences cover banking, asset management, venture capital, private equity, and biotechnology companies. Mr. Koo has received his MBA from Stern School of New York University. He graduated from Seoul National University majoring in Law.

We believe Mr. Koo's extensive financial knowledge qualifies him to serve on our Board.

Independent Directors:

Dr. Bennett Weintraub, PhD.

Dr. Weintraub has served as a director since October 2023. Dr. Weintraub currently serves as the President of inThought Research ("inThought"), a healthcare business intelligence consulting firm which he founded in 2009. inThought provides business development support, competitive intelligence monitoring, medical conference coverage, and other services both to professional investors and to pharma/ biotech companies. Dr. Weintraub has also served as the Chief Scientific Officer of inPhronesis since 2018.

After completing his training in immunology and biochemistry, Dr. Weintraub co-founded Biotech Tracker, an online tool for investors, where he served as a financial analyst from 2000 to 2008. From 2006 to 2008, Dr. Weintraub served as an analyst at Reuters Insight, providing analysis of drug development and trends in medicine to professional investors. Dr. Weintraub served as a licensed security analyst with Variant Research from 2005 to 2006.

From 1999 to 2000, Dr. Weintraub was senior scientific editor for the biology research journals Cell and Molecular Cell. Dr. Weintraub performed biochemistry and immunology research at Stanford University and at the John Curtin School of Medical Research in Canberra, Australia. He earned his doctorate in Biology from the University of California, San Diego, and a Bachelor of Science in Life Science from the Massachusetts Institute of Technology.

We believe Mr. Weintraub's extensive science background qualifies him to serve on our Board.

Carol O'Donnell

Carol O'Donnell has served as a director since October 2023. Ms. O'Donnell is currently a Director and Member of the Audit Committee of Sono-Tek Corporation (NASDAQ: SOTK), where she has served since November 2018. Prior to that, she served as General Counsel to Boothbay Fund Management LLC, a registered investment adviser, from December 2019 through May 2021. Ms. O'Donnell joined Protégé Partners and MOV37, an industry leading firm investing in and seeding smaller and emerging hedge fund managers in April 2016 and has served as Chief Executive Officer since January 2018. Prior to joining Protégé Partners and MOV37, Ms. O'Donnell was the Director of Legal and Compliance with DARA Capital US, Inc., a Swiss-owned boutique registered investment advisory and wealth management firm from January 2013 to March 2016. She served as General Counsel and Chief Compliance Officer of each of the Permal Group and Framework Investment Group from June 2004 through February 2011 and from January 2002 to May 2004, respectively. She also served as a director of FSI Low Beta from 2012 to 2021. Ms. O'Donnell was named one of the Top 50 Women in Hedge Funds in September 2018 and is currently admitted to practice law in the State of Connecticut.

We believe Ms. O'Donnell's extensive experience in the financial industry qualifies her to serve on our Board.

Hankil Yoon, PhD.

Hankil Yoon has served as a director since October 2023. Dr. Yoon has extensive experience in front-end business areas such as product strategy and planning, software technology and product development, mobile services, global partnership, sales, investment, and mergers and acquisitions and extensive knowledge of the entire software stack, ranging from firmware and OS, middleware. He is the owner of multiple patents on data mining and mobile technology.

Dr. Yoon was previously the Chief Executive Officer of Digital Domain Virtual Human, Inc. from January 2020 to November 2021 where he managed a global organization of developers throughout the United States, Canada and Taiwan using AI technology to implement best quality digital human at optimal speed using minimal amount of facial data and created partnerships with Google, Amazon, and Microsoft to implement "AI with a human face". He served as the Executive Advisor to the Chief Executive Officer of Flipboard, Inc. from January 2019 to December 2020. Prior to that, Mr. Yoon served as the Senior Vice President at Samsung Electronics, from May 2005 to December 2018. He served as the Chairperson at the Tizen Association from January 2015 to December 2018. Mr. Yoon served as the Chief Technology Officer at Oracle Corporation, US, from August 2000 to May 2005. Dr. Yoon has BS in Computer Engineering, Seoul National University (1985) and an MBA (2017) in Global Management, an MS in Electrical & Computer Engineering, University of California at Irvine (1995), PhD, in Computer & Information Science & Engineering, University of Florida (2000).

We believe Mr. Yoon's extensive experience in product strategy and planning, software technology and product development qualifies him to serve on our Board.

Elona Kogan

Elona Kogan has served as a director since October 2024. Beginning in August 2024, Ms. Kogan has served as the Chief Legal Officer of Terns Pharmaceutical, Inc. (Nasdaq: TERNs), a publicly traded biopharmaceutical company, Prior to joining us, from November 2020 through August 2024, Ms. Kogan served as the General Counsel and Chief Legal Officer of Seer Inc. (Nasdaq: SEER), a publicly traded life science company. From May 2018 through August 2021, Ms. Kogan served as a director of Cardax, Inc., a biotechnology company operating in the inflammatory health space. From March 2019 through August 2020, Ms. Kogan served as the General Counsel of Selecta Biosciences, Inc., a clinical-stage biotechnology company. Ms. Kogan is a graduate of Southwestern University School of Law. Ms. Kogan graduated from Columbia University, Barnard College, with a B.A. in Economics.

We believe Ms. Kogan's extensive experience in biopharmaceutical and life science space, in addition to her experience serving as general counsel and chief legal officer of other publicly traded companies qualifies her to serve on our Board.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our executive officers or directors were involved in any legal proceedings described in Item 401(f) of Regulation S-K in the past ten years.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934, requires our directors, executive officers and persons who own more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other of our equity securities. During the year ended December 31, 2024, our officers, directors and 10% stockholders were not required to make filings pursuant to Section 16(a).

Code of Business Conduct and Ethics

In accordance with the information required by this Item 10 relating to the code of ethics required by Item 406 of Regulation S-K, the Company has a Code of Business Conduct and Ethics (the "Code"), which applies to its directors, officers (including its principal executive officer, the principal financial officer and principal accounting officer), and all other employees (collectively, the "Covered Persons" and each a "Covered Person"). The full text of the Code is available on the "Investors" section of the Company's website. The Company intends to satisfy the SEC's requirements regarding amendments to, or waivers from, the Code by posting such information on its website or by filing a Current Report on Form 8-K to disclose such information.

Procedures for Stockholders to Recommend Director Nominees

The Company's bylaws (the "Bylaws") were adopted on May 12, 2020. On February 7, 2025, the Company established the nominating and corporate governance committee of the Board and adopted the nominating and corporate governance committee's written charter. Pursuant to the nominating and corporate governance committee's charter, the committee may, if it deems appropriate, establish procedures to be followed by stockholders in submitting recommendations for Board candidates. Except as discussed in the foregoing sentences, there have been no material changes to the procedures by which security holders may recommend nominees to our Board.

Audit Committee Information

The Company's Board has a standing audit committee. Our audit committee is chaired by Carol O'Donnell and its other members are Elona Kogan and Dr. Bennet Weintraub. Each member of the audit committee is financially literate. Carol O'Donnell qualifies as an "audit committee financial expert" as defined in applicable SEC rules.

Insider Trading Policy

The Company has an insider trading policy (the "Insider Trading Policy") which prohibits Covered Persons from buying or selling the Company's securities while the Covered Person is aware of material nonpublic information about the Company. The Company believes that its Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and any applicable listing standards. A copy of the Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

Item 11. Executive Compensation

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

As an “emerging growth company,” we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such term is defined in the rules promulgated under the Securities Act. Accordingly, we are required to provide a Summary Compensation Table, as well as limited narrative disclosures regarding executive compensation for our last two completed fiscal years and an Outstanding Equity Awards at Fiscal Year End Table for our last completed fiscal year. These reporting obligations extend only to “named executive officers.” Individuals we refer to as our “named executive officers” include (i) all individuals serving as our principal executive officer during the fiscal year ended December 31, 2024 and (ii) our two most highly compensated executive officers, as defined in Exchange Act Rule 3b-7, other than our principal executive officer, who were serving as executive officers at the end of the fiscal year ended December 31, 2024, whose salary and bonus for services rendered in all capacities exceeded \$100,000 during the fiscal year ended December 31, 2024.

Our named executive officer for the year ended December 31, 2024, was our principal executive officer, Erik Emerson. No other executive officer of the Company received total compensation during the fiscal year ended December 31, 2024 in excess of \$100,000, and thus disclosure is not required for any other person.

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officer for the years ended December 31, 2024, and 2023.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)	Nonequity Incentive Plan Compensation	All Other Compensation	Total (\$)
					(\$)	(\$)	
Erik Emerson Chief Executive Officer	2024	300,000	—	—	—	—	300,000
	2023	90,000	—	—	—	—	90,000

Narrative to Summary Compensation Table

Our executive compensation program is based on a pay for performance philosophy. Compensation for our Chief Executive Officer is composed primarily of the following main components: base salary, bonus, and equity incentives in the form of stock options. Like all full-time employees, our Chief Executive Officer is eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation philosophy and compensation plans and arrangements as circumstances require.

Employment Agreement with Erik Emerson

The Company entered into an employment agreement with Erik Emerson on September 21, 2023 (the “Emerson Agreement”). Pursuant to the Emerson Employment Agreement, he will serve as the Company’s Chief Executive Officer and receive a yearly salary of \$300,000. Mr. Emerson’s employment shall continue for one year from the date of execution and shall automatically renew for successive one year periods in the event of a closing on a public offering of the company during the initial term unless either party gives 30 days’ written notice of its intent not to renew the Emerson Agreement prior to the end of the then-current term.

If Mr. Emerson becomes disabled such that he is unable to perform his obligations hereunder, with or without reasonable accommodation, for a period of 180 days or more over a rolling consecutive twelve month period of time, or it is determined that Mr. Emerson is not able to perform the essential functions of his duties (incurs a “Disability”) the Company may terminate Mr. Emerson’s employment, unless otherwise required by law. In the event employment is terminated as a result of Mr. Emerson Disability, the Company shall have no further obligation to pay any unaccrued compensation or unaccrued benefits to Mr. Emerson for periods after the date of such termination.

Mr. Emerson may be terminated with or without Cause (as defined in the Emerson Agreement) upon thirty (30) days' written notice to Mr. Emerson.

Mr. Emerson will not be eligible to receive an annual bonus at any time prior to the closing on a public offering (as defined in the Emerson Agreement) of the Company. For all fiscal years following the closing on a public offering of the Company, including any fiscal year during which the closing on a public offering occurs, Mr. Emerson will be eligible to receive an annual bonus based on the achievement of goals for the Company's and/or Mr. Emerson's performance, as determined by the Board in its sole discretion.

Mr. Emerson is entitled to receive such other employee benefits and perquisites offered by the Company to any of the Company's similarly-situated corporate employees, provided that the Company shall retain discretion to cancel, modify or amend such benefits provided to Mr. Emerson and similarly situated employees in its discretion.

Upon the closing on a public offering, Mr. Emerson shall receive an incentive stock option to purchase a number of shares of the Company's common stock equal to 3% of the post-public offering capitalization of the Company (the "Equity Award"), of which 40% of the options shall vest upon grant and the remainder will vest in three equal installments on the annual anniversary of the date of grant. Mr. Emerson will agree not to sell any shares underlying the Equity Award, even if exercised, for a period of three years from the date of grant. Mr. Emerson will be eligible for future equity incentive awards in the discretion of the Board.

Mr. Emerson irrevocably assigns to the Company (or its designees), and agrees to hold in trust for the sole right and benefit of the Company, without any additional consideration, and to promptly make full written disclosure to the Company of, all of his right, title, and interest in and to any and all Inventions (as defined in the Emerson Agreement) that Mr. Emerson invents during his employment and for a period of one year following the termination of his employment with the Company.

There is customary confidentiality and non-solicitation clauses in Mr. Emerson's agreement whereby he has agreed to keep all confidential information confidential and will not directly or indirectly solicit any of the Company's employees or vendors after his employment with the Company ends.

While the Company employs Mr. Emerson, he agrees that he will not, without the Board's prior written consent, directly or indirectly, provide services to any other person for which Mr. Emerson receives compensation, nor will he otherwise engage in activities that would conflict or interfere with his full and faithful performance of his duties as an employee of the Company.

Stock Option Award to Dr. Christopher Kim

On May 12, 2020 the Company granted Dr. Christopher Kim, the Company's Chairman and Chief Medical Officer, a non-qualified stock option award to purchase 138,900 shares of the Company's common stock at an exercise price of \$11.28 per share. The option vested in three equal installments and vested fully on May 12, 2023. The options have a term of ten years from the date of grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of the option grant agreement between the Company and Dr. Kim.

Consulting Agreement with Mark Corrao

On October 4, 2024, the Company entered into a consulting agreement with Mark Corrao (the "CFO Consulting Agreement") to engage Mr. Corrao (the "Consultant"), to provide consulting services as the Company's non-employee chief financial officer prior to the completion of the Company's initial public offering. It is anticipated that following the completion of the Company's initial public offering, the Consultant will become an employee of the Company on a full-time basis.

The Consultant has been duly appointed as the chief financial officer and principal financial and accounting officer of the Company and will remain as an executive officer of the Company during the term of the CFO Consulting Agreement. The Consultant will report directly to Erik Emerson, Chief Executive Officer and to any other party designated by Mr. Emerson in connection with the performance of the duties under the CFO Consulting Agreement and shall fulfill any other duties reasonably requested by the Company and agreed to by the Consultant.

The initial term of the CFO Consulting Agreement is one year. The CFO Consulting Agreement may only be extended thereafter by mutual agreement, unless earlier terminated. Either party may terminate the CFO Consulting Agreement at any time by providing thirty days’ written notice to the other party.

As compensation for the services rendered pursuant to the CFO Consulting Agreement, the Company shall pay Consultant a minimum \$2,500 upon signing, and \$2,500 per month for up to eight hours of services rendered per month, payable on the first business day of each month. Additional hours in excess of eight hours per month, if any, shall be billed at \$250.00 per hour.

Outstanding Equity Awards at Fiscal-Year End 2024

There were no outstanding equity-based awards of the Company held by the named executive officer as of December 31, 2024.

Policies and Practices for Granting Certain Equity Awards

We do not schedule equity award grants in anticipation of the release of material nonpublic information, nor do we time the release of material nonpublic information based on equity grant dates.

Director Compensation Table

None of our directors received any form of compensation for the year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters *Securities*

Authorized for Issuance under Share-Based Compensation Plans

Equity Compensation Plan Information

The following table sets forth, as of December 31, 2024, information regarding awards previously granted and outstanding, and securities authorized for future issuance, under the Company's equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants or Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants or Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Outstanding Options, Warrants, or Rights)
Equity compensation plans approved by shareholders	—	—	1,000,000
Equity compensation plans not approved by shareholders	213,692	7.332	—

(1) Represents shares available for grant under the Company's Equity Incentive Plan (defined below) as of December 31, 2024.

Apimeds Pharmaceuticals US, Inc. Equity Incentive Plan

On September 18, 2024, we adopted an equity incentive plan for our employees, the Apimeds Pharmaceuticals US, Inc. 2024 Equity Incentive Plan (the "Equity Incentive Plan"). The purposes of the Equity Incentive Plan are to provide additional incentives to selected employees, directors and independent contractors of, and consultants to, the Company or its affiliates, to strengthen their commitment, motivate them to faithfully and diligently perform their responsibilities and to attract and retain competent and dedicated persons who are essential to the success of our business and whose efforts will impact our long-term growth and profitability.

Awards

The Equity Incentive Plan allows the Company to make equity and equity-based incentive awards to officers, employees, directors, consultants, and advisors. The Board anticipates that providing such persons with a direct stake in the Company will assure a closer alignment of the interests of such individuals with those of the Company and its stockholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company.

The Equity Incentive Plan provides for the grant of non-qualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, stock bonus awards, and performance compensation awards. All awards will be set forth in an award agreement which will detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations.

A brief description of each award type follows.

- *Non-Qualified Stock Options* means the right to purchase shares pursuant to terms and conditions that are not intended to be, or do not qualify as, an Incentive Stock Options;
- *Incentive Stock Options* means the right to purchase shares pursuant terms and conditions that are intended to qualify as, and that satisfy the requirements applicable to, an incentive equity option within the meaning of Code Section 422 of the United States Internal Revenue Code of 1986, as amended;
- *Stock Appreciation Rights* means a right, designated as an SAR, to receive the appreciation in the fair market value of shares;

- *Restricted Stock* means an award of shares subject to vesting conditions;
- *Restricted Stock Units* shall mean a right to receive shares or cash upon vesting;
- *Stock Bonus Awards* means unrestricted common stock, or other awards denominated in common stock, either alone or in tandem with other awards; and
- *Performance Compensation Awards* means an award granted to a participant that entitles the participant to delivery of shares or cash upon achievement of performance goals.

1,000,000 shares of common stock have initially been reserved for the issuance of awards under the Equity Incentive Plan (the “Initial Limit”). The Initial Limit is subject to adjustment in the event of a reorganization, recapitalization, reclassification, stock split, stock dividend, reverse stock split or other similar change in the Company’s capitalization. The maximum aggregate number of shares of common stock of the Company that may be issued upon exercise of incentive stock options under the Equity Incentive Plan shall not exceed the Initial Limit, as adjusted. Shares underlying any awards under the Equity Incentive Plan that are forfeited, cancelled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding, satisfied without the issuance of stock or otherwise terminated (other than by exercise) will be added back to the shares available for issuance under the Equity Incentive Plan and, to the extent permitted under Section 422 of the Code and the regulations promulgated thereunder, the shares that may be issued as incentive stock options.

The Equity Incentive Plan is currently administered by a committee of at least two people as the Board may appoint to administer the Equity Incentive Plan or, if no such committee has been appointed by the Board, the Board, pursuant to the terms of the Equity Incentive Plan (the “Committee”). The plan administrator, which initially will be the Committee, has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the Equity Incentive Plan. The plan administrator may delegate to a committee consisting of one or more officers of the Company, the authority to awards to individuals who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not members of the delegated committee, subject to certain limitations and guidelines.

Persons eligible to participate in the Equity Incentive Plan will be officers, employees, non-employee directors, consultants, and advisors of the Company and its subsidiaries as selected from time to time by the plan administrator in its discretion. As of the date of this Annual Report, approximately 12 individuals are eligible to participate in the Equity Incentive Plan, which includes approximately two officers, no employees who are not officers, five non-employee directors, and five consultants/independent contractors.

Options

The Equity Incentive Plan permits the granting of both options to purchase common stock of the Company intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. Options granted under the Equity Incentive Plan will be non-qualified options if they fail to qualify as incentive stock options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and its subsidiaries. Non-qualified options may be granted to any persons eligible to receive awards under the Equity Incentive Plan. The option exercise price of each option will be determined by the plan administrator but generally may not be less than 100% of the fair market value of the common stock of the Company on the date of grant or, in the case of an incentive stock option granted to a ten percent stockholder, 110% of such share’s fair market value. The term of each option will be fixed by the plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each option may be exercised, including the ability to accelerate the vesting of such options.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the plan administrator or by delivery (or attestation to the ownership) of shares of common stock of the Company that are beneficially owned by the optionee free of restrictions or were purchased in the open market. Subject to applicable law, the exercise price may also be delivered by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the plan administrator may permit non-qualified options to be exercised using a “net exercise” arrangement that reduces the number of shares issued to the optionee by the largest whole number of shares with fair market value that does not exceed the aggregate exercise price.

Stock Appreciation Rights

The plan administrator may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock of the Company, or cash, equal to the value of the appreciation in the Company's stock price over the exercise price. The exercise price generally may not be less than 100% of the fair market value of common stock of the Company on the date of grant. The term of each stock appreciation right will be fixed by the plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each stock appreciation right may be exercised, including the ability to accelerate the vesting of such stock appreciation rights.

Restricted Stock and Restricted Stock Units

The plan administrator may award restricted shares of common stock of the Company and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with the Company through a specified vesting period. The plan administrator may also grant shares of common stock of the Company that are free from any restrictions under the Equity Incentive Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant. The plan administrator may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock of the Company.

Stock Bonus Awards

The plan administration may issue unrestricted common stock, or other awards denominated in common stock, under the Equity Incentive Plan to participants, either alone or in tandem with other awards, in such amounts as the plan administration shall from time to time in its sole discretion determine.

Performance Compensation Awards

The plan administrator may grant awards under the Equity Incentive Plan to participants, which may be cash-based, subject to the achievement of certain performance goals, including continued employment with the Company.

Other Material Features

The Equity Incentive Plan requires the plan administrator to make appropriate adjustments to the number of shares of common stock that are subject to the Equity Incentive Plan, to certain limits in the Equity Incentive Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

Except as set forth in a stock award agreement issued under the Equity Incentive Plan, in the event of (i) a transfer of all or substantially all of the Company's assets, (ii) a merger, consolidation or other capital reorganization or business combination transaction of the Company with or into another corporation, entity or person, or (iii) the consummation of a transaction, or series of related transactions, in which any person becomes the beneficial owner directly or indirectly, of more than 50% of Company's then outstanding capital stock, each outstanding stock award (vested or unvested) will be treated as the plan administrator determines, which may include (a) Company's continuation of such outstanding stock awards (if Company is the surviving corporation); (b) the assumption of such outstanding stock awards by the surviving corporation or its parent; (c) the substitution by the surviving corporation or its parent of new stock options or other equity awards for such stock awards; (d) the cancellation of such stock awards in exchange for a payment to the participants equal to the excess of (1) the fair market value of the shares subject to such stock awards as of the closing date of such corporate transaction over (2) the exercise price or purchase price paid or to be paid (if any) for the shares subject to the stock awards (which payment may be subject to the same conditions that apply to the consideration that will be paid to holders of shares in connection with the transaction, subject to applicable law); or (e) the opportunity for participants to exercise the stock options prior to the occurrence of the corporate transaction and the termination (for no consideration) upon the consummation of such corporate transaction of any stock options not exercised prior thereto.

The Equity Incentive Plan provides that a stock award may be subject to additional acceleration of vesting and exercisability upon or after a "Change in Control" (as defined in the Equity Incentive Plan) as may be provided in the award agreement for such stock award or as may be provided in any other written agreement between the Company or any affiliate and the participant, but in the absence of such provision, no such acceleration will occur.

Participants in the Equity Incentive Plan are responsible for the payment of any federal, state or local taxes that the Company or its subsidiaries are required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. The plan administrator may cause any tax withholding obligation of the Company or its subsidiaries to be satisfied, in whole or in part, by the applicable entity withholding from shares of common stock of the Company to be issued pursuant to an award shares with an aggregate fair market value that would satisfy the withholding amount due. The plan administrator may also require any tax withholding obligation of the Company or its subsidiaries to be satisfied, in whole or in part, by an arrangement whereby a certain number of shares issued pursuant to any award are immediately sold and proceeds from such sale are remitted to the Company or its subsidiaries in an amount that would satisfy the withholding amount due.

The Equity Incentive Plan generally does not allow for the transfer or assignment of awards, other than by will or by the laws of descent and distribution or pursuant to a domestic relations order; however, the plan administrator may permit the transfer of non-qualified stock options by gift to an immediate family member, to trusts for the benefit of family members, or to partnerships in which such family members are the only partners.

The plan administrator may amend or discontinue the Equity Incentive Plan and the plan administrator may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder's consent. Certain amendments to the Equity Incentive Plan will require the approval of the Company's stockholders. Generally, without shareholder approval, (i) no amendment or modification of the Equity Incentive Plan may reduce the exercise price of any stock option or the strike price of any stock appreciation right, (ii) the plan administrator may not cancel any outstanding stock option or stock appreciation right where the fair market value of the common stock underlying such stock option or stock appreciation right is less than its exercise price and replace it with a new option or stock appreciation right, another award or cash and (iii) the plan administrator may not take any other action that is considered a "repricing" for purposes of the shareholder approval rules of the applicable securities exchange.

All awards granted under the Equity Incentive Plan will be subject to recoupment in accordance with any clawback policy that Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which Company securities are listed or as is otherwise required by the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in a stock award agreement as the Board determines necessary or appropriate.

No options or stock appreciation rights may be granted under the Equity Incentive Plan after the date that is ten years from the Equity Incentive Plan Effective Date. No awards under the Equity Incentive Plan have been made prior to the date of this Annual Report.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth, as of April 15, 2025, certain information as to the Company's common stock beneficially owned by persons known by the Company to own in excess of 5% of the outstanding shares of such stock. In addition, the table includes information regarding the shares of the Company's common stock beneficially owned by (i) each named executive officer, (ii) each of the Company's directors and (iii) the Company's directors and executive officers as a group. Management knows of no person, except as listed below, who beneficially owned more than 5% of the outstanding shares of the Company's common stock as of April 15, 2025. Except as otherwise indicated, the information provided in the following table was obtained from filings with the SEC and the Company pursuant to the Exchange Act. For purposes of the following table, in accordance with Rule 13d-3 under the Exchange Act, a person is deemed to be the beneficial owner of any shares of the Company's common stock which he or she has or shares, directly or indirectly, voting or investment power, or which he or she has the right to acquire beneficial ownership of at any time within 60 days after April 15, 2025. As used herein, "voting power" is the power to vote, or direct the voting of, shares, and "investment power" includes the power to dispose of, or direct the disposition of, such shares. Unless otherwise noted, each beneficial owner has sole voting and sole investment power over the shares beneficially owned. Unless otherwise noted, the business address of each of the following entities or individuals is 65-1277 Ki Rd., Kamuela, Hawaii 96743.

Name of Beneficial Owner	Number of Shares Beneficially Owned	% of Common Stock
Directors and Named Executive Officers:		
Christopher Kim, MD ⁽¹⁾	213,692	2.54%
Erik Emerson	—	—
Mark Corrao	—	—
Bennett Weintraub, PhD	—	—
Hankil Yoon	—	—
Carol O'Donnell	—	—
Jakap Koo	615,385	7.32%
All directors and officers as a group (7 individuals)	829,077	9.86%
5% or Greater Stockholders:		
Inscobee Inc. ⁽²⁾	5,908,783	70.28%
Dominus IB, Inc. ⁽³⁾	800,000	9.52%
Seed 1 ho ⁽⁴⁾	600,000	7.14%

(1) Represents 213,692 shares issuable pursuant to outstanding options, which are exercisable within 60 days of the date hereof.

(2) Represents 1,596,760 shares or 18.99% held directly by Inscobee Inc. and 4,312,023 shares or 51.29% held through its wholly owned subsidiary, Apimeds Inc. Inscobee Inc. has voting and investment control over the shares held by Apimeds Inc. Millenium Holdings has voting and investment control with respect to the shares held by Inscobee Inc. Millenium Holdings is controlled by You In Soo, and as such, Mr. Yoo may be deemed to have beneficial ownership over the shares held by both Inscobee Inc. and Apimeds Inc. The business address for Inscobee Inc. is Room 613, Digital-ro 130, 6F, Geumcheon-gu, Seoul, 08580 Republic of Korea. The business address for Millenium Holdings is 107, Gasan Digital 2-ro, Geumcheon-gu, Seoul, Korea. Each of the parties named in this footnote disclaims any beneficial ownership of the reported shares other than to the extent of any pecuniary interest the party may have therein.

(3) Dominus IB, Inc. is controlled by its Chief Executive Officer and largest shareholder, Park Kyoung Jin, who may be deemed to have voting and investment control with respect to the shares held by Dominus IB, Inc. The business address for Dominus IB, Inc. is 144, Dobong-ro, Gangbuk, Seoul, Republic of Korea.

(4) Seed 1 ho is controlled by its Chief Executive Officer and largest shareholder, Son Hyoung Jin, who may be deemed to have voting and investment control with respect to the shares held by Seed 1 ho. The business address for Seed 1 ho is 116, Sindae-gil, Okcheon-myeon, Yangpyeong-gun, Gyeonggi-do, Republic of Korea.

Changes in Control

Management of the Company knows of no arrangements, including any pledge by any person or securities of the Company, the operation of which may at a subsequent date result in a change in control of the registrant.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Certain Relationships and Related Transactions

Other than as listed below, during 2024 and 2023, we were not a participant in any transaction or series of transactions in which the amount involved did exceed or may exceed the lesser of \$120,000 or 1% of the average of our total assets at year-end for 2024 and 2023 in which any directors, director nominees, executive officers, greater than 5% beneficial owners and their respective immediate family members (each, a “Related Person”) had or will have a direct or indirect material interest, other than the compensation arrangements (including with respect to equity compensation) described in “Executive Compensation” beginning on page 38 and “Director Compensation” on page 40.

Business Agreement

On August 2, 2021, we entered into an agreement with Apimeds Korea, a principal stockholder of the Company (the “Business Agreement”). Pursuant to the Business Agreement, Apimeds Korea granted to the Company a sublicenseable, royalty-bearing license to research, develop, manufacture and commercialize and sell Apitox in the United States. In exchange for this license, the Company will pay Apimeds Korea a perpetual royalty of 5% of the Company’s earnings before interest and taxes as determined consistent with GAAP, derived from the sale or license of Apitox, less any shipping, handling, and insurance charges, credits (arising from returns or other adjustments), discounts, rebates, or allowances of any kind (if any). The Business Agreement may be terminated by mutual written agreement by the parties and will automatically terminate upon the bankruptcy or dissolution of the Company.

Assignment Agreement

On October 12, 2021 we entered into an intellectual property assignment agreement (the “Assignment Agreement”) with Apimeds Korea and Dr. Christopher Kim, the Company’s Chairman and Chief Medical Officer and founder of Apimeds Korea, effective as of May 12, 2021. Pursuant to the Assignment Agreement Dr. Kim transferred to Apimeds Korea all right, title, interest and good will in all of the intellectual property as it relates to Apitoxin, which will be marketed in the United States as Apitox (the “Assigned IP”).

Dr. Kim retained no right to use the Assigned IP. Additionally, the Assignment Agreement acknowledged that the Assigned IP was licensed to us to use via the Business Agreement, as described above.

Patent License Agreement

On October 12, 2021, we entered into a patent license agreement (the “Patent License Agreement”) Dr. Christopher Kim, the Company’s Chairman and Chief Medical Officer and the founder of Apimeds Korea. During Dr. Kim’s engagement with Apimeds Korea, he contributed to the development of the intellectual property as it relates to Apitoxin. Pursuant to the Patent License Agreement, we were licensed certain patents. In consideration of its license under the Patent License Agreement, the Company paid Dr. Kim \$1.00.

The patents expired in 2023 and, presently, the Company does not intend renew the expired patents or apply for any additional patents.

Business Establishment Agreement

On March 3, 2020, Apimeds Korea entered into a business establishment agreement with the Company pursuant to which Apimeds Korea agreed provide funding to us in the form of two tranches consisting of \$500,000 each (for a total of \$1,000,000). The first tranche was funded in March 2020 and the second tranche was funded in May 2020.

August 2021 Promissory Note

The Company issued to Apimeds Korea a convertible promissory note in the principal amount of \$400,000, on August 30, 2021 (the “August 2021 Note”). The August 2021 Note is due and payable on the earlier of (i) August 30, 2026 or (ii) a sale of the Company (as defined in the August 2021 Note) (the “Maturity Date”). The August 2021 Note bears interest at an annual rate equal to the lesser of (i) 5% per annum, or (ii) the maximum rate permissible by law.

The Company may prepay the August 2021 Note at any time without penalty. If not previously paid by the Company, principal and accrued interest on the August 2021 Note will automatically convert into common stock (i) immediately prior to the closing of the Company’s firm commitment underwritten initial public offering resulting in at least \$40,000,000 gross proceeds to the Company (a “Qualified IPO”), (ii) immediately prior to the closing of the Company’s initial listing of its common stock on an international exchange by means of an effective registration statement on Form S-1 that results in at least \$40,000,000 of gross proceeds to the selling stockholders (a “Qualified Direct Listing”), or (iii) upon the consummation of the Company’s merger, consolidation, share exchange or other transaction with a publicly traded “special purpose acquisition company” resulting in a stock exchange listing (a “SPAC Transaction”). The number of shares of common stock shall be determined by dividing (x) the outstanding principal balance of the Apimeds Korea Note plus accrued but unpaid interest by (y) as applicable, (i) in case of a Qualified IPO, the per share price for which shares of common stock are initially offered in the Qualified IPO as reflected in the final prospectus, (b) in case of a Qualified Direct Listing, the first closing price of the common stock on the first trading day, following the Qualified Direct Listing, and (c) in case of a SPAC Transaction, the price per share of the successor entity that is established in connection with such SPAC Transaction.

If there shall be any Event of Default (as defined below), the August 2021 Note shall accelerate and all principal and unpaid accrued interest shall become immediately due and payable, provided that the Company shall have 20 days from receipt of such notice to cure an Event of Default. The occurrence of any one or more of the following shall constitute an “Event of Default”: (a) the Company fails to pay timely all or any part of the principal amount or accrued interest due under the August 2021 Note, (b) the Company files any petition or action for relief under any bankruptcy, reorganization, insolvency or moratorium law or any other law for the relief of, or relating to, debtors, or makes any assignment for the benefit of creditors or takes any corporate action in furtherance of any of the foregoing, or (c) an involuntary petition is filed against the Company, or a custodian, receiver, trustee, assignee for the benefit of creditors (or other similar official) is appointed to take possession, custody or control of any property of the Company.

The terms of the August 2021 Note may only be amended with the written consent of both parties and may only be transferred upon its surrender to the Company for registration of transfer or accompanied by a duly executed written instrument of transfer in the form satisfactory to the Company.

On December 5, 2023, the Company and Apimeds Korea amended the August 2021 Note (the “August 2021 Note Amendment”) as follows: the maturity date was extended to the earlier of (i) December 31, 2026, or (ii) the consummation of an offering of our common stock (and other securities potentially) resulting in the listing for trading of our common stock on the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing) (“Qualified Offering”).

Additionally, the August 2021 Note Amendment provided for conversion of the note, including accrued and unpaid interest, at a conversion price of \$2.60 per share as follows: (i) at the option of the holder, in its sole discretion, in whole or in part, and (ii) mandatorily simultaneous with the consummation of a Qualified Offering, in each case, into fully paid and nonassessable shares of common stock at the conversion price.

On June 12, 2024, Apimeds Korea assigned the August 2021 Note to Inscobee, Inc. a South Korean company, and the parent company of Apimeds Korea, (“Inscobee”).

If not converted earlier, upon the closing of a Qualified Offering, the August 2021 Note will automatically convert into approximately 179,283 shares of common stock.

March 2022 Promissory Note

The Company issued to Apimeds Korea, a promissory note in the principal amount of \$160,000 on March 21, 2022 (the “March 2022 Note”). The March 2022 Note bears interest at a rate equal to 5% per annum (the “Interest Rate”). The March 2022 Note is due and payable on the earlier of (i) the closing of an equity financing by the Company with gross proceeds to the Company of at least \$3,000,000, or (ii) July 15, 2022.

The Company may prepay the March 2022 Note at any time without penalty. If any payment due on the March 2022 Note is not paid within five days after the amount becomes due, the payment shall be considered in default and the interest rate will increase by an additional 5% on the defaulted payment amount and Inscobee may also, in its sole discretion, without notice or demand, declare the entire unpaid principal balance plus accrued interest due and payable immediately.

On December 5, 2023, the Company and Apimeds Korea amended the March 2022 Note (the “March 2022 Note Amendment”) as follows: the maturity date was extended to the earlier of (i) December 31, 2026, or (ii) the consummation of a Qualified Offering.

Additionally, the March 2022 Note Amendment provided for conversion of the note, including accrued and unpaid interest, at a conversion price of \$2.60 per share as follows: (i) at the option of the holder, in its sole discretion, in whole or in part, and (ii) mandatorily simultaneous with the consummation of a Qualified Offering, in each case, into fully paid and nonassessable shares of common stock at the conversion price.

On June 12, 2024, Apimeds Korea assigned the March 2022 Note to Inscobee.

If not converted earlier, upon the closing of a Qualified Offering, the March 2022 Note will automatically convert into approximately 70,002 shares of common stock.

June 2022 Promissory Note

On June 3, 2022, the Company issued to Inscobee, Inc. a South Korean company, and the parent company of Apimeds Korea, (“Inscobee”) a \$100,000 promissory note (the “June 2022 Note”). Interest on the outstanding principal balance of the Second Loan accrues at a rate equal to 5% per annum, and interest on the outstanding principal balance of the First Loan shall accrue and be payable on the maturity date. The maturity date was the earlier of (i) the closing of an equity financing by the Company with gross proceeds to the Company of at least \$3,000,000, and (ii) July 15, 2022.

On December 5, 2023, the Company and Inscobee amended the June 2022 Note (the “June 2022 Note Amendment”) as follows: the maturity date was extended to (i) December 31, 2026, or (ii) consummation of a Qualified Offering.

Additionally, the June 2022 Note Amendment provided for conversion of the note, including accrued and unpaid interest, at a conversion price of \$2.60 per share as follows: (i) at the option of the holder, in its sole discretion, in whole or in part, and (ii) mandatorily simultaneous with the consummation of a Qualified Offering, in each case, into fully paid and nonassessable shares of common stock at the conversion price.

Upon the closing of a Qualified Offering, the June 2022 Note will automatically convert into approximately 43,361 shares of common stock.

On June 12, 2024, the Company and Inscobee amended the June 2022 Note to correct a scrivener’s error.

May 2024 Promissory Note

On May 20, 2024, the Company issued to Inscobee a \$100,000 promissory note (the “May 2024 Note”). The May 2024 Note bears interest at a rate equal to 5% per annum (the “Interest Rate”). The May 2024 Note is due and payable on the earlier of (i) the closing of an equity financing by the Company with gross proceeds to the Company of at least \$3,000,000, or (ii) May 19, 2025.

The Company may prepay the May 2024 Note at any time without penalty. If any payment due on the May 2024 Note is not paid within five days after the amount becomes due, the payment shall be considered in default and the interest rate will increase by an additional 5% on the defaulted payment amount and Inscobee may also, in its sole discretion, without notice or demand, declare the entire unpaid principal balance plus accrued interest due and payable immediately.

August 2024 Note

On August 19, 2024, the Company issued to Inscobee a \$150,000 principal amount promissory note (the “August 2024 Note”). The August 2024 Note bears interest at a rate equal to 5% per annum (the “Interest Rate”). The August 2024 Note is due and payable on the earlier of (i) the closing of an equity financing by the Company with gross proceeds to the Company of at least \$3,000,000, or (ii) May 19, 2025. The outstanding principal and interest on the August 2024 Note will be repaid upon the closing of a Qualified Offering.

The Company may prepay the August 2024 Note at any time without penalty. If any payment due on the August 2024 Note is not paid within five days after the amount becomes due, the payment shall be considered in default and the interest rate will increase by an additional 5% on the defaulted payment amount and Inscobee may also, in its sole discretion, without notice or demand, declare the entire unpaid principal balance plus accrued interest due and payable immediately.

March 2025 Promissory Note

On March 31, 2025, the Company received \$250,000 in a promissory note (the “March 2025 Note”) agreement with Apimeds, Inc., one of its shareholders. The Promissory Notes bear interest at 5% per annum and mature on the earlier of (a) December 31, 2026 or (b) consummation of a Qualified Offering (the “Maturity Date”). “Qualified Offering” shall mean an offering of Common Stock (and other securities potentially) resulting in the listing for trading of the Common Stock on the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

The Company may prepay the March 2025 Note at any time without penalty. If any payment due on the March 2025 Note is not paid within five days after the amount becomes due, the payment shall be considered in default and the interest rate will increase by an additional 5% on the defaulted payment amount and may also, in its sole discretion, without notice or demand, declare the entire unpaid principal balance plus accrued interest due and payable immediately.

Cash Advance Loans

On October 5, 2022, November 10, 2022 and March 16, 2023, Dr. Christopher Kim, the Company’s Chairman and Chief Medical Officer and founder of Apimeds Korea, loaned the Company \$9,900, \$13,000 and \$9,000 respectively. These loans carried no interest and did not have a maturity date. The loans were used for operating purposes. As of September 2023, all the loan amounts were repaid.

It is the responsibility of our audit committee to review and approval all related party transactions that would need to be disclosed pursuant to Item 404(a) of Regulation S-K (each a “Related Party Transaction”). The Board has adopted a related party transaction policy that makes up a part of the audit committee’s charter (the “Related Party Transactions Policy”). Pursuant to the Related Party Transactions Policy, each of the Company’s directors and executive officers shall promptly inform the chairperson of the audit committee of any potential Related Party Transactions. In addition, each such director and executive officer shall complete a questionnaire on an annual basis designed to elicit information about any potential Related Party Transactions. Any potential Related Party Transactions that are brought to the audit committee’s attention shall be analyzed by the audit committee, in consultation with outside counsel or members of management, as appropriate, to determine whether the transaction or relationship does, in fact, constitute a Related Party Transaction requiring compliance with the Related Party Transactions Policy. In determining whether to approve a Related Party Transaction, the audit committee shall consider, among other factors, the following factors to the extent relevant to the Related Party Transaction: (i) whether the terms of the Related Party Transaction are fair to the Company and on the same basis as would apply if the transaction did not involve a Related Party (as defined in the Related Party Transactions Policy); (ii) whether there are business reasons for the Company to enter into the Related Party Transaction; (iii) whether the Related Party Transaction would impair the independence of an outside director; (iv) whether the Related Party Transaction would present an improper conflict of interest for any director or executive officer of the Company, taking into account the size of the transaction, the overall financial position of the director, executive officer or Related Party, the direct or indirect nature of the director’s, executive officer’s or Related Party’s interest in the transaction and the ongoing nature of any proposed relationship, and any other factors the Committee deems relevant; and (v) any pre-existing contractual obligations. All of the transactions described in this section occurred prior to the adoption of this policy.

Director Independence

The Company’s Board has determined that Dr. Bennet Weintraub PhD, Dr. Hankil Yoon PhD, Carol O’Donnell and Elona Kogan, who together comprise a majority of the Board, are independent under applicable rules and regulations of the SEC. The Board made such independence determinations using the definition of independence set forth in the rules of the NYSE American based on a review of transactions and relationships between each director or any member of his or her immediate family, on the one hand, and the Company and its subsidiaries and affiliates, on the other hand, as well as transactions and relationships between each director or his affiliates, on the one hand, and members of the Company’s management or their affiliates, on the other hand.

Item 14. Principal Accountant Fees and Services

Kreit & Chiu CPA LLP served as the independent registered public accounting firm for the Company for 2024 and 2023. The following table sets forth the fees billed to the Company by Kreit & Chiu CPA LLP for 2024 and 2023.

	2024	2023
(in thousands)		
Audit Fees (1)	\$ 142,918	\$ 74,950
Audit-Related Fees	-	-
All Other Fees	-	-
Total Fees	<u>\$ 142,918</u>	<u>\$ 74,950</u>

(1) Represents, for each year, fees for services related to the Company’s annual financial statement audit and quarterly reviews.

Under its charter, the Company’s audit committee must review and pre-approve both audit and permitted non-audit services provided by the Company’s independent registered public accounting firm and shall not engage the independent registered public accounting firm to perform any non-audit services prohibited by law or regulation. The independent registered public accounting firm’s retention to audit the Company’s financial statements, including the associated fee, is subject to approval each year by the audit committee. The audit committee does not regularly evaluate potential engagements of the independent registered public accounting firm and approve or reject such potential engagements. At each audit committee meeting, the audit committee receives updates on the services actually provided by the independent registered public accounting firm, and management may present additional services for pre-approval. The audit committee may delegate to the chairman of the audit committee the authority to evaluate and approve engagements on behalf of the audit committee in the event that a need arises for pre-approval between regular audit committee meetings. If the chairman so approves any such engagements, he will report that approval to the full audit committee at the next audit committee meeting. The audit committee was established on February 7, 2025, and therefore, the Company’s audit committee did not pre-approve all of the foregoing services.

PART IV

Item 15. Exhibit and Financial Statement Schedules

(a) Documents filed as part of this report

(1) All financial statements

<u>Report of Independent Registered Public Accounting Firm (PCAOB ID: 6651)</u>	F-2
<u>Balance Sheets as of December 31, 2024 and 2023</u>	F-3
<u>Statements of Operations for the Years Ended December 31, 2024 and 2023</u>	F-4
<u>Statements of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2024 and 2023</u>	F-5
<u>Statements of Cash Flows for the Years Ended December 31, 2024 and 2023</u>	F-6
<u>Notes to Financial Statements</u>	F-7

(2) Financial Statement Schedules

All financial statement schedules are omitted because they are either inapplicable or not required, or because the required information is included in the Financial Statements or notes thereto contained in this Annual Report on Form 10-K.

(3) Exhibits required by Item 601 of Regulation S-K

Exhibit No.	Description
3.1	<u>Amended and Restated Certificate of Incorporation of Apimeds Pharmaceuticals US, Inc. (incorporated herein by reference to Exhibit 3.1 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
3.2*	<u>Certificate of Amendment to the Amended and Restated Certificate of Incorporation</u>
3.3*	<u>Amended and Restated Bylaws of Apimeds Pharmaceuticals US, Inc.</u>
4.1*	<u>Description of Securities</u>
10.1	<u>Letter Agreement by and between Apimeds Pharmaceuticals US, Inc. and Apico Inc., dated November 3, 2021 (incorporated herein by reference to Exhibit 10.1 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.2	<u>Business Agreement by and between Apimeds Pharmaceuticals US, Inc. and Apimeds Inc., dated August 2, 2021 (incorporated herein by reference to Exhibit 10.2 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.3	<u>Assignment Agreement by and between Apimeds Pharmaceuticals US, Inc. and Apimeds Inc., dated October 12, 2021 (incorporated herein by reference to Exhibit 10.3 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.4	<u>Apimeds Pharmaceuticals US, Inc. 2024 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.5	<u>Business Establishment Agreement by and between Apimeds Pharmaceuticals US, Inc. and Apimeds Inc., dated March 3, 2020 (incorporated herein by reference to Exhibit 10.5 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.6	<u>August 2021 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Apimeds Inc., dated August 30, 2021 (incorporated herein by reference to Exhibit 10.6 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.7	<u>Amendment to the August 2021 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Apimeds Inc., dated December 5, 2023 (incorporated herein by reference to Exhibit 10.7 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>

10.8	<u>March 2022 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Apimeds Inc., dated March 21, 2022 (incorporated herein by reference to Exhibit 10.8 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.9	<u>Amendment to the March 2022 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Apimeds Inc., dated December 5, 2023 (incorporated herein by reference to Exhibit 10.9 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.10	<u>June 2022 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Inscobee Inc., dated June 3, 2022 (incorporated herein by reference to Exhibit 10.10 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.11	<u>Amendment to the June 2022 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Inscobee Inc., dated December 5, 2023 (incorporated herein by reference to Exhibit 10.11 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.12	<u>Intellectual Property Assignment Agreement by and between Apimeds Pharmaceuticals US, Inc. Apimeds Inc. and Christopher Kim, dated October 12, 2021 (incorporated herein by reference to Exhibit 10.12 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.13	<u>Patent License Agreement by and between Apimeds Pharmaceuticals US, Inc. and Dr. Christopher Kim, dated October 12, 2021 (incorporated herein by reference to Exhibit 10.13 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.14	<u>Employment Agreement dated September 21, 2023 between Apimeds Pharmaceuticals US, Inc. and Erik Emerson (incorporated herein by reference to Exhibit 10.14 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.15	<u>Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.15 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.16	<u>Loan Agreement by and between Apimeds Pharmaceuticals US, Inc. and Dr. Christopher Kim, dated October 5, 2022 (incorporated herein by reference to Exhibit 10.16 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.17	<u>Loan Agreement by and between Apimeds Pharmaceuticals US, Inc. and Dr. Christopher Kim, dated November 10, 2022 (incorporated herein by reference to Exhibit 10.17 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.18	<u>Loan Agreement by and between Apimeds Pharmaceuticals US, Inc. and Dr. Christopher Kim, dated March 16, 2023 (incorporated herein by reference to Exhibit 10.18 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.19	<u>Advisory Agreement by and between Apimeds Pharmaceuticals US, Inc. and Murdock Capital Partners, dated September 8, 2023 (incorporated herein by reference to Exhibit 10.19 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.20	<u>May 2024 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Inscobee Inc., dated May 20, 2024 (incorporated herein by reference to Exhibit 10.20 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.21	<u>Convertible Note Assignment Agreement (August 2021 Promissory Note), by and between Apimeds Pharmaceuticals US, Inc., Apimeds, Inc., and Inscobee Inc., dated June 12, 2024 (incorporated herein by reference to Exhibit 10.21 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.22	<u>Convertible Note Assignment Agreement (March 2022 Promissory Note), by and between Apimeds Pharmaceuticals US, Inc., Apimeds, Inc., and Inscobee Inc., dated June 12, 2024 (incorporated herein by reference to Exhibit 10.22 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.23	<u>Amended Amendment to the June 2022 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Inscobee Inc., dated June 12, 2024 (incorporated herein by reference to Exhibit 10.23 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.24	<u>CFO Consulting Agreement, by and between Apimeds Pharmaceuticals US, Inc. and Mark Corrao, dated October 4, 2024 (incorporated herein by reference to Exhibit 10.24 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.25	<u>August 2024 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Inscobee Inc., dated August 19, 2024 (incorporated herein by reference to Exhibit 10.25 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
10.26*	<u>March 2025 Promissory Note by and between Apimeds Pharmaceuticals US, Inc. and Apimeds, Inc., dated March 21, 2025.</u>
14.1	<u>Code of Business Conduct and Ethics (incorporated herein by reference to Exhibit 99.1 to our Registration Statement on Form S-1 filed on September 25, 2024).</u>
19.1*	<u>Insider Trading Policy.</u>

21.1	Subsidiaries of the Registrant (incorporated herein by reference to Exhibit 21.1 to our Registration Statement on Form S-1 filed on September 25, 2024).
31.1*	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Executive Compensation Recovery Policy.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit).
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.

* Filed or furnished herewith.

Item 16. Form 10-K Summary

None.

INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Apimeds Pharmaceuticals US, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Apimeds Pharmaceuticals US, Inc. as of December 31, 2024 and 2023, and the related statements of operations, changes in shareholders' equity (deficit), and cash flows for each of the two 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 Apimeds Pharmaceuticals US, Inc. as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the entity will continue as a going concern. As discussed in Note 1 to the financial statements, the entity has suffered recurring losses from operations and has accumulated deficit that raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these 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 Apimeds Pharmaceuticals US, Inc. 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. Apimeds Pharmaceuticals US, Inc. 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 entity'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.

/s/ Kreit & Chiu CPA LLP

We have served as Apimeds Pharmaceuticals US, Inc.'s auditor since 2023.
New York, New York
April 15, 2025

Apimeds Pharmaceuticals US, Inc.
Balance Sheets

	<u>December 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Assets		
Current assets:		
Cash	\$ 3,455	\$ 410,481
Prepaid expenses and other current assets	9,602	11,595
Total current assets	<u>13,057</u>	<u>422,076</u>
Total assets	<u>\$ 13,057</u>	<u>\$ 422,076</u>
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable and accrued expenses	\$ 591,191	\$ 54,438
Accrued interest - related party	106,643	68,878
Advance payable to related party	76,500	-
Notes payable - related party	250,000	-
Total current liabilities	<u>1,024,334</u>	<u>123,316</u>
Convertible note - related party	346,844	266,891
Total liabilities	<u>1,371,178</u>	<u>390,207</u>
Commitments and contingencies (note 6)		
Shareholders' equity (deficit):		
Preferred stock, par value \$0.01, 10,000,000 shares authorized; none issued and outstanding as of December 31, 2024 and December 31, 2023	-	-
Common stock, par value \$0.01, 100,000,000 shares authorized; 7,903,850 issued and outstanding as of December 31, 2024 and December 31, 2023	79,039	79,039
Additional paid-in capital	2,954,764	2,954,764
Accumulated deficit	<u>(4,391,924)</u>	<u>(3,001,934)</u>
Total shareholders' equity (deficit)	<u>(1,358,121)</u>	<u>31,869</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 13,057</u>	<u>\$ 422,076</u>

The accompanying notes are an integral part of these financial statements.

Apimeds Pharmaceuticals US, Inc.
Statements of Operations

	For the year ended December 31,	
	2024	2023
Operating expenses:		
Research and development expenses	\$ -	\$ 98,544
General and administrative expenses	1,275,095	648,892
Loss from operations	<u>(1,275,095)</u>	<u>(747,436)</u>
Other (expenses) income		
Interest income	2,824	7,811
Interest expense	<u>(117,719)</u>	<u>(38,069)</u>
Total other expense	<u>(114,895)</u>	<u>(30,258)</u>
Net loss	<u>\$ (1,389,990)</u>	<u>\$ (777,694)</u>
Weighted average shares outstanding	<u>7,903,850</u>	<u>4,598,265</u>
Basic and diluted loss per share	<u>\$ (0.18)</u>	<u>\$ (0.17)</u>

The accompanying notes are an integral part of these financial statements.

Apimeds Pharmaceuticals US, Inc.
Statement of Changes in Shareholders' Equity (Deficit)

	Preferred Stock		Common Stock		Additional Paid-in capital	Accumulated Deficit	Total
	Number of Shares	Amount	Number of Shares	Amount			
Balance at December 31, 2022	-	\$ -	3,846,154	\$ 38,462	\$ 1,472,172	\$ (2,224,240)	\$ (713,606)
Stock-based compensation expense	-	-	-	-	69,993	-	69,993
Issuance of shares to shareholders	-	-	4,057,696	40,577	1,014,423	-	1,055,000
Embedded conversion feature of convertible notes	-	-	-	-	398,176	-	398,176
Net loss	-	-	-	-	-	(777,694)	(777,694)
Balance at December 31, 2023	-	\$ -	7,903,850	\$ 79,039	\$ 2,954,764	\$ (3,001,934)	\$ 31,869
Net loss	-	-	-	-	-	(1,389,990)	(1,389,990)
Balance at December 31, 2024	-	\$ -	7,903,850	\$ 79,039	\$ 2,954,764	\$ (4,391,924)	\$ (1,358,121)

The accompanying notes are an integral part of these financial statements.

Apimeds Pharmaceuticals US, Inc.
Statements of Cash flows

	For the Years Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (1,389,990)	\$ (777,694)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	-	69,993
Accrued interest expense - related parties	37,766	33,000
Accretion expense	79,953	5,069
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	1,993	(11,594)
Accounts payable and accrued expenses	536,752	53,436
Net cash used in operating activities	(733,526)	(627,790)
Cash flows from investing activities:		
Net cash provided by investing activities	-	-
Cash flows from financing activities:		
Proceeds from notes payable - related parties	250,000	-
Cash advances from related parties	76,500	9,000
Cash advances paid to related parties	-	(31,900)
Issuance of shares for cash received	-	1,055,000
Net cash provided by financing activities	326,500	1,032,100
Net (decrease) increase in cash	(407,026)	404,310
Cash, beginning of year	410,481	6,171
Cash, end of year	\$ 3,455	\$ 410,481

The accompanying notes are an integral part of these financial statements.

Apimeds Pharmaceuticals US, Inc.
Notes to Financial Statements

1. DESCRIPTION OF BUSINESS

Business Description

Apimeds Pharmaceuticals US, Inc. (the “Company” or “Apimeds”) was formed as a corporation in May 2020 and was incorporated in the State of Delaware. On August 21, 2021, Apimeds Inc., the shareholder of the Company (“Apimeds Korea”), and Apimeds Pharmaceuticals US Inc. entered into the business agreement, under which the Company was designated to operate a pharmaceutical business which provides the biological drug named Apitox™ to clients in the biological drug commercial transaction area.

Apimeds is a clinical stage company that is in the process of developing Apitox™, a proprietary intradermally administered bee venom-based toxin which completed a positive Phase 3 trial for the treatment of pain associated with Osteoarthritis in 2018 and is now proceeding with FDA discussions on next steps in approval. In the future, the Company plans to investigate potential uses for Apitox™ for in treating multiple sclerosis (“MS”), and intends to conduct non-registered corporate sponsorship studies to identify appropriate MS patient populations. Apitox™ is currently marketed and sold by Apimeds Korea in South Korea (Republic of Korea) as “Apitoxin” for the treatment of osteoarthritis. Apimeds Inc. holds the majority of the Company’s outstanding common stock and is a subsidiary of Inscobee Inc. (“Inscobee”).

The success of the Company is dependent on obtaining the necessary regulatory approvals of its product candidates, marketing its products and achieving profitable operations. The continuation of the research and development activities and the commercialization of its products, if approved, are dependent on the Company’s ability to successfully complete these activities and to obtain additional financing through a combination of financing activities and operations. It is not possible to predict either the outcome of future research and development or commercialization programs, or the Company’s ability to fund these programs.

Going Concern

The Company has evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the issuance date of these financial statements. As of December 31, 2024, the Company had accumulated losses amount to \$4,391,924. The Company incurred net losses of \$1,389,990 for the year ended December 31, 2024, and expects to continue to incur substantial losses in the future. Based on such conditions and the Company’s current plans, which are subject to change, management believes that the Company’s existing cash as of December 31, 2024, is not sufficient to satisfy its operating cash needs for 12 months from the issuance date of the report

The accompanying financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

If the Company is unable to obtain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all.

2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The Company has prepared its financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASUs”) promulgated by the Financial Accounting Standards Board (“FASB”).

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make certain estimates, judgements and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to, stock-based compensation and estimates that are related to convertible instruments. Actual results could differ from those estimates, and such differences could be material to the financial statements.

Fair Value Measurement

The fair value of the Company’s financial assets and liabilities reflects management’s estimate of amounts that the Company would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of its assets and liabilities, the Company seeks to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (internal assumptions about how market participants would price assets and liabilities). The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value the assets and liabilities:

Level 1 — Quoted prices in active markets for identical assets or liabilities. An active market for an asset or liability is a market in which transactions for the asset or liability occur with sufficient frequency and volume to provide pricing information on an ongoing basis.

Level 2 — Observable inputs other than Level 1 inputs. Examples of Level 2 inputs include quoted prices in active markets for similar assets or liabilities and quoted prices for identical assets or liabilities in markets that are not active.

Level 3 — Unobservable inputs based on the Company’s assessment of the assumptions that market participants would use in pricing the asset or liability.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

Common Stock Reverse Stock Split

On February 7, 2025, the Board approved and implemented a reverse stock split ratio of 1-for-2.6, which provided that every 2.6 shares of its issued and outstanding Common Stock was automatically be combined into *one* issued and outstanding share of Common Stock, without any change in the par value per share. All share and per share amounts in the accompanying financial statements and footnotes have been retrospectively adjusted for the reverse split.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in financial institutions which, at times, may exceed the federal depository insurance corporation limit of \$250,000. As of December 31, 2024, the Company has not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker (“CODM”), or decision-making group, in making decisions on how to allocate resources and assess performance. The Company has one operating segment.

Cash

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2024 and 2023, the Company had no cash equivalents.

Accrued Expenses

Accrued expenses consist of accrued interest for the convertible and promissory notes held with related parties, monies owed to vendors, as well as others, such as the taxing authority and employees.

As December 31, 2024, and 2023, the accounts payable and accrued expenses balance consists of the following:

	As of December 31,	
	2024	2023
Professional fees payable	\$ 410,641	\$ 54,438
Accrued compensation	180,550	-
	\$ 591,191	\$ 54,438

Convertible Instruments

The Company evaluates and accounts for conversion options embedded in convertible instruments in accordance with ASC 815 “Derivatives and Hedging Activities”.

Applicable U.S. GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free-standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under other U.S. GAAP with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible instruments (when we have determined that the embedded conversion options should not be bifurcated from their host instruments) as follows: The Company records when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are accreted over the term of the related debt to their stated date of redemption.

If a security or instrument becomes convertible only upon the occurrence of a future event outside the control of the Company, or, is convertible from inception, but contains conversion terms that change upon the occurrence of a future event, then any contingent beneficial conversion feature is measured and recognized when the triggering event occurs and contingency has been resolved.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying statements of operations.

Leases

The Company accounts for a contract as a lease when it has the right to direct the use of the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines the initial classification and measurement of its right-of-use assets ("ROU") and lease liabilities at the lease commencement date and thereafter if modified. ROU assets and liabilities are to be represented on the balance sheet at the present value of future minimum lease payments to be made over the lease term. The Company has elected as an accounting policy not to apply the recognition requirements in ASC 2016-02, *Leases* ("ASC 842") to short-term leases. Short-term leases are leases that have a term of 12 months or less and do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise. The Company recognizes the lease payments for short-term leases on a straight-line basis over the lease term. As of December 31, 2024 and 2023, the Company did not have leases that qualified as ROU assets.

Related Parties

The Company follows ASC 850, *Related Party Disclosures* for the identification of related parties and disclosure of related party transactions.

General and Administrative

General and administrative expenses consist primarily of management personnel costs, professional service fees, and other general overhead and facility costs, including rent and insurance, which relate to the Company's general and administrative functions.

Research and Development

Research and development expenses consist primarily of consulting, regulatory and manufacturing related costs, third-party license fees and external costs of vendors engaged to conduct preclinical development activities. These costs are expensed as incurred and non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized in prepaid expenses and other current assets.

The Company enters into arrangements with contract research organizations in connection with pre-clinical and clinical trials. Such arrangements often provide for payment prior to commencing the project or based upon predetermined milestones throughout the period during which services are expected to be performed. As part of the process of preparing the Company's financial statements, management is required to estimate prepaid and accrued clinical trial expenses. The date on which services commence, the level of services performed on or before a given date, and the cost of such services are often determined based on subjective judgments informed by the facts and circumstances known to management from the terms of the contract and the Company's ongoing monitoring of service performance. The Company makes these judgments based upon the facts and circumstances known to management based on the terms of the contract and the Company's ongoing monitoring of service performance.

In line with the guidance suggested under ASC 450, *Contingencies* and ASC 730, *Research and Development*, all research and development costs will be expensed as incurred. Development and regulatory milestone payments are accounted for by estimating the probability of milestone achievement.

Stock Based Compensation

The Company accounts for share-based compensation in accordance with the fair value recognition provision of FASB ASC 718, *Compensation – Stock Compensation* ("ASC 718"), which prescribes accounting and reporting standards for all share-based payment transactions in which employee services are acquired. Transactions include incurring liabilities, or issuing or offering to issue shares, options, and other equity instruments such as employee stock ownership plans and stock appreciation rights. Share-based payments to employees, including grants of employee stock options, are recognized as compensation expense in the financial statements based on the estimated grant date fair values. That expense is recognized over the period during which an employee is required to provide services in exchange for the award, known as the requisite service period (usually the vesting period). The Company accounts for forfeitures as they occur. The Company classifies share-based compensation expense in its statements of operations in the same manner in which the award recipient's cash compensation costs are classified.

Given the absence of an active market for the Company's equity, the Company and the board of directors were required to estimate the fair value of the Company's common stock and equity awards at the time of each grant. The Company and the board of directors determined the estimated fair value of the Company's equity instruments based on a number of factors, including external market conditions affecting the pharmaceutical industry sector. The Company and the board of directors utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, Valuation of Privately Held Company Equity Securities Issued as Compensation, to estimate the fair value of its equity instrument. Each valuation methodology includes estimates and assumptions that require the Company's judgment.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences attributable to differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax reporting purposes and for operating loss and tax credit carryforwards. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes.

The Company's deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which these temporary differences are expected to be recovered or settled. A valuation allowance is recorded to reduce deferred tax assets if it is determined that it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent earnings results, expectations of future taxable income, carryforward periods available and other relevant factors. The Company records changes in the required valuation allowance in the period that the determination is made.

The Company assesses its income tax position and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the financial statements. The Company records interest and penalties related to uncertain tax positions, if applicable, as a component of income tax expense.

Basic and Diluted Loss per share

Basic loss per share data for each period presented is computed using the weighted average number of shares of common stock outstanding during each such period. Diluted net loss per share is computed by giving effect to all potential shares of common stock to the extent they are dilutive.

The following table sets forth the number of potential shares of common stock that have been excluded from basic net loss per share because their effect was anti-dilutive:

	As of December 31,	
	2024	2023
Employee stock options	211,538	211,538
Convertible notes and interest	294,863	280,337
	506,401	491,875

Emerging Growth Company

The Company intends to elect as an Emerging Growth Company, as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Prior period reclassifications

We have reclassified certain amounts in prior periods to conform with current presentation. Accrued interest – related party in the amount of \$68,878, was reported within accounts payable and accrued expenses at December 31, 2023, and have been reclassified on the balance sheet and statement of cash flows.

Recently Issued Accounting Pronouncements

The Company considers the applicability and impact of all Accounting Standard Updates. ASUs not discussed in these financial statements were assessed and determined to be either not applicable or are expected to have minimal impact on the financial statements.

In November 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2023-07 - *Segment Reporting* (ASC 280): Improvements to Reportable Segment Disclosures, which enables investors to better understand an entity’s overall performance and assess potential future cash flows through improved reportable segment disclosure requirements. The amendments enhance disclosures about significant segment expenses, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, provide new segment disclosure requirements for entities with a single reportable segment, and contain other disclosure requirements. ASU 2023-07 is effective for annual periods beginning after December 15, 2023. The Company adopted ASU No. 2023-07 on December 31, 2024. The adoption of the standard did not result in any significant disclosure changes in the Notes to the Financial Statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes – Improvements to Income Tax Disclosures (Topic 740)*. The amendments require that public business entities on an annual basis disclose specific categories in the rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. The amendments also require that all entities disclose on an annual basis the income taxes paid disaggregated by jurisdiction. The amendments eliminate the requirement for all entities to disclose the nature and estimate of the range of the reasonably possible change in the unrecognized tax benefits balance in the next 12 months or make a statement that an estimate of the range cannot be made. The amendments are effective for fiscal years beginning after December 15, 2024. The amendments should be applied on a prospective basis, although early adoption is permitted. The Company is currently evaluating the potential impact adopting ASU 2023-09 will have on the Company’s financial statements and related disclosures.

In November 2024, the FASB issued Accounting Standards Update No. 2024-03, *Disaggregation of Income Statement Expenses*. This guidance will require additional disclosures and disaggregation of certain costs and expenses presented on the face of the income statement. The amendments are effective for annual reporting periods beginning after December 15, 2026 and interim reporting period beginning after December 15, 2027 with early adoption permitted. The Company is currently evaluating the impact of this new guidance to our financial statements.

3. LICENSE AGREEMENTS

On August 2, 2021, the Company entered into a business agreement with Apimeds Korea. Under the agreement, the Company received the right to continue any clinical trial and acquire the permits and approval necessary from the U.S. Food and Drug Administration. The Company will pay Apimeds Korea a royalty of 5% of the earnings before interest and taxes, delivered from the sale or license of Apitox less any credits and charges, however, the royalty terms shall not apply when shares of the Company are transferred or sold through merger, acquisition, or share transfer agreement to a third party.

On October 12, 2021, the Company entered into an exclusive patent license agreement with Apimeds Korea, a shareholder of the Company. Under the agreement, the Company was granted the exclusive right and license under the licensed patents to make and sell the licensed products in the United States of America.

The agreement shall commence on the effective date and shall remain in force for each licensed product on a licensed-product-by-licensed-product basis for rights and obligations concerning the licensed patent, until the expiration of the last to expire valid claim of a licensed patent. The total consideration exchanged for the exclusive license agreement was \$1.

4. DEBT

2022 Convertible notes (amended from notes payable) – related parties

On March 21, 2022, the Company entered into a promissory note agreement in the amount of \$160,000 with Inscobee, one of its shareholders. On June 3, 2022, the Company received an additional \$100,000 from Inscobee, as part of another promissory note agreement (together as “2022 Convertible Notes”). The 2022 *Convertible Notes* bear interest at 5% per annum and mature on the earlier of (a) the closing of an equity financing with proceeds to the Company of at least \$3 million, or (b) July 15, 2022.

On December 5, 2023, the Company amended their promissory notes to be convertible and extended the maturity date of the convertible notes with the related parties to be the earlier of (i) December 31, 2026 or (ii) consummation of a qualified offering. The notes are convertible at a price of \$1 per share. The purchase of convertible notes and cancellation of the old promissory notes was accounted for as a debt extinguishment that did not result in a gain/loss on extinguishment due to related party treatment. The conversion option was valued utilizing the Black-Scholes model, with the following inputs: volatility of 92.22%, current stock price of \$1.96, expected dividend yield of 0% and a risk-free rate of return of 4.33%. The resulting value of the convertible option of \$158,099 based on the allocation of relative fair value to cash proceeds, was applied towards additional paid-in capital and added as a discount on the convertible note. The note will be accreted over the remaining period through maturity at the calculated effective interest rate of approximately 41.4%.

As of December 31, 2024 and 2023, there was accrued interest in connection to the 2022 Convertible Notes of \$34,745 and \$22,137, respectively. Interest expenses were \$12,608 and \$13,000 for the years ended December 31, 2024 and 2023, respectively, and are included within accrued interest - related party on the accompanying balance sheet. There was accretion on the note's debt discount of \$31,569 and \$1,997 for the years ended December 31, 2024 and 2023.

As of December 31, 2024 and 2023, the outstanding balance on the 2022 Convertible notes agreement, net of the unamortized debt discounts of \$124,534 and \$156,102, was \$135,466 and \$103,898, respectively.

2021 Convertible note – related party

On August 30, 2021, the Company received \$400,000 in a convertible note agreement (“2021 Convertible Note”) with Apimeds Korea, one of its shareholders. The 2021 Convertible Note bears interest at 5% per annum and matures on the earlier of (a) the sale of the Company or (b) August 30, 2026. The 2021 Convertible Note is convertible at any time up through the maturity date. The number of shares of common stock shall be determined by dividing (x) the outstanding principal balance hereof plus accrued but unpaid interest by the first closing price on the first day of trading following a Qualified Direct Listing.

On December 5, 2023, the Company amended their convertible note to be convertible at \$1 per share and extended the maturity date to be the earlier of (i) December 31, 2026 or (ii) consummation of a qualified offering. The repurchase and cancellation of the old note was accounted for as a debt extinguishment that did not result in any gain/loss on extinguishment due to related party treatment. The conversion option was valued utilizing the Black-Scholes model, with the following inputs: volatility of 92.22%, the fair value of the stock of \$1.96, expected dividend yield of 0%, and a risk-free rate of return of 4.33%. The resulting value of the convertible option of \$240,079, based on the allocation of relative fair value to cash proceeds, was applied towards additional paid-in capital and added as a discount on the convertible note. The note will be accreted over the remaining period through maturity at the calculated effective interest rate of approximately 40.6%.

As December 31, 2024 and 2023, there was accrued interest in connection with the 2021 Convertible Note of \$66,137 and \$46,740, respectively, and is included within accrued interest - related party on the accompanying unaudited condensed balance sheets. Interest expense was \$19,397 and 20,000 as of December 31, 2024 and 2023, respectively. Accretion on the 2021 Convertible Note discount was \$48,385 for year ended December 31, 2024 respectively, which is included within interest expense on the unaudited condensed statement of operations. There was accretion on the 2021 Convertible Note debt discount of \$48,385 and \$3,072 for the years ended December 31, 2024 and 2023.

As of December 31, 2024 and 2023, the outstanding balance on the 2021 Convertible Note, net of the unamortized debt discounts of \$188,622 and \$237,007, was \$211,378 and \$162,993, respectively.

2024 Promissory Notes – Related Parties

On May 20, 2024, the Company received \$100,000 in a promissory note agreement with Inscobee Inc., one of its shareholders. On Aug 19, 2024, the Company received an additional \$150,000 from Inscobee, as part of another promissory note agreement (together as “2024 Promissory Notes”). The 2024 Promissory Notes bear interest at 5% per annum and mature on the earlier of (a) the closing of an equity financing by the Company with gross proceeds of at least \$3,000,000; or (b) May 19, 2025.

As of December 31, 2024, there was accrued interest in connection with the 2024 Promissory Notes of \$5,760. Interest expense was \$5,760 for the year ended December 31, 2024, and is included within accrued interest - related party on the accompanying unaudited condensed balance sheet.

2024 Short Term Borrowing

On July 19, 2024, the Company entered into a non-interest-bearing loan agreement with a private lender for \$20,000. The note matured on August 31, 2024, or may be extended upon mutual agreement. This loan was paid off in full on August 27, 2024.

5. ADVANCE PAYABLE – RELATED PARTY

As of December 31, 2024, the Company received \$76,500 from an officer of the Company that is outstanding as of the year ended December 31, 2024.

In March 2023, the Company received \$9,000 from the officer and remitted \$31,900 back to the officer, leaving a net balance of \$22,900 as of December 31, 2023.

These advance payables carry no interest and do not have a maturity date. The cash proceeds from these advance payables were used for operating purposes.

6. COMMITMENTS AND CONTINGENCIES

Legal

Periodically, the Company reviews the status of any significant matters that exist and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation. As of December 31, 2024 and 2023, there are no pending claims or litigation that are expected to materially affect the Company's results going forward.

Executive employee agreement

On September 21, 2023, the Company signed an executive employee agreement with the CEO of the Company. Under the executive employee agreement terms, if the Company closes on a public offering, the CEO will be eligible to receive an incentive stock option to purchase a number of shares of the Company's common stock equal to 3% of the post-Public Offering capitalization of the Company. 40% of the options shall vest immediately upon grant and the remainder will vest in three equal installments on the annual anniversary of the date of grant.

7. SHAREHOLDERS' DEFICIT

Common Stock

As of December 31, 2024 and 2023, the Company had 100,000,000 authorized shares of common stock, respectively, at a par value of \$0.01. The Company had 7,903,850 common shares issued and outstanding, as of December 31, 2024 and 2023, respectively. Each Common share is entitled to one vote.

On February 7, 2025, the Board approved and implemented a reverse stock split ratio of 1-for-2.6, which provided that every 2.6 shares of its issued and outstanding Common Stock were automatically combined into *one* issued and outstanding share of Common Stock, without any change in the par value per share. All share and per share amounts in the accompanying financial statements and footnotes have been retrospectively adjusted for the reverse split.

Preferred Stock

On December 5, 2023, the Company authorized 10,000,000 shares of preferred stock with a par value of \$0.01. The rights and preferences of preferred shareholders have not been determined as of the date of filing. The Company had no preferred shares issued or outstanding as of the year ended December 31, 2024 and 2023, respectively.

Activity during the period ended December 31, 2023

On September 7, 2023, the Company issued 1,923,076 shares of common stock of the Company to related parties for cash consideration in aggregate of \$500,000.

On December 5, 2023, the Company established a preferred stock class by authorizing 10,000,000 shares with a par value of \$0.01.

On December 6, 2023, the Company issued 2,134,616 shares of common stock of the Company to related parties for cash consideration in aggregate of \$555,000.

8. STOCK-BASED COMPENSATION

Stock Options

On September 18, 2024, the Company adopted an equity incentive plan for its employees, the Apimeds Pharmaceuticals US, Inc. 2024 Equity Incentive Plan (the “2024 Equity Incentive Plan”). 1,000,000 shares of common stock have initially been reserved for the issuance of awards under the 2024 Equity Incentive Plan with no stock options granted or outstanding as of the issuance date of the financial statements.

On May 12, 2020, the Company granted one of its executive officers a total of 213,692 nonqualified stock option awards issued outside of the 2024 Equity Incentive Plan. The stock options vested in three equal tranches of 71,231 on the grant anniversary date through May 12, 2023. The shares have an exercise price of \$7.33 per share and expire in 10 years on May 12, 2030.

The following is a summary of stock options issued and outstanding as of December 31, 2024 and 2023:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	213,692	\$ 7.33	6.37	—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Outstanding as of December 31, 2024	213,692	\$ 7.33	5.36	—
Exercisable as of December 31, 2024	213,692	\$ 7.33	5.36	—

During the years ended December 31, 2024 and 2023, there was \$0 and \$69,993, respectively, of stock-based compensation recognized.

The options were valued utilizing the Black-Scholes options pricing model with the following inputs: 0.20% risk-free rate, 66.8% volatility, 0% dividend rate, vesting term of 3 years, and the expected term of 6.5 years. The total fair value of shares vested during each of the years ended December 31, 2023 was \$69,993.

As of December 31, 2024, there were no remaining unrecognized compensation costs related to unvested options.

9. INCOME TAXES

There were no income tax expenses reflected in the results of operations for the years ended December 31, 2024 and 2023.

	Year Ended December 31,	
	2024	2023
Net loss per book	\$ (1,389,990)	\$ (777,694)
Federal statutory income tax rate (21%)	(291,899)	(163,315)
State income tax, net of federal benefit	(62,455)	(32,268)
State rate change	-	34,245
Permanent item	16,888	1,083
Prior period adjustment	(3,228)	3,549
Change in valuation allowance	340,694	156,706
Income tax	\$ -	\$ -

The tax effects of temporary differences which give rise to deferred tax assets (liabilities) are summarized as follows:

	Year Ended December 31,	
	2024	2023
Net operating loss carry forwards	\$ 741,321	\$ 537,878
Stock-based compensation	151,750	172,436
Accrued compensation	182,509	-
Capitalized research and development	66,117	90,501
Intangible assets	(824)	(638)
Total deferred tax assets	1,140,873	800,177
Valuation allowance	(1,140,873)	(800,177)
Net deferred tax assets	\$ -	\$ -

The Company had cumulative federal net operating losses of approximately \$2.85 million and state net operating losses of approximately \$2.76 million, which do not expire but are subject to an 80% utilization against future taxable income.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Deferred tax assets consist primarily of the tax effect of NOL carry-forwards. The Company has provided a full valuation allowance on the deferred tax assets because of the uncertainty regarding its realizability.

The Company's policy is to record interest and penalties associated with unrecognized tax benefits as additional income taxes in the statement of operations. As of December 31, 2024, the Company had no unrecognized tax benefits. There were no changes in the Company's unrecognized tax benefits during the years ended December 31, 2024 and 2023. The Company did not recognize any interest or penalties during the 2024 fiscal year related to unrecognized tax benefits.

10. SUBSEQUENT EVENTS

The Company evaluated subsequent events through the issuance date of the financial statements and determined that there have been no subsequent events except those mentioned throughout the footnotes that would require recognition in the financial statements or disclosure in the notes to the financial statements.

Subsequent to the year ended December 31, 2024, the Company received an additional \$17,000 from an officer of the Company as advance payable to the related party.

March 2025 Promissory Note

On March 31, 2025, the Company received \$250,000 in a promissory note agreement with Apimeds, Inc., one of its shareholders. The Promissory Notes bear interest at 5% per annum and mature on the earlier of (a) December 31, 2026 or (b) consummation of a Qualified Offering (the "Maturity Date"). "Qualified Offering" shall mean an offering of Common Stock (and other securities potentially) resulting in the listing for trading of the Common Stock on the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

The Company may prepay the March 2025 Note at any time without penalty. If any payment due on the March 2025 Note is not paid within five days after the amount becomes due, the payment shall be considered in default and the interest rate will increase by an additional 5% on the defaulted payment amount and may also, in its sole discretion, without notice or demand, declare the entire unpaid principal balance plus accrued interest due and payable immediately.

SIGNATURES

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

APIMEDS PHARMACEUTICALS US, INC.

Date: April 15, 2025

/s/ Erik C. Emerson
Name: Erik C. Emerson
Title: Chief Executive Officer
(Principal Executive Officer)t

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

<u>SIGNATURE</u>	<u>TITLE</u>	<u>DATE</u>
<u>/s/ Erik Emerson</u> Erik Emerson	Chief Executive Officer and Director (Principal Executive Officer)	April 15, 2025
<u>/s/ Mark Corrao</u> Mark Corrao	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	April 15, 2025
<u>/s/ Dr. Christopher Kim</u> Dr. Christopher Kim	Chairman of the Board and Chief Medical Officer	April 15, 2025
<u>/s/ Jakap Koo</u> Jakap Koo	Director	April 15, 2025
<u>/s/ Bennett Weintraub, PhD</u> Bennett Weintraub, PhD	Director	April 15, 2025
<u>/s/ Hankil Yoon</u> Hankil Yoon	Director	April 15, 2025
<u>/s/ Carol O'Donnell</u> Carol O'Donnell	Director	April 15, 2025
<u>/s/ Elona Kogan</u> Elona Kogan	Director	April 15, 2025

Delaware

The First State

Page 1

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "APIMEDS PHARMACEUTICALS US, INC.", FILED IN THIS OFFICE ON THE TWENTY-FIFTH DAY OF FEBRUARY, A.D. 2025, AT 9:48 O'CLOCK A.M.



A handwritten signature in cursive script, reading "C. P. Sanchez".

Charuni Patibanda-Sanchez, Secretary of State

7965446 8100

SR# 20250711403

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203016374

Date: 02-25-25

CERTIFICATE OF AMENDMENT
OF AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF APIMEDS PHARMACEUTICALS US, INC.

Apimeds Pharmaceuticals US, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), does hereby certify as follows:

1. The name of the Corporation is Apimeds Pharmaceuticals US, Inc. The original certificate of incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on May 11, 2020 (the "Certificate"). The Amended and Restated Certificate of Incorporation (the "Amended and Restated Certificate") was filed with the Secretary of State of the State of Delaware on December 6, 2023, which both restated and amended the provisions of the Certificate.
2. The Amended and Restated Certificate of the Corporation is amended by replacing article FOURTH with the following:

"The Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Company is authorized to issue is 110,000,000 shares. 100,000,000 shares shall be Common Stock, each having a par value of \$0.01. 10,000,000 shares shall be Preferred Stock, each having a par value of \$0.01.

The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Corporation is hereby expressly authorized to provide for the issue of any or all of the unissued and undesignated shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board of Directors of the Corporation providing for the issuance of such shares and as may be permitted by the DGCL. The Board of Directors of the Corporation is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the stock of the Company entitled to vote thereon, without a separate vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of Preferred Stock.

Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote; provided, however, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series of Preferred Stock are entitled, either separately or together as a class with the holders of one or more other such series of Preferred Stock, to vote thereon by law or pursuant to this Amended and Restated Certificate (including any certificate of designation filed with respect to any series of Preferred Stock).

State of Delaware
Secretary of State
Division of Corporations
Delivered 09:48 AM 02/25/2025
FILED 09:48 AM 02/25/2025
SR 20250711403 - File Number 7965446

Upon the filing and effectiveness (the “Effective Time”) of this amendment to the Corporation’s Amended and Restated Certificate, pursuant to the DGCL, each 2.6 shares of the Common Stock issued immediately prior to the Effective Time (the “Old Common Stock”) shall be reclassified and combined into one validly issued, fully paid and non-assessable share of the Corporation’s Common Stock, \$0.01 par value per share (the “New Common Stock”), without any action by the holder thereof, subject to the treatment of fractional share interests as described below (the “Reverse Stock Split”). No fractional shares of New Common Stock shall be issued as a result of the Reverse Stock Split and, any person who would otherwise be entitled to a fractional share of New Common Stock as a result of the Reverse Stock Split, following the Effective Time, shall be entitled to receive a whole share of New Common Stock in lieu of any fractional share created as a result of such Reverse Stock Split. Each book entry position that theretofore represented shares of Old Common Stock shall thereafter represent that number of shares of New Common Stock into which the shares of Old Common Stock represented by such book entry position shall have been reclassified and combined.

The Reverse Stock Split shall not affect the total number of shares of capital stock, including the Common Stock, that the Corporation is authorized to issue, which shall remain as set forth under this article.”

- 1. This Certificate of Amendment has been duly adopted by the Board of Directors of the Corporation and stockholders of the Corporation in accordance with Section 242 of the General Corporation Law of the State of Delaware.
- 2. This Certificate of Amendment shall become effective immediately upon filing.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be duly executed in its corporate name as of the 25 day of February, 2025.

APIMEDS PHARMACEUTICALS US, INC.

By: /s/ Erik Emerson
Name: Erik Emerson
Name: Chief Executive Officer

AMENDED AND RESTATED
BYLAWS
OF
APIMEDS PHARMACEUTICALS US, INC.

ARTICLE I

OFFICES

Section 1. Registered Office. The registered office of the corporation in the State of Delaware shall be at 251 Little Falls Drive, City of Wilmington, County of New Castle, Delaware 19801.

The name of the registered agent at such address is Corporation Service Company, 251 Little Falls Drive, City of Wilmington, County of New Castle, Delaware 19801.

Section 2. Other Offices. The corporation shall also have and maintain an office or principal place of business at such place as may be fixed by the corporation's Board of Directors (the "**Board of Directors**"), and may also have offices at such other places, both within and without the State of Delaware as the Board of Directors may from time to time determine or the business of the corporation may require.

ARTICLE II

CORPORATE SEAL

Section 3. Corporate Seal. The Board of Directors may adopt a corporate seal. The corporate seal shall consist of a die bearing the name of the corporation and the inscription, "Corporate Seal-Delaware." Said seal may be used by causing it or a facsimile thereof to be impressed or affixed or reproduced or otherwise.

ARTICLE III

STOCKHOLDERS' MEETINGS

Section 4. Place of Meetings. Meetings of the stockholders of the corporation may be held at such place, either within or without the State of Delaware, as may be determined from time to time by the Board of Directors. The Board of Directors may, in its sole discretion, determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication as provided under the Delaware General Corporation Law (the "**DGCL**").

Section 5. Annual Meetings.

(a) The annual meeting of the stockholders of the corporation, for the purpose of election of directors and for such other business as may properly come before it, shall be held on such date and at such time as may be designated from time to time by the Board of Directors. Nominations of persons for election to the Board of Directors of the corporation and the proposal of business to be considered by the stockholders may be made at an annual meeting of stockholders: (i) pursuant to the corporation's notice of meeting of stockholders (with respect to business other than nominations); (ii) brought specifically by or at the direction of the Board of Directors; or (iii) by any stockholder of the corporation who was a stockholder of record at the time of giving the stockholder's notice provided for in Section 5(b) of these Amended and Restated Bylaws (the "**Bylaws**"), who is entitled to vote at the meeting and who complied with the notice procedures set forth in this Section 5. For the avoidance of doubt, clause (iii) above shall be the exclusive means for a stockholder to make nominations and submit other business (other than matters properly included in the corporation's notice of meeting of stockholders and proxy statement under Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (the "**1934 Act**")) before an annual meeting of stockholders.

(b) At an annual meeting of the stockholders, only such business shall be conducted as is a proper matter for stockholder action under Delaware law and as shall have been properly brought before the meeting.

(i) For nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 5(a) of these Bylaws, the stockholder must deliver written notice to the Secretary at the principal executive offices of the corporation on a timely basis as set forth in Section 5(b)(iii) of these Bylaws and must update and supplement such written notice on a timely basis as set forth in Section 5(c) of these Bylaws. Such stockholder's notice shall set forth: (A) as to each nominee such stockholder proposes to nominate at the meeting: (1) the name, age, business address and residence address of such nominee; (2) the principal occupation or employment of such nominee; (3) the class and number of shares of each class of capital stock of the corporation which are owned of record and beneficially by such nominee; (4) the date or dates on which such shares were acquired and the investment intent of such acquisition; (5) with respect to each nominee for election or re-election to the Board of Directors, include a completed and signed questionnaire, representation and agreement required by Section 5(e) of these Bylaws; and (6) such other information concerning such nominee as would be required to be disclosed in a proxy statement soliciting proxies for the election of such nominee as a director in an election contest (even if an election contest is not involved), or that is otherwise required to be disclosed pursuant to Section 14 of the 1934 Act and the rules and regulations promulgated thereunder (including such person's written consent to being named as a nominee and to serving as a director if elected); and (B) the information required by Section 5(b)(iv) of these Bylaws. The corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the corporation or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such proposed nominee.

(ii) Other than proposals sought to be included in the corporation's proxy materials pursuant to Rule 14(a)-8 under the 1934 Act, for business other than nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 5(a) of these Bylaws, the stockholder must deliver written notice to the Secretary at the principal executive offices of the corporation on a timely basis as set forth in Section 5(b)(iii) of these Bylaws, and must update and supplement such written notice on a timely basis as set forth in Section 5(c) of these Bylaws. Such stockholder's notice shall set forth: (A) as to each matter such stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting, and any material interest (including any anticipated benefit of such business to any Proponent (as defined below) other than solely as a result of its ownership of the corporation's capital stock, that is material to any Proponent individually, or to the Proponents in the aggregate) in such business of any Proponent; and (B) the information required by Section 5(b)(iv) of these Bylaws.

(iii) To be timely, the written notice required by Section 5(b)(i) or 5(b)(ii) of these Bylaws must be received by the Secretary at the principal executive offices of the corporation not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; *provided, however*, that, subject to the last sentence of this Section 5(b)(iii), in the event that the date of the annual meeting is advanced more than 30 days prior to or delayed by more than 30 days after the anniversary of the preceding year's annual meeting, notice by the stockholder to be timely must be so received not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. In no event shall an adjournment or a postponement of an annual meeting for which notice has been given, or the public announcement thereof has been made, commence a new time period for the giving of a stockholder's notice as described above.

(iv) The written notice required by Section 5(b)(i) or 5(b)(ii) of these Bylaws shall also set forth, as of the date of the notice and as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (each, a “**Proponent**” and collectively, the “**Proponents**”): (A) the name and address of each Proponent, as they appear on the corporation's books; (B) the class, series and number of shares of the corporation that are owned beneficially and of record by each Proponent; (C) a description of any agreement, arrangement or understanding (whether oral or in writing) with respect to such nomination or proposal between or among any Proponent and any of its affiliates or associates, and any others (including their names) acting in concert, or otherwise under the agreement, arrangement or understanding, with any of the foregoing; (D) a representation that the Proponents are holders of record or beneficial owners, as the case may be, of shares of the corporation entitled to vote at the meeting and intend to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice (with respect to a notice under Section 5(b)(i) of these Bylaws) or to propose the business that is specified in the notice (with respect to a notice under Section 5(b)(ii) of these Bylaws); (E) a representation as to whether the Proponents intend to deliver a proxy statement and form of proxy to holders of a sufficient number of holders of the corporation's voting shares to elect such nominee or nominees (with respect to a notice under Section 5(b)(i) of these Bylaws) or to carry such proposal (with respect to a notice under Section 5(b)(ii) of these Bylaws); (F) to the extent known by any Proponent, the name and address of any other stockholder supporting the proposal on the date of such stockholder's notice; and (G) a description of all Derivative Transactions (as defined below) by each Proponent during the previous 12 month period, including the date of the transactions and the class, series and number of securities involved in, and the material economic terms of, such Derivative Transactions.

For purposes of Sections 5 and 6 of these Bylaws, a “**Derivative Transaction**” means any agreement, arrangement, interest or understanding entered into by, or on behalf or for the benefit of, any Proponent or any of its affiliates or associates, whether record or beneficial:

- (w) the value of which is derived in whole or in part from the value of any class or series of shares or other securities of the corporation;
- (x) which otherwise provides any direct or indirect opportunity to gain or share in any gain derived from a change in the value of securities of the corporation;
- (y) the effect or intent of which is to mitigate loss, manage risk or benefit of security value or price changes; or
- (z) which provides the right to vote or increase or decrease the voting power of, such Proponent, or any of its affiliates or associates, with respect to any securities of the corporation,

which agreement, arrangement, interest or understanding may include, without limitation, any option, warrant, debt position, note, bond, convertible security, swap, stock appreciation right, short position, profit interest, hedge, right to dividends, voting agreement, performance-related fee or arrangement to borrow or lend shares (whether or not subject to payment, settlement, exercise or conversion in any such class or series), and any proportionate interest of such Proponent in the securities of the corporation held by any general or limited partnership, or any limited liability company, of which such Proponent is, directly or indirectly, a general partner or managing member.

(c) A stockholder providing written notice required by Section 5(b)(i) or (ii) of these Bylaws shall update and supplement such notice in writing, if necessary, so that the information provided or required to be provided in such notice is true and correct in all material respects as of (i) the record date for the meeting and (ii) the date that is five business days prior to the meeting and, in the event of any adjournment or postponement thereof, five business days prior to such adjourned or postponed meeting. In the case of an update and supplement pursuant to clause (i) of this Section 5(c), such update and supplement shall be received by the Secretary at the principal executive offices of the corporation not later than five business days after the record date for the meeting. In the case of an update and supplement pursuant to clause (ii) of this Section 5(c), such update and supplement shall be received by the Secretary at the principal executive offices of the corporation not later than two business days prior to the date for the meeting, and, in the event of any adjournment or postponement thereof, two business days prior to such adjourned or postponed meeting.

(d) Notwithstanding anything in Section 5(b)(iii) of these Bylaws to the contrary, in the event that the number of directors is increased and there is no public announcement of the appointment of a director, or, if no appointment was made, of the vacancy, made by the corporation at least 10 days before the last day a stockholder may deliver a notice of nomination in accordance with Section 5(b)(iii) of these Bylaws, a stockholder’s notice required by this Section 5 and which complies with the requirements in Section 5(b)(i) of these Bylaws, other than the timing requirements in Section 5(b)(iii) of these Bylaws, shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be received by the Secretary at the principal executive offices of the corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the corporation.

(e) To be eligible to be a nominee for election or re-election as a director of the corporation pursuant to a nomination under clause (iii) of Section 5(a) of these Bylaws, such proposed nominee or a person on such proposed nominee's behalf must deliver (in accordance with the time periods prescribed for delivery of notice under Section 5(b)(iii) or 5(d) of these Bylaws, as applicable) to the Secretary at the principal executive offices of the corporation a written questionnaire with respect to the background and qualification of such proposed nominee and the background of any other person or entity on whose behalf the nomination is being made (which questionnaire shall be provided by the Secretary upon written request) and a written representation and agreement (in the form provided by the Secretary upon written request) that such person (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the corporation, will act or vote on any issue or question (a "***Voting Commitment***") that has not been disclosed to the corporation in the questionnaire or (B) any Voting Commitment that could limit or interfere with such person's ability to comply, if elected as a director of the corporation, with such person's fiduciary duties under applicable law; (ii) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director of the corporation that has not been disclosed therein; and (iii) in such person's individual capacity and on behalf of any person or entity on whose behalf the nomination is being made, would be in compliance, if elected as a director of the corporation, and will comply with, all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the corporation.

(f) A person shall not be eligible for election or re-election as a director unless the person is nominated either in accordance with clause (ii) of Section 5(a) of these Bylaws, or in accordance with clause (iii) of Section 5(a) of these Bylaws. Except as otherwise required by law, the chairman of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made, or proposed, as the case may be, in accordance with the procedures set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws, or the Proponent does not act in accordance with the representations in Sections 5(b)(iv)(D) and 5(b)(iv)(E) of these Bylaws, to declare that such proposal or nomination shall not be presented for stockholder action at the meeting and shall be disregarded, notwithstanding that proxies in respect of such nominations or such business may have been solicited or received.

(g) Notwithstanding the foregoing provisions of this Section 5, in order to include information with respect to a stockholder proposal in the proxy statement and form of proxy for a stockholders' meeting, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however*, that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to proposals and/or nominations to be considered pursuant to Section 5(a)(iii) of these Bylaws.

(h) For purposes of Sections 5 and 6 of these Bylaws,

(i) "**public announcement**" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act; and

(ii) "**affiliates**" and "**associates**" shall have the meanings set forth in Rule 405 under the Securities Act of 1933, as amended (the "**1933 Act**").

Section 6. Special Meetings.

(a) Special meetings of the stockholders of the corporation may be called, for any purpose as is a proper matter for stockholder action under Delaware law, by (i) the Chairman of the Board of Directors, (ii) the Chief Executive Officer, or (iii) the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any such resolution is presented to the Board of Directors for adoption).

(b) The Board of Directors shall determine the time and place, if any, of such special meeting. Upon determination of the time and place, if any, of the meeting, the Secretary shall cause a notice of meeting to be given to the stockholders entitled to vote, in accordance with the provisions of Section 7 of these Bylaws. No business may be transacted at such special meeting otherwise than specified in the notice of meeting.

(c) Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the corporation who is a stockholder of record at the time of giving notice provided for in this paragraph, who shall be entitled to vote at the meeting and who delivers written notice to the Secretary of the corporation setting forth the information required by Section 5(b)(i) of these Bylaws. In the event the corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any such stockholder of record may nominate a person or persons (as the case may be), for election to such position(s) as specified in the corporation's notice of meeting, if written notice setting forth the information required by Section 5(b)(i) of these Bylaws shall be received by the Secretary at the principal executive offices of the corporation not later than the close of business on the later of the 90th day prior to such meeting or the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting. The stockholder shall also update and supplement such information as required under Section 5(c) of these Bylaws. In no event shall an adjournment or a postponement of a special meeting for which notice has been given, or the public announcement thereof has been made, commence a new time period for the giving of a stockholder's notice as described above.

(d) Notwithstanding the foregoing provisions of this Section 6, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder with respect to matters set forth in this Section 6. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however*, that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to nominations for the election to the Board of Directors to be considered pursuant to Section 6(c) of these Bylaws.

Section 7. Notice of Meetings. Except as otherwise provided by law, notice, given in writing or by electronic transmission, of each meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting, such notice to specify the place, if any, date and hour, in the case of special meetings, the purpose or purposes of the meeting, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at any such meeting. If mailed, notice is deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. If sent via electronic transmission, notice is deemed given as of the sending time recorded at the time of transmission. Notice of the time, place, if any, and purpose of any meeting of stockholders may be waived in writing, signed by the person entitled to notice thereof, or by electronic transmission by such person, either before or after such meeting, and will be waived by any stockholder by his attendance thereat in person, by remote communication, if applicable, or by proxy, except when the stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given.

Section 8. Quorum. At all meetings of stockholders, except where otherwise provided by statute or by the corporation's Amended and Restated Certificate of Incorporation (as amended or restated from time to time, the "*Certificate of Incorporation*"), or by these Bylaws, the presence, in person, by remote communication, if applicable, or by proxy duly authorized, of the holders of 33 1/3% of the outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business. In the absence of a quorum, any meeting of stockholders may be adjourned, from time to time, either by the chairman of the meeting or by vote of the holders of a majority of the shares represented thereat, but no other business shall be transacted at such meeting. The stockholders present at a duly called or convened meeting, at which a quorum is present, may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Except as otherwise provided by statute or by applicable stock exchange rules, or by the Certificate of Incorporation or these Bylaws, in all matters other than the election of directors, the affirmative vote of the majority of shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise provided by statute, the Certificate of Incorporation or these Bylaws, directors shall be elected by a plurality of the votes of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the election of directors. Where a separate vote by a class or classes or series is required, except where otherwise provided by the statute or by the Certificate of Incorporation or these Bylaws, a majority of the outstanding shares of such class or classes or series, present in person, by remote communication, if applicable, or represented by proxy duly authorized, shall constitute a quorum entitled to take action with respect to that vote on that matter. Except where otherwise provided by statute or by the Certificate of Incorporation or these Bylaws, the affirmative vote of the majority (plurality, in the case of the election of directors) of shares of such class or classes or series present in person, by remote communication, if applicable, or represented by proxy at the meeting shall be the act of such class or classes or series.

Section 9. Adjournment and Notice of Adjourned Meetings. Any meeting of stockholders, whether annual or special, may be adjourned from time to time either by the chairman of the meeting or by the vote of a majority of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting. When a meeting is adjourned to another time or place, if any, notice need not be given of the adjourned meeting if the time and place, if any, thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 10. Voting Rights. For the purpose of determining those stockholders entitled to vote at any meeting of the stockholders, except as otherwise provided by law, only persons in whose names shares stand on the stock records of the corporation on the record date, as provided in Section 12 of these Bylaws, shall be entitled to vote at any meeting of stockholders. Every person entitled to vote shall have the right to do so either in person, by remote communication, if applicable, or by an agent or agents authorized by a proxy granted in accordance with Delaware law. An agent so appointed need not be a stockholder. No proxy shall be voted after three years from its date of creation unless the proxy provides for a longer period.

Section 11. Joint Owners of Stock. If shares or other securities having voting power stand of record in the names of two or more persons, whether fiduciaries, members of a partnership, joint tenants, tenants in common, tenants by the entirety, or otherwise, or if two or more persons have the same fiduciary relationship respecting the same shares, unless the Secretary is given written notice to the contrary and is furnished with a copy of the instrument or order appointing them or creating the relationship wherein it is so provided, their acts with respect to voting shall have the following effect: (a) if only one votes, his act binds all; (b) if more than one votes, the act of the majority so voting binds all; or (c) if more than one votes, but the vote is evenly split on any particular matter, each faction may vote the securities in question proportionally, or may apply to the Delaware Court of Chancery for relief as provided in the DGCL, Section 217(b). If the instrument filed with the Secretary shows that any such tenancy is held in unequal interests, a majority or even-split for the purpose of clause (c) of this Section 11 shall be a majority or even-split in interest.

Section 12. List of Stockholders. The Secretary shall prepare and make, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at said meeting, arranged in alphabetical order, showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation.

Section 13. Action Without Meeting. No action shall be taken by the stockholders except at an annual or special meeting of stockholders called in accordance with these Bylaws, and no action shall be taken by the stockholders by written consent or electronic transmission.

Section 14. Organization.

(a) At every meeting of stockholders, the Chairman of the Board of Directors, or, if a Chairman has not been appointed or is absent, the President, or, if the President is absent, if applicable, the Lead Independent Director (as defined below), or, if the Lead Independent Director is absent, a chairman of the meeting chosen by a majority in interest of the stockholders entitled to vote, present in person or by proxy, shall act as chairman. The Secretary, or, in his or her absence, an Assistant Secretary directed to do so by the President, shall act as secretary of the meeting.

(b) The Board of Directors of the corporation shall be entitled to make such rules or regulations for the conduct of meetings of stockholders as it shall deem necessary, appropriate or convenient. Subject to such rules and regulations of the Board of Directors, if any, the chairman of the meeting shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are necessary, appropriate or convenient for the proper conduct of the meeting, including, without limitation, establishing an agenda or order of business for the meeting, rules and procedures for maintaining order at the meeting and the safety of those present, limitations on participation in such meeting to stockholders of record of the corporation and their duly authorized and constituted proxies and such other persons as the chairman shall permit, restrictions on entry to the meeting after the time fixed for the commencement thereof, limitations on the time allotted to questions or comments by participants and regulation of the opening and closing of the polls for balloting on matters which are to be voted on by ballot. The date and time of the opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required to be held in accordance with rules of parliamentary procedure.

ARTICLE IV

DIRECTORS

Section 15. Number and Term of Office. The Board of Directors shall consist of not less than one and not more than seven directors as fixed from time to time solely by resolution of a majority of the total number of directors that the corporation would have if there were no vacancies. Directors need not be stockholders unless so required by the Certificate of Incorporation. If for any cause, the directors shall not have been elected at an annual meeting, they may be elected as soon thereafter as convenient at a special meeting of the stockholders called for that purpose in the manner provided in these Bylaws. Each director shall serve until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Section 16. Powers. The business and affairs of the corporation shall be managed by or under the direction of the Board of Directors, except as may be otherwise provided by statute or by the Certificate of Incorporation.

Section 17. Vacancies. Unless otherwise provided in the Certificate of Incorporation, and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders, *provided, however*, that whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the Certificate of Incorporation, vacancies and newly created directorships of such class or classes or series shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board of Directors shall be deemed to exist under this Bylaw in the case of the death, removal or resignation of any director.

Section 18. Resignation. Any director may resign at any time by delivering his or her notice in writing or by electronic transmission to the Secretary, such resignation to specify whether it will be effective at a particular time. If no such specification is made, it shall be deemed effective at the time of delivery to the Secretary. When one or more directors shall resign from the Board of Directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office for the unexpired portion of the term of the director whose place shall be vacated and until his successor shall have been duly elected and qualified.

Section 19. Removal.

(a) Subject to the rights of any series of Preferred Stock to elect additional directors under specified circumstances, neither the Board of Directors nor any individual director may be removed without cause.

(b) Subject to any limitation imposed by law, any individual director or directors may be removed with cause by the affirmative vote of the holders of at least 66 2/3% of the voting power of all then outstanding shares of capital stock of the corporation entitled to vote generally at an election of directors.

Section 20. Meetings.

(a) **Regular Meetings.** Unless otherwise restricted by the Certificate of Incorporation, regular meetings of the Board of Directors may be held at any time or date and at any place within or without the State of Delaware which has been designated by the Board of Directors and publicized among all directors, either orally or in writing, by telephone, including a voice-messaging system or other system designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means. No further notice shall be required for regular meetings of the Board of Directors.

(b) **Special Meetings.** Unless otherwise restricted by the Certificate of Incorporation, special meetings of the Board of Directors may be held at any time and place within or without the State of Delaware whenever called by the Chairman of the Board, the Chief Executive Officer or a majority of the authorized number of directors.

(c) **Meetings by Electronic Communications Equipment.** Any member of the Board of Directors, or of any committee thereof, may participate in a meeting by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

(d) **Notice of Special Meetings.** Notice of the time and place of all special meetings of the Board of Directors shall be orally or in writing, by telephone, including a voice messaging system or other system or technology designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other electronic means, during normal business hours, at least 24 hours before the date and time of the meeting. If notice is sent by U.S. mail, it shall be sent by first class mail, charges prepaid, at least three days before the date of the meeting. Notice of any meeting may be waived in writing, or by electronic transmission, at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

(e) **Waiver of Notice.** The transaction of all business at any meeting of the Board of Directors, or any committee thereof, however called or noticed, or wherever held, shall be as valid as though it had been transacted at a meeting duly held after regular call and notice, if a quorum be present and if, either before or after the meeting, each of the directors not present who did not receive notice shall sign a written waiver of notice or shall waive notice by electronic transmission. All such waivers shall be filed with the corporate records or made a part of the minutes of the meeting.

Section 21. Quorum and Voting.

(a) Unless the Certificate of Incorporation requires a greater number, and except with respect to questions related to indemnification arising under Section 44 of these Bylaws for which a quorum shall be one-third of the exact number of directors fixed from time to time, a quorum of the Board of Directors shall consist of a majority of the exact number of directors fixed from time to time by the Board of Directors in accordance with the Certificate of Incorporation; *provided, however*, at any meeting whether a quorum be present or otherwise, a majority of the directors present may adjourn from time to time until the time fixed for the next regular meeting of the Board of Directors, without notice other than by announcement at the meeting.

(b) At each meeting of the Board of Directors at which a quorum is present, all questions and business shall be determined by the affirmative vote of a majority of the directors present, unless a different vote be required by law, the Certificate of Incorporation or these Bylaws.

Section 22. Action Without Meeting. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission, and such writing or writings or transmission or transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 23. Fees and Compensation. Directors shall be entitled to such compensation for their services as may be approved by the Board of Directors, including, if so approved, by resolution of the Board of Directors, a fixed sum and expenses of attendance, if any, for attendance at each regular or special meeting of the Board of Directors and at any meeting of a committee of the Board of Directors. Nothing herein contained shall be construed to preclude any director from serving the corporation in any other capacity as an officer, agent, employee, or otherwise and receiving compensation therefor.

Section 24. Committees.

(a) Executive Committee. The Board of Directors may appoint an Executive Committee to consist of one or more members of the Board of Directors. The Executive Committee, to the extent permitted by law and provided in the resolution of the Board of Directors shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to (i) approving or adopting, or recommending to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopting, amending or repealing any Bylaw of the corporation.

(b) Other Committees. The Board of Directors may, from time to time, appoint such other committees as may be permitted by law. Such other committees appointed by the Board of Directors shall consist of one or more members of the Board of Directors and shall have such powers and perform such duties as may be prescribed by the resolution or resolutions creating such committees, but in no event shall any such committee have the powers denied to the Executive Committee in these Bylaws.

(c) Term. The Board of Directors, subject to any requirements of any outstanding series of Preferred Stock and the provisions of subsections (a) or (b) of this Section 24, may at any time increase or decrease the number of members of a committee or terminate the existence of a committee. The membership of a committee member shall terminate on the date of his death or voluntary resignation from the committee or from the Board of Directors. The Board of Directors may at any time for any reason remove any individual committee member and the Board of Directors may fill any committee vacancy created by death, resignation, removal or increase in the number of members of the committee. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee, and, in addition, in the absence or disqualification of any member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member.

(d) Meetings. Unless the Board of Directors shall otherwise provide, regular meetings of the Executive Committee or any other committee appointed pursuant to this Section 24 shall be held at such times and places as are determined by the Board of Directors, or by any such committee, and when notice thereof has been given to each member of such committee, no further notice of such regular meetings need be given thereafter. Special meetings of any such committee may be held at any place which has been determined from time to time by such committee, and may be called by any director who is a member of such committee, upon notice to the members of such committee of the time and place of such special meeting given in the manner provided for the giving of notice to members of the Board of Directors of the time and place of special meetings of the Board of Directors. Notice of any special meeting of any committee may be waived in writing or by electronic transmission at any time before or after the meeting and will be waived by any director by attendance thereat, except when the director attends such special meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Unless otherwise provided by the Board of Directors in the resolutions authorizing the creation of the committee, a majority of the authorized number of members of any such committee shall constitute a quorum for the transaction of business, and the act of a majority of those present at any meeting at which a quorum is present shall be the act of such committee.

Section 25. Duties of Chairman of the Board of Directors. The Chairman of the Board of Directors, when present, shall preside at all meetings of the stockholders and the Board of Directors. The Chairman of the Board of Directors shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

Section 26. Lead Independent Director. The Chairman of the Board of Directors, or if the Chairman is not an independent director, one of the independent directors, may be designated by the Board of Directors as lead independent director ("**Lead Independent Director**") to serve until replaced by the Board of Directors. The Lead Independent Director will: with the Chairman of the Board of Directors, establish the agenda for regular Board meetings and serve as chairman of Board of Directors meetings in the absence of the Chairman of the Board of Directors; establish the agenda for meetings of the independent directors; coordinate with the committee chairs regarding meeting agendas and informational requirements; preside over meetings of the independent directors; preside over any portions of meetings of the Board of Directors at which the evaluation or compensation of the Chief Executive Officer is presented or discussed; preside over any portions of meetings of the Board of Directors at which the performance of the Board of Directors is presented or discussed; and perform such other duties as may be established or delegated by the Chairman of the Board of Directors.

Section 27. Organization. At every meeting of the directors, the Chairman of the Board of Directors, or, if a Chairman has not been appointed or is absent, the Lead Independent Director, or if the Lead Independent Director is absent, the Chief Executive Officer (if a director), or, if a Chief Executive Officer is absent, the President (if a director), or if the President is absent, the most senior Vice President (if a director), or, in the absence of any such person, a chairman of the meeting chosen by a majority of the directors present, shall preside over the meeting. The Secretary, or in his absence, any Assistant Secretary or other officer or director directed to do so by the Chairman, shall act as secretary of the meeting.

ARTICLE V

OFFICERS

Section 28. Officers Designated. The officers of the corporation shall include, if and when designated by the Board of Directors, the Chairman of the Board of Directors, the Chief Executive Officer, the President, one or more Vice Presidents, the Secretary, the Chief Financial Officer and the Treasurer. The Board of Directors may also appoint one or more Assistant Secretaries and Assistant Treasurers and such other officers and agents with such powers and duties as it shall deem necessary. The Board of Directors may assign such additional titles to one or more of the officers as it shall deem appropriate. Any one person may hold any number of offices of the corporation at any one time unless specifically prohibited therefrom by law. The salaries and other compensation of the officers of the corporation shall be fixed by or in the manner designated by the Board of Directors.

Section 29. Tenure and Duties of Officers.

(a) General. All officers shall hold office at the pleasure of the Board of Directors and until their successors shall have been duly elected and qualified, unless sooner removed. Any officer elected or appointed by the Board of Directors may be removed at any time by the Board of Directors. If the office of any officer becomes vacant for any reason, the vacancy may be filled by the Board of Directors.

(b) Duties of Chief Executive Officer. The Chief Executive Officer shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chairman of the Board of Directors or the Lead Independent Director has been appointed and is present. Unless an officer has been appointed Chief Executive Officer of the corporation, the President shall be the Chief Executive Officer of the corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the corporation. To the extent that a Chief Executive Officer has been appointed and no President has been appointed, all references in these Bylaws to the President shall be deemed references to the Chief Executive Officer. The Chief Executive Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

(c) Duties of President. The President shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chairman of the Board of Directors, the Lead Independent Director, or the Chief Executive Officer has been appointed and is present. Unless another officer has been appointed Chief Executive Officer of the corporation, the President shall be the Chief Executive Officer of the corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the corporation. The President shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

(d) Duties of Vice Presidents. The Vice Presidents may assume and perform the duties of the President in the absence or disability of the President or whenever the office of President is vacant. The Vice Presidents shall perform other duties commonly incident to their office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer, or, if the Chief Executive Officer has not been appointed or is absent, the President shall designate from time to time.

(e) Duties of Secretary. The Secretary shall attend all meetings of the stockholders and of the Board of Directors and shall record all acts and proceedings thereof in the minute book of the corporation. The Secretary shall give notice in conformity with these Bylaws of all meetings of the stockholders and of all meetings of the Board of Directors and any committee thereof requiring notice. The Secretary shall perform all other duties provided for in these Bylaws and other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time. The President may direct any Assistant Secretary or other officer to assume and perform the duties of the Secretary in the absence or disability of the Secretary, and each Assistant Secretary shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

(f) Duties of Chief Financial Officer. The Chief Financial Officer shall keep or cause to be kept the books of account of the corporation in a thorough and proper manner and shall render statements of the financial affairs of the corporation in such form and as often as required by the Board of Directors or the President. The Chief Financial Officer, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the corporation. The Chief Financial Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time. To the extent that a Chief Financial Officer has been appointed and no Treasurer has been appointed, all references in these Bylaws to the Treasurer shall be deemed references to the Chief Financial Officer. The President may direct the Treasurer, if any, or any Assistant Treasurer, or the Controller or any Assistant Controller to assume and perform the duties of the Chief Financial Officer in the absence or disability of the Chief Financial Officer, and each Treasurer and Assistant Treasurer and each Controller and Assistant Controller shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

(g) Duties of Treasurer. Unless another officer has been appointed Chief Financial Officer of the corporation, the Treasurer shall be the chief financial officer of the corporation and shall keep or cause to be kept the books of account of the corporation in a thorough and proper manner and shall render statements of the financial affairs of the corporation in such form and as often as required by the Board of Directors or the President, and, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the corporation. The Treasurer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

Section 30. Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

Section 31. Resignations. Any officer may resign at any time by giving notice in writing or by electronic transmission to the Board of Directors or to the President or to the Secretary. Any such resignation shall be effective when received by the person or persons to whom such notice is given, unless a later time is specified therein, in which event the resignation shall become effective at such later time. Unless otherwise specified in such notice, the acceptance of any such resignation shall not be necessary to make it effective. Any resignation shall be without prejudice to the rights, if any, of the corporation under any contract with the resigning officer.

Section 32. Removal. Any officer may be removed from office at any time, either with or without cause, by the affirmative vote of a majority of the directors in office at the time, or by the unanimous written consent of the directors in office at the time, or by any committee or by the Chief Executive Officer or by other superior officers upon whom such power of removal may have been conferred by the Board of Directors.

ARTICLE VI

EXECUTION OF CORPORATE INSTRUMENTS AND VOTING OF SECURITIES OWNED BY THE CORPORATION

Section 33. Execution of Corporate Instruments. The Board of Directors may, in its discretion, determine the method and designate the signatory officer or officers, or other person or persons, to execute on behalf of the corporation any corporate instrument or document, or to sign on behalf of the corporation the corporate name without limitation, or to enter into contracts on behalf of the corporation, except where otherwise provided by law or these Bylaws, and such execution or signature shall be binding upon the corporation.

All checks and drafts drawn on banks or other depositories on funds to the credit of the corporation or in special accounts of the corporation shall be signed by such person or persons as the Board of Directors shall authorize so to do.

Unless authorized or ratified by the Board of Directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

Section 34. Voting of Securities Owned by the Corporation. All stock and other securities of other corporations owned or held by the corporation for itself, or for other parties in any capacity, shall be voted, and all proxies with respect thereto shall be executed, by the person authorized so to do by resolution of the Board of Directors, or, in the absence of such authorization, by the Chairman of the Board of Directors, the Chief Executive Officer, the President, or any Vice President.

ARTICLE VII

SHARES OF STOCK

Section 35. Form and Execution of Certificates. The shares of the corporation shall be represented by certificates, or shall be uncertificated if so provided by resolution or resolutions of the Board of Directors. Certificates for the shares of stock of the corporation, if any, shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock represented by certificate in the corporation shall be entitled to have a certificate signed by or in the name of the corporation by the Chairman of the Board of Directors, the Chief Executive Officer, or the President or any Vice President and by the Chief Financial Officer, Treasurer or Assistant Treasurer or the Secretary or Assistant Secretary, certifying the number of shares owned by him in the corporation. Any or all of the signatures on the certificate may be facsimiles. In case any officer, transfer agent, or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent, or registrar before such certificate is issued, it may be issued with the same effect as if he were such officer, transfer agent, or registrar at the date of issue.

Section 36. Lost Certificates. A new certificate or certificates shall be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen, or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen, or destroyed. The corporation may require, as a condition precedent to the issuance of a new certificate or certificates, the owner of such lost, stolen, or destroyed certificate or certificates, or the owner's legal representative, to agree to indemnify the corporation in such manner as it shall require or to give the corporation a surety bond in such form and amount as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen, or destroyed.

Section 37. Transfers.

(a) Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by attorney duly authorized, and, in the case of stock represented by certificate, upon the surrender of a properly endorsed certificate or certificates for a like number of shares.

(b) The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

Section 38. Fixing Record Dates.

(a) In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, subject to applicable law, not be more than 60 nor less than 10 days before the date of such meeting. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board of Directors may fix a new record date for the adjourned meeting.

(b) In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

Section 39. Registered Stockholders. The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends, and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VIII

OTHER SECURITIES OF THE CORPORATION

Section 40. Execution of Other Securities. All bonds, debentures and other corporate securities of the corporation, other than stock certificates (covered in Section 35 of these Bylaws), may be signed by the Chairman of the Board of Directors, the Chief Executive Officer, the President or any Vice President, or such other person as may be authorized by the Board of Directors, and the corporate seal impressed thereon or a facsimile of such seal imprinted thereon and attested by the signature of the Secretary or an Assistant Secretary, or the Chief Financial Officer or Treasurer or an Assistant Treasurer; *provided, however,* that where any such bond, debenture or other corporate security shall be authenticated by the manual signature, or where permissible facsimile signature, of a trustee under an indenture pursuant to which such bond, debenture or other corporate security shall be issued, the signatures of the persons signing and attesting the corporate seal on such bond, debenture or other corporate security may be the imprinted facsimile of the signatures of such persons. Interest coupons appertaining to any such bond, debenture or other corporate security, authenticated by a trustee as aforesaid, shall be signed by the Treasurer or an Assistant Treasurer of the corporation or such other person as may be authorized by the Board of Directors, or bear imprinted thereon the facsimile signature of such person. In case any officer who shall have signed or attested any bond, debenture or other corporate security, or whose facsimile signature shall appear thereon or on any such interest coupon, shall have ceased to be such officer before the bond, debenture or other corporate security so signed or attested shall have been delivered, such bond, debenture or other corporate security nevertheless may be adopted by the corporation and issued and delivered as though the person who signed the same or whose facsimile signature shall have been used thereon had not ceased to be such officer of the corporation.

ARTICLE IX

DIVIDENDS

Section 41. Declaration of Dividends. Dividends upon the capital stock of the corporation, subject to the provisions of the Certificate of Incorporation and applicable law, if any, may be declared by the Board of Directors pursuant to law at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation and applicable law.

Section 42. Dividend Reserve. Before payment of any dividend, there may be set aside out of any funds of the corporation available for dividends such sum or sums as the Board of Directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the corporation, or for such other purpose as the Board of Directors shall think conducive to the interests of the corporation, and the Board of Directors may modify or abolish any such reserve in the manner in which it was created.

ARTICLE X

FISCAL YEAR

Section 43. Fiscal Year. The fiscal year of the corporation shall be fixed by resolution of the Board of Directors.

ARTICLE XI

INDEMNIFICATION

Section 44. Indemnification of Directors, Officers, Employees and Other Agents.

(a) Directors and Officers. The corporation shall indemnify its directors and officers to the extent not prohibited by the DGCL or any other applicable law; *provided, however*, that the corporation may modify the extent of such indemnification by individual contracts with its directors and officers; and, *provided, further*, that the corporation shall not be required to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the Board of Directors of the corporation, (iii) such indemnification is provided by the corporation, in its sole discretion, pursuant to the powers vested in the corporation under the DGCL or any other applicable law or (iv) such indemnification is required to be made under subsection (d).

(b) Employees and Other Agents. The corporation shall have power to indemnify its employees and other agents as set forth in the DGCL or any other applicable law. The Board of Directors shall have the power to delegate the determination of whether indemnification shall be given to any such person (except for officers) or other persons as the Board of Directors shall determine.

(c) Expenses. The corporation shall advance to any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or officer, of the corporation, or is or was serving at the request of the corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, prior to the final disposition of the proceeding, promptly following request therefor, all expenses incurred by any director or officer in connection with such proceeding provided, however, that if the DGCL requires, an advancement of expenses incurred by a director or officer in his or her capacity as a director or officer (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to the corporation of an undertaking (hereinafter an “*undertaking*”), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (hereinafter a “*final adjudication*”) that such indemnitee is not entitled to be indemnified for such expenses under this Section 44 or otherwise.

Notwithstanding the foregoing, unless otherwise determined pursuant to paragraph (e) of this Section 44, no advance shall be made by the corporation to an officer of the corporation (except by reason of the fact that such officer is or was a director of the corporation in which event this paragraph shall not apply) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made (i) by a majority vote of directors who were not parties to the proceeding, even if not a quorum, or (ii) by a committee of such directors designated by a majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or such directors so direct, by independent legal counsel in a written opinion, that the facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the corporation.

(d) Enforcement. Without the necessity of entering into an express contract, all rights to indemnification and advances to directors and officers under this Section 44 shall be deemed to be contractual rights and be effective to the same extent and as if provided for in a contract between the corporation and the director or officer. Any right to indemnification or advances granted by this Section 44 to a director or officer shall be enforceable by or on behalf of the person holding such right in any court of competent jurisdiction if (i) the claim for indemnification or advances is denied, in whole or in part, or (ii) no disposition of such claim is made within 90 days of request therefor. To the extent permitted by law, the claimant in such enforcement action, if successful in whole or in part, shall be entitled to be paid also the expense of prosecuting the claim. In connection with any claim for indemnification, the corporation shall be entitled to raise as a defense to any such action that the claimant has not met the standards of conduct that make it permissible under the DGCL or any other applicable law for the corporation to indemnify the claimant for the amount claimed. In connection with any claim by an officer of the corporation (except in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such officer is or was a director of the corporation) for advances, the corporation shall be entitled to raise a defense as to any such action clear and convincing evidence that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the corporation, or with respect to any criminal action or proceeding that such person acted without reasonable cause to believe that his conduct was lawful. Neither the failure of the corporation (including its Board of Directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because the director or officer has met the applicable standard of conduct set forth in the DGCL or any other applicable law, nor an actual determination by the corporation (including its Board of Directors, independent legal counsel or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that claimant has not met the applicable standard of conduct. In any suit brought by a director or officer to enforce a right to indemnification or to an advancement of expenses hereunder, the burden of proving that the director or officer is not entitled to be indemnified, or to such advancement of expenses, under this Section 44 or otherwise shall be on the corporation.

(e) Non-Exclusivity of Rights. The rights conferred on any person by this Bylaw shall not be exclusive of any other right which such person may have or hereafter acquire under any applicable statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advances, to the fullest extent not prohibited by the DGCL, or by any other applicable law.

(f) Survival of Rights. The rights conferred on any person by this Bylaw shall continue as to a person who has ceased to be a director or officer, or, if applicable, employee or other agent, and shall inure to the benefit of the heirs, executors and administrators of such a person.

(g) Insurance. To the fullest extent permitted by the DGCL or any other applicable law, the corporation, upon approval by the Board of Directors, may purchase insurance on behalf of any person required or permitted to be indemnified pursuant to this Section 44.

(h) Amendments. Any repeal or modification of this Section 44 shall only be prospective and shall not affect the rights under this Bylaw in effect at the time of the alleged occurrence of any action or omission to act that is the cause of any proceeding against any agent of the corporation.

(i) Saving Clause. If this Bylaw or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the corporation shall nevertheless indemnify each director and officer to the full extent not prohibited by any applicable portion of this Section 44 that shall not have been invalidated, or by any other applicable law. If this Section 44 shall be invalid due to the application of the indemnification provisions of another jurisdiction, then the corporation shall indemnify each director and officer to the full extent under any other applicable law.

(j) Certain Definitions. For the purposes of this Bylaw, the following definitions shall apply:

(i) The term "*proceeding*" shall be broadly construed and shall include, without limitation, the investigation, preparation, prosecution, defense, settlement, arbitration and appeal of, and the giving of testimony in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative.

(ii) The term “*expenses*” shall be broadly construed and shall include, without limitation, court costs, attorneys’ fees, witness fees, fines, amounts paid in settlement or judgment and any other costs and expenses of any nature or kind incurred in connection with any proceeding.

(iii) The term the “*corporation*” shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Section 44 with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

(iv) References to a “*director*,” “*officer*,” “*employee*,” or “*agent*” of the corporation shall include, without limitation, situations where such person is serving at the request of the corporation as, respectively, a director, officer, employee, trustee or agent of another corporation, partnership, joint venture, trust or other enterprise.

(v) References to “*other enterprises*” shall include employee benefit plans; references to “*fines*” shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to “*serving at the request of the corporation*” shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “*not opposed to the best interests of the corporation*” as referred to in this Section 44.

ARTICLE XII

NOTICES

Section 46. Notices.

(a) **Notice to Stockholders.** Written notice to stockholders of stockholder meetings shall be given as provided in Section 7 of these Bylaws. Without limiting the manner by which notice may otherwise be given effectively to stockholders under any agreement or contract with such stockholder, and except as otherwise required by law, written notice to stockholders for purposes other than stockholder meetings may be sent by U.S. mail or nationally recognized overnight courier, or by facsimile, telegraph or telex, or by electronic mail or other electronic means.

(b) Notice to Directors. Any notice required to be given to any director may be given by the method stated in subsection (a), or as otherwise provided in these Bylaws, except that such notice other than one which is delivered personally shall be sent to such address as such director shall have filed in writing with the Secretary, or, in the absence of such filing, to the last known post office address of such director.

(c) Affidavit of Mailing. An affidavit of mailing, executed by a duly authorized and competent employee of the corporation or its transfer agent appointed with respect to the class of stock affected, or other agent, specifying the name and address or the names and addresses of the stockholder or stockholders, or director or directors, to whom any such notice or notices was or were given, and the time and method of giving the same, shall in the absence of fraud, be prima facie evidence of the facts therein contained.

(d) Methods of Notice. It shall not be necessary that the same method of giving notice be employed in respect of all recipients of notice, but one permissible method may be employed in respect of any one or more, and any other permissible method or methods may be employed in respect of any other or others.

(e) Notice to Person With Whom Communication is Unlawful. Whenever notice is required to be given, under any provision of law or of the Certificate of Incorporation or Bylaws of the corporation, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under any provision of the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

(f) Notice to Stockholders Sharing an Address. Except as otherwise prohibited under the DGCL, any notice given under the provisions of the DGCL, the Certificate of Incorporation or the Bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Such consent shall have been deemed to have been given if such stockholder fails to object in writing to the corporation within 60 days of having been given notice by the corporation of its intention to send the single notice. Any consent shall be revocable by the stockholder by written notice to the corporation.

ARTICLE XIII

AMENDMENTS

Section 47. Amendments. Subject to the limitations set forth in Section 44(h) of these Bylaws or the provisions of the Certificate of Incorporation, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the corporation. Any adoption, amendment or repeal of the Bylaws of the corporation by the Board of Directors shall require the approval of a majority of the authorized number of directors. The stockholders also shall have power to adopt, amend or repeal the Bylaws of the corporation; *provided, however,* that, in addition to any vote of the holders of any class or series of stock of the corporation required by law or by the Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of the capital stock of the corporation entitled to vote generally in the election of directors, voting together as a single class.

ARTICLE XIV
MISCELLANEOUS

Section 47. Forum.

(a) Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall be the sole and exclusive forum for the following claims or causes of action under Delaware statutory or common law: (A) any derivative claim or cause of action brought on behalf of the corporation; (B) any claim or cause of action for breach of a fiduciary duty owed by any current or former director, officer or other employee of the corporation, to the corporation or the corporation's stockholders; (C) any claim or cause of action against the corporation or any current or former director, officer or other employee of the corporation, arising out of or pursuant to any provision of the DGCL, the Certificate of Incorporation or the Bylaws of the corporation (as each may be amended from time to time); (D) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the Certificate of Incorporation or the Bylaws of the corporation (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (E) any claim or cause of action as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and (F) any claim or cause of action against the corporation or any current or former director, officer or other employee of the corporation, governed by the internal-affairs doctrine or otherwise related to the corporation's internal affairs, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants. This Section 47 of Article XV shall not apply to claims or causes of action brought to enforce a duty or liability created by the 1933 Act or the 1934 Act or any other claim for which the federal courts have exclusive jurisdiction.

(b) Unless the corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the 1933 Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by the corporation, its officers and directors, the underwriters for any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

Adopted by the Board of Directors of the Corporation on April 11, 2025.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

The following summary of the capital stock of Apimeds Pharmaceuticals US, Inc. (the "Company"), does not purport to be complete and is qualified in its entirety by reference to our Certificate of Incorporation, as amended (the "Charter"), and our amended and restated bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K (the "Annual Report"), of which this exhibit is a part, and certain provisions of the Delaware General Corporation Law ("DGCL"). Unless the context requires otherwise, all references to the "Company," "Apimeds," "we," "our," and "us" in this Exhibit refer to Apimeds Pharmaceuticals US, Inc. Capitalized terms used but not defined herein have the meanings set forth in the Annual Report to which this description is an exhibit.

DESCRIPTION OF SECURITIES

The following summary of the material terms of our securities and is not intended to be a complete summary of the rights and preferences of such securities. We urge you to read our Charter and Bylaws in their entirety for a complete description of the rights and preferences of our securities.

General

The following descriptions of our capital stock and certain provisions of our Charter and Bylaws are summaries. The full text of our Charter and our Bylaws are filed as exhibits to the registration statement, of which this prospectus is a part. We urge you to read our Charter and our Bylaws in their entirety for a complete description of the rights and preferences of our capital stock.

Authorized Capitalization

Our Charter authorizes the issuance of 100,000,000 shares of common stock, par value \$0.01 per share and 10,000,000 shares of preferred stock, par value \$0.01 per share.

Forward Stock Split

On January 6, 2022, we amended our Charter to effect a forward stock split of our outstanding shares of common stock by a ratio of 1-for-10,000.

Reverse Stock Split

On February 25, 2025, we amended our Charter to effect a 1-for-2.6 reverse stock split, pursuant to which each 2.6 shares of common stock held of record by the holder thereof were reclassified into one share of common stock. No fractional shares were issued.

As of the date of this prospectus, there were 7,903,850 shares of common stock issued and outstanding held of record by nine stockholders. No shares of preferred stock are issued and outstanding.

Upon completion of this offering, there will be 11,696,497 shares of common stock outstanding.

Common Stock

Voting Rights. The holders of shares of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of shareholders.

Dividends. The board of directors of our company may cause dividends to be paid to the holders of shares of common stock out of funds legally available for the payment of dividends by declaring an amount per share as a dividend. When and as dividends are declared on the common stock, whether payable in cash, in property or in shares of stock or other securities of our company, the holders of common stock shall be entitled to share ratably according to the number of shares of common stock held by them, in such dividends.

Liquidation Rights. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of our company, the holders of shares of common stock shall be entitled to share ratably, according to the number of shares of common stock held by them, in all remaining assets of our company available for distribution to its shareholders.

Blank Check Preferred Stock

Our board of directors has the authority to issue undesignated shares of “blank check” preferred stock in one or more series and to fix the designation, relative powers, preferences and rights and qualifications, limitations or restrictions of all shares of each such series, including, without limitation, dividend rates, conversion rights, voting rights, redemption and sinking fund provisions, liquidation preferences and the number of shares constituting each such series, without any further vote or action by the shareholders. The issuance of additional preferred stock could decrease the amount of earnings and assets available for distribution to holders of our common stock or adversely affect the rights and powers, including voting rights, of the holders of our common stock and could, among other things, have the effect of delaying, deferring or preventing a change in control of our company without further action by the stockholders. We have no present plans to issue any shares of preferred stock.

Anti-Takeover Provisions of the Charter and Bylaws

Stockholder Action; Special Meetings of Stockholders

The Bylaws provide that stockholders may not take action by written consent, but may only take action at annual or special meetings of stockholders. As a result, a holder controlling a majority of Company capital stock would not be able to amend the Bylaws or remove directors without holding a meeting of stockholders called in accordance with the Bylaws. Further, the Bylaws provide that only the chairperson of the Board, a majority of the board of directors or the Chief Executive Officer may call special meetings of stockholders, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of stockholders to force consideration of a proposal or for stockholders controlling a majority of Company capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

In addition, the Bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting or special meeting of stockholders. Generally, in order for any matter to be “properly brought” before a meeting, the matter must be (a) specified in a notice of meeting given by or at the direction of the board of directors, (b) if not specified in a notice of meeting, otherwise brought before the meeting by the board of directors or the chairperson of the meeting, or (c) otherwise properly brought before the meeting by a stockholder present in person who (1) was a stockholder at the time of giving the notice, (2) is entitled to vote at the meeting, and (3) has complied with the advance notice procedures specified in the Bylaws or properly made such proposal in accordance with Rule 14a-8 under the Exchange Act and the rules and regulations thereunder, which proposal has been included in the proxy statement for the annual meeting. Further, for business to be properly brought before an annual meeting by a stockholder, the stockholder must (a) provide Timely Notice (as defined below) thereof in writing and in proper form to the secretary and (b) provide any updates or supplements to such notice at the times and in the forms required by the Bylaws. To be timely, a stockholder’s notice must be delivered to, or mailed and received at, the Company’s principal executive offices not less than ninety (90) days nor more than one hundred twenty (120) days prior to the one-year anniversary of the preceding year’s annual meeting; provided, however, that if the date of the annual meeting is more than thirty (30) days before or more than thirty (30) days after such anniversary date, notice by the stockholder to be timely must be so delivered, or mailed and received, not earlier than the close of business on the 120th day prior to such annual meeting and not later than the 90th day prior to such annual meeting or, the 10th day following the day on which public disclosure of the date of such annual meeting was first made (such notice within such time periods, “Timely Notice”). These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of the outstanding voting securities until the next stockholder meeting.

No Cumulative Voting

Under the DGCL, there is no right to vote cumulatively (which allows stockholders to cast all of the votes such stockholder is entitled to for a single nominee for a board of directors rather than only being able to vote the number of shares such stockholder holds for or against each nominee) unless expressly authorized in the certificate of incorporation. The Charter does not authorize cumulative voting.

Amendment of Charter or Bylaws

The DGCL provides generally that the affirmative vote of a majority of the outstanding stock entitled to vote on amendments to a corporation's certificate of incorporation or bylaws is required to approve such amendment, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our Bylaws may be amended or repealed by a majority vote of the board of directors or by the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares entitled to vote generally in the election of directors, voting together as a single class.

Authorized but Unissued Capital Stock

Delaware law does not require stockholder approval for any issuance of authorized shares. However, the listing requirements of the NYSE American, which would apply if and so long as the common stock remains listed on the NYSE American, require stockholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. Additional shares that may be issued in the future may be used for a variety of corporate purposes, including future public offerings, to raise additional capital or to facilitate acquisitions.

One of the effects of the existence of unissued and unreserved common stock may be to enable our company to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise and thereby protect the continuity of management and possibly deprive stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Limitations on Liability and Indemnification of Officers and Directors

The DGCL authorizes corporations to limit or eliminate the personal liability of directors to corporations and their stockholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. We have entered into, or expect to enter into, agreements to indemnify our directors, executive officers and other employees as determined by our board of directors.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, stockholders will have appraisal rights in connection with a merger or consolidation of the Company. Pursuant to Section 262 of the DGCL, stockholders who properly demand and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Stockholders' Derivative Actions

Under the DGCL, any of the Company's stockholders may bring an action in the company's name to procure a judgment in its favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of the Company's shares at the time of the transaction to which the action relates.

Forum Selection

The Bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of the Company; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of the Company's current or former directors, officers, or other of the Company or its stockholders; (iii) any action or proceeding asserting a claim against the Company or any of its current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, the Charter or the Bylaws; (iv) any action or proceeding to interpret, apply, enforce, or determine the validity of the Charter or the Bylaws; (v) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against the Company or any of its directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, the Bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by the Company, its officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying this offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, the Company would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of the Bylaws.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock upon the closing of this offering will be VStock Transfer, LLC. The transfer agent and registrar's address are 18 Lafayette Place, Woodmere, NY 11598.

National Securities Exchange Listing

We have received approval to have our common stock listed on the NYSE American under the symbol "APUS."

APIMEDS PHARMACEUTICALS US, INC.
PROMISSORY NOTE

\$250,000.00

March 21, 2025

FOR VALUE RECEIVED, APIMEDS PHARMACEUTICALS US, INC., a Delaware limited liability company ("**Borrower**"), promises to pay to the order of APIMEDS INC., a South Korean company ("**Payee**"), at such place as Payee may from time to time designate, the principal sum of TWO HUNDRED FIFTY AND 00/100 DOLLARS (\$250,000.00) (the "**Loan**"), together with interest on the unpaid principal balance outstanding from time to time, all as hereinafter set forth. Payments of both principal and interest shall be paid in lawful money of the United States of America, which shall be legal tender in payment of all debts and dues.

1. Use of Loan Proceeds. The proceeds of the Loan shall be used by Borrower for payment of outstanding fees and expenses and other general working capital purposes.

2. Interest. Interest on the outstanding principal balance of the Loan shall accrue at a rate equal to five percent (5%) per annum (the "**Interest Rate**") and shall be computed on the actual number of days outstanding based on a three hundred sixty-five (365) day year. Interest on the outstanding principal balance of the Loan shall accrue and be payable on the Maturity Date (as defined below).

3. Loan Term. The outstanding principal balance and all accrued and updated interest thereon shall be due upon the earlier of (a) December 31, 2026, or (b) consummation of a Qualified Offering (the "**Maturity Date**"). "**Qualified Offering**" shall mean an offering of Common Stock (and other securities potentially) resulting in the listing for trading of the Common Stock on the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market or the New York Stock Exchange (or any successors to any of the foregoing).

4. Prepayment. This Promissory Note (this "**Note**") may be prepaid, without penalty or premium, which consent shall not be unreasonably withheld, delayed or conditioned. Any prepayment shall be accompanied by payment of all unpaid late payment penalties, if any, which are due plus all accrued and unpaid interest due as of the date of such prepayment. All partial prepayments of principal shall be applied to any principal installment payments in the inverse order of their maturity.

5. Events of Default: Acceleration. If any payment due hereunder is not paid within five (5) days after the date that the amount was due, a default interest rate of the Interest Rate plus five percent (5%) shall be assessed against the defaulted payment (and any future defaults) until such payment (and any future defaulted payments) is made in full to Payee. In addition, Payee, in Payee's sole discretion and without notice or demand, may declare the entire unpaid principal balance plus accrued interest and all other sums due hereunder immediately due and payable. Failure by Payee to exercise this option shall not constitute a waiver of the right to exercise the same in the event of any subsequent default. Notwithstanding any other provision contained herein, if, at any time, any rate of interest charged under this Note shall be deemed by any competent court of law, governmental agency or tribunal to exceed the maximum rate of interest permitted by any applicable law, for such time as such rate of interest would be deemed excessive, its application shall be suspended and there shall be charged instead the maximum rate of interest permitted under such laws.

6. Costs and Expenses; Waiver by Borrower. Borrower shall pay to Payee and reimburse Payee for any and all costs and expenses, including attorney's fees and court costs, if any, incurred by Payee to enforce or collect this Note. Borrower waives presentment, protest and demand, notice of protest, notice of dishonor and nonpayment of this Note and expressly agrees that this Note or any payment hereunder may be extended from time to time without in any way affecting the liability of any Borrower hereunder.

7. Cumulative Remedies; No Waiver by Payee. The rights and remedies of Payee hereunder shall be cumulative and concurrent and may be pursued singularly, successively or together at the sole discretion of Payee, and may be exercised as often as occasion therefor shall occur, and the failure to exercise any such right or remedy shall in no event be construed as a waiver or release of the same or any other right or remedy.

8. Evidence of Indebtedness. This Note is given and accepted as evidence of indebtedness only, and not in payment or satisfaction of any indebtedness or obligation.

9. Headings. The headings used in this Note are for convenience only and are not to be interpreted as a part of this Note.

10. Governing Law. This Note, its validity, enforcement and interpretation, shall be governed by the laws of the State of Delaware, without regard to conflict of law principles.

11. Waiver of Jury Trial. EACH PARTY WAIVES ANY RIGHT TO A TRIAL BY JURY IN ANY ACTION OR PROCEEDING TO ENFORCE OR DEFEND ANY RIGHTS UNDER, OR IN ANY PROCEEDING IN ANY WAY ARISING OUT OF OR IN CONNECTION WITH THIS NOTE OR ANY OTHER DOCUMENT OR AGREEMENT EXECUTED AND DELIVERED IN CONNECTION HERewith, WHETHER IN CONTRACT OR TORT, AT LAW OR IN EQUITY, AND EACH PARTY AGREES THAT ANY SUCH ACTION OR PROCEEDING SHALL BE TRIED BEFORE A COURT AND NOT BEFORE A JURY, AND THAT THE OTHER PARTY MAY FILE AN ORIGINAL COUNTERPART OR A COPY OF THIS SECTION WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES TO THE WAIVER OF THEIR RIGHTS TO TRIAL BY JURY. EACH PARTY ACKNOWLEDGES THAT IT HAS HAD THE OPPORTUNITY TO CONSULT WITH COUNSEL REGARDING THIS SECTION, THAT IT FULLY UNDERSTANDS ITS TERMS, CONTENT AND EFFECT, AND THAT IT VOLUNTARILY AND KNOWINGLY AGREES TO THE TERMS OF THIS SECTION.

12. Confession of Judgement. UPON THE OCCURRENCE OF AN EVENT OF DEFAULT HEREUNDER, BORROWER HEREBY IRREVOCABLY AUTHORIZES AND EMPOWERS ANY ATTORNEY OR THE PROTHONOTARY OR CLERK OF ANY COURT IN THE STATE OF DELAWARE, OR ELSEWHERE, TO APPEAR AT ANY TIME FOR BORROWER IN ANY ACTION BROUGHT AGAINST BORROWER ON THIS NOTE, WITH OR WITHOUT DECLARATION FILED, AS TO ANY TERM, AND THEREIN TO CONFESS OR ENTER JUDGMENT AGAINST BORROWER FOR THE ENTIRE UNPAID PRINCIPAL AND INTEREST OF THIS NOTE AND ALL ARREARAGES OF INTEREST THEREON, INCLUDING BUT NOT LIMITED TO REASONABLE COUNSEL FEES TOGETHER WITH COSTS OF SUIT; AND BORROWER HEREBY RELEASES ALL ERRORS IN SUCH PROCEEDINGS. IF A COPY OF THIS NOTE, VERIFIED BY AN AFFIDAVIT, SHALL HAVE BEEN FILED IN SAID ACTION, IT SHALL NOT BE NECESSARY TO FILE THE ORIGINAL AS A WARRANT OF ATTORNEY. BORROWER WAIVES THE RIGHT TO ANY STAY OF EXECUTION AND THE BENEFIT OF ALL EXEMPTION LAWS NOW OR HEREINAFTER IN EFFECT. NO SINGLE EXERCISE OF THE FOREGOING WARRANT AND POWER TO BRING ANY ACTION OR TO CONFESS JUDGMENT THEREIN SHALL BE DEEMED TO EXHAUST THE POWER, BUT THE POWER SHALL CONTINUE UNDIMINISHED AND MAY BE EXERCISED FROM TIME TO TIME AS OFTEN AS PAYEE SHALL ELECT UNTIL ALL AMOUNTS PAYABLE TO PAYEE UNDER THIS NOTE SHALL HAVE BEEN PAID IN FULL. BORROWER, IN GRANTING THE WARRANT OF ATTORNEY TO CONFESS JUDGMENT, HEREBY ACKNOWLEDGES THAT, WITH RESPECT TO THE ENTRY OF JUDGMENT AUTHORIZED BY THE WARRANT OF ATTORNEY HEREIN, BORROWER KNOWINGLY, INTENTIONALLY, VOLUNTARILY AND UNCONDITIONALLY, WAIVES ANY AND ALL RIGHTS WHICH BORROWER HAS OR MAY HAVE TO PRIOR NOTICE AND AN OPPORTUNITY FOR HEARING PRIOR TO THE ENTRY OF SUCH JUDGMENT. IN ADDITION, BORROWER ACKNOWLEDGES THAT: (I) BORROWER HAS HAD THE OPPORTUNITY TO BE REPRESENTED BY LEGAL COUNSEL IN CONNECTION WITH THIS NOTE; AND (II) IN THE EVENT PAYEE EXERCISES THE WARRANT OF ATTORNEY GRANTED HEREIN, SUCH ACTION MAY BE ADVERSE TO BORROWER'S INTERESTS. BORROWER HEREBY EXPRESSLY WAIVES THE DUTIES THAT MAY BE IMPOSED UPON PAYEE PURSUANT TO STATE LAW IN EXERCISING ITS RIGHTS HEREUNDER.

14. Successors and Assigns. This Note shall bind Borrower and the successors and assigns of Borrower and the benefits hereof shall inure to the benefit of Payee and its successors and assigns. All references herein to "Borrower" shall be deemed to apply to Borrower and to the successors and assigns of Borrower, and all references herein to "Payee" shall be deemed to apply to Payee and its successors and assigns.

IN WITNESS WHEREOF, Borrower and Payee have executed this Note as of the date first written above.

BORROWER:

APIMEDS PHARMACEUTICALS US, INC.

By: /s/ Erik Emerson

Name: Erik Emerson

Title: Chief Executive Officer

Accepted and agreed on the date hereof by:

PAYEE:

APIMEDS, INC.

By: /s/ Japak Koo

Name: Jakap Koo

Title: CEO

APIMEDS PHARMACEUTICALS US, INC.
INSIDER TRADING COMPLIANCE POLICY
(Effective as of February 7, 2025)

Apimeds Pharmaceuticals US, Inc. (the “Company”) has a culture which requires integrity, ethical conduct and fair dealing. It is the purpose of this policy to set forth basic guidelines for trading in the Company’s securities (including, without limitation, its common stock) and to preserve its confidential information so as to avoid any situation that might have the potential to damage the Company’s reputation or which could constitute a violation of federal or state securities law by the Company, its officers, directors, or employees. Toward these ends, it is the intention of the Company that it and all its employees shall comply with and observe all applicable securities laws, including the Securities Exchange Act of 1934 (the “Exchange Act”), as amended by the Insider Trading and Securities Fraud Enforcement Act of 1988, by the Sarbanes-Oxley Act of 2002, and by other acts.

I. MATERIAL NON-PUBLIC INFORMATION.

A. General

Under the Federal securities laws, “insiders” (*i.e.*, officers, members of the Board of Directors and other individuals having access to material non-public information) are prohibited from trading in common stock and other securities on the basis of such material non-public information until after the information has been disclosed to the public. This prohibition reflects the need, as determined by Congress, the Securities and Exchange Commission (“SEC”) and the courts, to ensure equality of information between corporate insiders and members of the investing public. The Company takes seriously our obligation, and that of our employees, to prevent insider trading violations.

All matters regarding the “materiality” or “non-public” nature of any information shall be determined by the Secretary of the Company.

Insider trading restrictions come into play only if the information you possess is “material.” Materiality, however, involves a relatively low threshold. Information is generally regarded as “material” if it has market significance, that is, if its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision.

Information dealing with the following subjects is reasonably likely to be found material in particular situations:

- (i) significant changes in the Company’s prospects;
- (ii) significant write-downs in assets or increases in reserves;
- (iii) developments regarding significant litigation or government agency investigations;
- (iv) liquidity problems;
- (v) changes in earnings estimates or unusual gains or losses in major operations;
- (vi) major changes in the Company’s management or the board of directors;
- (vii) changes in dividends;
- (viii) extraordinary borrowings;
- (ix) major changes in accounting methods or policies;

- (x) award or loss of a significant contract;
- (xi) cybersecurity risks and incidents, including vulnerabilities and breaches;
- (xii) changes in debt ratings;
- (xiii) proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets; and
- (xiv) offerings of Company securities.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular nonpublic information is material, you should presume it is material. If you are unsure whether information is material, you should either consult the Secretary before making any decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates or assume that the information is material.

Insider trading prohibitions come into play only when you possess information that is material and "nonpublic." The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. Even after public disclosure of information about the Company, you must wait until the close of business on the second trading day after the information was publicly disclosed before you can treat the information as public.

Nonpublic information may include:

- (i) information available to a select group of analysts or brokers or institutional investors;
- (ii) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and
- (iii) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two trading days).

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Secretary or assume that the information is nonpublic and treat it as confidential.

B. Limitation of Access to and Use of Material Non-Public Information

The obligation not to trade on inside information applies not only to the Company and insiders, but also to persons who obtain such information from insiders and use it to their advantage. Thus, liability may be imposed upon the Company, its insiders and also outsiders who are the source of leaks of material information not yet disclosed to the public if the leaks coincide with purchases or sales of the Company's securities (i) by such insiders or outsiders, (ii) by the Company itself, or (iii) by "tippees" (including relatives, friends, investment analysts, etc.).

Material non-public information shall not be disseminated to any person outside the Company without that person signing a Non-Disclosure Agreement acknowledging that they are receiving material non-public information and must be distributed within the Company only on a strict “need to know” basis. No employee is permitted to disclose such information selectively or generally to any other employee or outside contact unless the person to whom disclosure is made has a clear right and need to know such information in order to fulfill job responsibilities and such disclosure is approved by the Secretary of the Company. It is permissible to have discussions with investment analysts, but material non-public information may not be disclosed to an investment analyst without the information being simultaneously released to the public. Under no circumstances should any employee discuss such information with family, relatives or business and social acquaintances.

Unless specifically authorized to do so, no employee, officer or director may disclose nonpublic information about the Company on the Internet (regardless of whether such information is material), and more specifically in investor discussion forums (like *Yahoo! Finance*, *Google Finance* or *The Motley Fool*) or chat rooms or message boards where companies and their prospects are discussed. Messages in these investor forums are typically posted by unsophisticated investors who are sometimes poorly informed, and generally are carelessly stated or, in some cases, malicious or manipulative and intended to benefit the message writers’ own stock positions. *Accordingly, no employee, officer or director of the Company may discuss the Company or Company-related information in such investor forums, regardless of the situation.* In addition, disclosures of material nonpublic information through this forum may amount to a “tip” or leak of such information, in violation of this Policy and applicable law. Despite any inaccuracies that may exist in these investor forums, postings in these forums can result in the disclosure of information that may be harmful to the Company.

Typically, public disclosure is accomplished by means of a press release cleared by the Chief Executive Officer and the President. Certain other disclosures are made by the Company in reports to the SEC. Only certain of the Company’s executive officers and investor relations personnel may communicate with securities market professionals, stockholders and members of the media. Employees, officers and directors should refer any such inquiries to the appropriate Company personnel as indicated above.

Insiders are also prohibited from trading in the securities of competitors, customers, vendors or joint venturers of the Company while in possession of material non-public information concerning those third parties.

No director, officer or employee or any of their immediate family members may purchase or sell, or offer to purchase or sell, any Company security, whether or not issued by the Company, while in possession of material nonpublic information about the Company.

No director, officer or employee or any of their immediate family members who knows of any material nonpublic information about the Company may communicate that information to (“tip”) any other person, including family members and friends, or otherwise disclose such information without the Company’s authorization.

No director, officer or employee or any of their immediate family members may purchase or sell any security of any other publicly-traded company while in possession of material nonpublic information that was obtained in the course of his or her involvement with the Company. No director, officer or employee or any of their immediate family members who knows of any such material nonpublic information may communicate that information to, or tip, any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

For compliance purposes, you should never trade, tip or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that you have reason to believe is material and nonpublic unless you first consult with, and obtain the advance approval of, the Secretary. Covered Persons must "pre-clear" all trading in securities of the Company in accordance with the procedures set forth below.

C. Possible Sanctions

Violation of any of the securities laws described in this Policy Statement may result in the institution of a prosecution or an SEC enforcement proceeding against the individual and the Company, or both. Some of the possible penalties for individuals who trade on inside information include:

- *Liability for Insider Trading.* Insiders may be subject to a civil penalty of up to three times the profit gained or loss avoided; a criminal fine of up to \$5 million (no matter how small the profit); and imprisonment for up to 20 years for trading in securities when in possession of material non-public information. In addition, if the Company or any "controlling person" (i.e., a person in a supervisory capacity) fails to take appropriate steps to prevent an employee from engaging in insider trading, the Company or controlling person faces potential civil penalties of the greater of \$1,000,000, up to 3 times the profits realized or losses avoided, and potential criminal penalties of up to \$25 million.
- *Liability for Tipping.* Insiders may also be liable for improper transactions by a tippee to whom they have disclosed material non-public information, or to whom they have made recommendations or expressed opinions on the basis of such information about trading securities. The SEC has imposed large penalties even when the disclosing person did not profit from the trading.
- *Possible Disciplinary Actions.* Employees who violate this policy will be subject to serious disciplinary action, which may include ineligibility for future participation in our equity incentive plans or termination of employment.

D. Quiet Periods and Pre-Trade Approvals

In order to provide a degree of certainty as to when insider trading is permissible with respect to the timing of quarterly and annual releases of financial information, the Company has established recurring “quiet periods” relative to such releases. Directors, all officers and employees with access to financial results, subject to their having adopted a valid 10b5-1 plan, as discussed below, are not permitted to buy or sell Company stock during the periods commencing on the 16th calendar day of the third month of each fiscal quarter and ending at the close of business on the second working day after quarterly or annual earnings are released to the public. Trading in Company stock at other times may be permissible, but all transactions in Company stock by directors, officers and other identified employees must be approved in advance by the Secretary and must be reported to the Secretary after consummating the transaction.

The Company may impose additional quiet periods during which trading will not be allowed when there are developments that give rise to the need for public disclosure. Affected stockholders will be advised by memorandum from the Secretary when these additional quiet periods are in effect.

E. 10b5-1 Trading Plans

The SEC has enacted rules (Rule 10b5-1 under the Exchange Act) that provide an affirmative defense against violations of the insider trading laws if you enter into a contract, provide instructions, or adopt a written plan for a transaction in securities when you are not in possession of material, nonpublic information, even if it turns out that you had such information when the transaction is actually completed. The contract, instructions, or plan must:

- specify the amount, price and date of the transaction,
- specify an objective method for determining the amount, price and date of the transaction, or
- place the discretion for determining amount, price, and date of the transaction in another person who is not, at the time of the transaction, in possession of material, nonpublic information.

You may not exercise discretion or influence over the amount, price, and date of the transaction after entering into the arrangement. In this Policy, we refer to these arrangements as “Trading Plans.” The rules regarding Trading Plans are extremely complex and must be complied with completely to be effective. You should consult with your own legal advisor before proceeding with entering into any Trading Plan.

Any restrictions under this Policy that apply to you when purchasing or selling the Company’s securities also apply to you when establishing a Trading Plan. Therefore, you may not establish a Trading Plan when you are in possession of material, nonpublic information about the Company and, to the extent trading windows and special blackout periods apply to you, those restrictions must be complied with in connection with establishing a Trading Plan. All employees, officers and directors are required to receive pre-clearance from the Secretary before entering into, modifying or terminating any Trading Plan. Once a Trading Plan has been pre-cleared by the Secretary, transactions executed pursuant to that Trading Plan do not require approval. *However, as noted in Section III, if you are a director or an executive officer, you must immediately report all transactions executed under a Trading Plan to the Secretary so that a Form 4 may be filed on your behalf.*

In establishing any Trading Plan, you should carefully consider the timing of your transactions under the Trading Plan. Even though transactions executed in accordance with a *bona-fide* Trading Plan are exempt from the insider trading rules, the trades may nonetheless occur at times shortly before the Company announces material news, and the media may not understand the nuances of trading pursuant to a Trading Plan. Finally, modification or termination of any Trading Plan carries with it considerable risk, including the risk that previously executed transactions that occurred under the Trading Plan may be viewed as improper insider trades. For this reason, you should not modify or terminate any Trading Plan without first consulting with your own legal advisor and obtaining prior approval from the Secretary.

II. RESTRICTION ON SHORT-SWING TRADING AND SHORT SALES

A. Purchases and Sales Within Six Months

Section 16(b) of the Exchange Act imposes liability on executive officers, members of the board of directors and certain large stockholders of the Company if they have a purchase and sale, or sale and purchase, of Company stock within a period of less than six months (referred to as a “short-swing” trade). This section provides that the Company, or any stockholder who brings a lawsuit on behalf of the Company, may recover the amount of any “profit” realized by such individual on a short-swing trade. It should be noted, *however*, that while Section 16(b) and the reporting requirements discussed under Section III rest on the premise that such persons are likely to possess inside information, the actual possession of the information is not a precondition to liability being imposed. In other words, because Section 16(b) is so strict, good faith in engaging in short-swing trading is irrelevant.

It does not matter whether the purchase or the sale occurs first and it is not necessary for the same shares to be involved in a pair of transactions. Nor can losses be offset against gains in a series of trades. The courts will match a pair of short-swing transactions (using a “lowest purchase price” and “highest sale price” approach) to obtain the maximum amount of spread between purchase and sale price so that one who even incurs an economic loss on a series of transactions may find himself giving up a “profit” which he never actually realized.

There are many types of transactions which constitute a “sale” or a “purchase” within the purview of this restriction. For example, the grant of an option to purchase Company stock pursuant to a stock option or similar plan may be a “purchase” in certain circumstances, so that if any shares are acquired through exercise and then sold within six months of the grant of the option, a short-swing trade will have occurred. Another example is an exchange of Company stock for property or in satisfaction of an obligation by transferring shares of Company stock, in which case the stockholder will be deemed to have sold them. In addition, a transaction involving Company stock which is effected by a person other than the stockholder, such as the stockholder’s spouse or minor child, will be deemed to have been made by the stockholder because the stockholder is regarded as being the “beneficial owner” of such stock. On the other hand, a true gift of stock will not be regarded as a sale.

In general, if a transaction is made by a person closely related to the stockholder, or by a person with respect to whom the stockholder has certain rights or powers in connection with Company stock (such as the trustee of a trust over whom the stockholder has the right to direct the disposition of Company stock), the stockholder will be regarded as having made the transaction.

Any departing executive officers or directors should not make an opposite trade within six months after the last transaction while an executive officer or director. Such a trade, if it were to occur, and the sales price be higher than the purchase price against it is matched, would subject the departing executive or director to potential 16(b) liability as discussed above.

B. Broad-Based Employee Benefit Plans

SEC Rule 16b-3 provides some relief to executive officers and directors who are participants in a Company's broad-based employee benefit plans (i.e., the Apimeds Pharmaceuticals US, Inc. 2024 Equity Incentive Plan). Specifically:

- Grants under these types of plans should be exempt from section 16(b) (the liability provision) because the plans are administered by our compensation committee, which is composed exclusively of "non-employee" directors. They, however, are not exempt from reporting under section 16(a) – if you receive an award, you typically will be required to file a Form 4 reporting the grant.
- Exercises or vesting of awards is exempt from section 16.
- Sales of shares on the open market are not exempt – they also have to be reported on a Form 4 and subject a person to section 16(b) liability if they have had a purchase transaction within 6 months (either before or after the sale).

At this time, we have no 401(k) plan or "company stock" account – however, if one were to be adopted:

- "Discretionary" transactions will only be exempt from "short-swing" liability if at least six months have passed since an "opposite way" transaction has occurred in the plan (or in any similar plan).
- Discretionary transactions include an intra-plan transfer involving Company stock (a so-called "fund switch") or a cash distribution funded by a volitional disposition of Company stock.

Therefore, if we were to adopt such a plan, among other things:

- Executive officers should not increase the amount of a "benefit" plan election to purchase Company stock within six months of a decrease in the amount of an election to purchase stock.
- Executive officers should not instruct the administrator of any plan to dispose of shares if they have made a new election to increase their investment in Company stock in any of the plans within the prior six months.
- As long as executive officers do not decrease the amount of the elections to purchase stock, they can continue to increase the amounts of funds they invest in Company stock more frequently than six months. After six months has elapsed since the last increase, executive officers can then begin to decrease the amounts invested in Company stock or dispose of the stock if the plan permits and continue to elect to decrease their elections or dispose of the stock more frequently than six months.

C. Short Sales

In addition to the foregoing, the Exchange Act prohibits the Company's directors, executive officers, and large stockholders from making sales of any equity securities of the Company which the seller does not own at the time or, if owned, securities that will not be delivered for a period longer than 20 days after the sale, referred to as "short sales."

D. Options Trading

In addition to the foregoing, the Exchange Act prohibits the Company's insiders from buying or selling puts or calls or other derivative securities on the Company's securities.

E. Trading on Margin or Pledging

In addition to the foregoing, the Exchange Act prohibits the Company's insiders from holding Company securities in a margin account or pledge Company securities as collateral for a loan.

F. Hedging

In addition to the foregoing, the Exchange Act prohibits the Company's insiders from entering into hedging or monetization transactions or similar arrangements with respect to Company securities.

III. REPORTING CHANGES IN OWNERSHIP OF COMPANY COMMON STOCK

A. General

Section 16(a) of the Exchange Act provides that executive officers, members of the board of directors and certain large shareholders of the Company must file with the SEC an initial report disclosing the amount of equity securities of the Company of which such person is a "beneficial owner." This initial report is made on Form 3. Section 16(a) requires that any reporting persons subject to Section 16(a) must file electronically a transaction report on Form 4 with the SEC before the end of the second business day following the day on which the transaction is executed. Section 16(a) requires that a Form 5 must generally be filed electronically within 45 days after the end of the Company's fiscal year.

B. Covered Persons

Section 16(a) applies to all directors and officers of a public company and all beneficial owners of more than 10% of a public company's registered equity securities. An "officer" is defined in the SEC's Rule 16a-1(f) to mean generally a company's president, principal financial officer, principal accounting officer, any vice president in charge of a principal business unit, division or function, and any other officer who performs a policy-making function. To distinguish the officers subject to Section 16(a) from other officers of the Company, this policy uses the term "executive officers" to describe those Company officers subject to Section 16(a).

In addition, because Section 16(a) is concerned with the beneficial ownership of securities, and because beneficial ownership entails voting and investment power rather than simply record ownership, reporting persons must be aware of and report the securities transactions effected by all related persons and entities whose stock ownership is attributable to them under Section 16(a) (e.g., family members living in the same household, trusts, partnerships, and corporations).

C. Covered Transactions

Section 16(a) applies to virtually every form of change in beneficial ownership of securities. Purchases and sales, gifts, contributions to trusts, stock option grants and exercises, restricted stock grants, stock grants under deferred compensation plans, intra-plan transfers involving an issuer equity security fund, Rule 10b5-1 plan transactions, and other transfers of securities must be reported on a Form 4 filed with the SEC before the end of the second business day following the day on which the transaction is executed.

D. Reports to the Company

The reporting requirements on Forms 3, 4 and 5 are the personal obligation of the reporting person. The Company will assist the reporting person in complying with these reporting requirements. In order to enable the Company to complete and file the reports on the reporting person's behalf, the reporting person must immediately notify the Company when a transaction is consummated. This notification must be received by the Secretary not later than the first business day after the date on which the transaction occurs and must include the following information: (i) date of transaction; (ii) number of shares acquired or disposed of; (iii) price per share; and (iv) number of shares beneficially owned at the end of the month.

In addition, the Company will notify reporting persons monthly of the number of shares of Company stock which are shown on the Company's records as being beneficially owned by them as of the end of each month. The reporting person must reconcile this information if it is incorrect.

E. Possible Sanctions

Any late or delinquent Form 4 filings are required to be reported in the Company's proxy statement. In addition, the SEC has been granted broad authority to seek "any equitable relief that may be appropriate or necessary for the benefit of investors" for violations of any provision of the federal securities laws. Such relief could take the form of SEC enforcement proceedings that result in civil or criminal penalties, including monetary fines and imprisonment in particularly egregious cases.

F. Sales of "Control" and Restricted Stock Pursuant to Rule 144

The Company will also assist directors and officers with the reporting requirements for sales under Rule 144 promulgated under the Securities Act of 1933, as amended. Questions about Rule 144 should be addressed to the Secretary prior to the consummation of a transaction.

IV. ACKNOWLEDGMENT AND CERTIFICATION

All Company insiders are required to sign the attached acknowledgment and certification.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Company's **Insider Trading Policy**. The undersigned has read and understands (or has had explained) such **Policy** and agrees to be governed by such **Policy** at all times in connection with the purchase and sale of securities and the confidentiality of nonpublic information.

(Signature)

(Please print name)

Date: _____

**CERTIFICATION PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, Erik Emerson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Apimeds Pharmaceuticals US, 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 (or persons performing the equivalent functions):
 - 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: April 15, 2025

/s/ Erik Emerson

Erik Emerson
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, Mark Corrao, certify that:

1. I have reviewed this Annual Report on Form 10-K of Apimeds Pharmaceuticals US, 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 (or persons performing the equivalent functions):
 - 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: April 15, 2025

/s/ Mark Corrao

Mark Corrao

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION 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 on Form 10-K of Apimed Pharmaceuticals US, Inc. (the “Company”), for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Erik Emerson, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered by the Report.

Date: April 15, 2025

By: /s/ Erik Emerson
Erik Emerson
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION 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 on Form 10-K of Apimed Pharmaceuticals US, Inc. (the “Company”), for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Mark Corrao, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered by the Report.

Date: April 15, 2025

By: /s/ Mark Corrao

Mark Corrao
Chief Financial Officer
(Principal Financial and Accounting Officer)

APIMEDS PHARMACEUTICALS US, INC.

**Incentive Compensation Recovery Policy (the “Policy”)
(Effective as of February 7, 2025)**

1. Recovery of Excess Incentive Compensation. If Apimed Pharmaceuticals US, Inc. (the “Company”) is required to prepare a Restatement, the Company’s board of directors (the “Board”) shall, unless the Board’s Compensation Committee determines it to be Impracticable, take reasonably prompt action to recover all Recoverable Compensation from any Covered Person. The Company’s obligation to recover Recoverable Compensation is not dependent on if or when the restated financial statements are filed. Subject to applicable law, the Board may seek to recover Recoverable Compensation by requiring a Covered Person to repay such amount to the Company; by adding “holdback” or deferral policies to incentive compensation; by adding post-vesting “holding” or “no transfer” policies to equity awards; by set-off of a Covered Person’s other compensation; by reducing future compensation; or by such other means or combination of means as the Board, in its sole discretion, determines to be appropriate. This Policy is in addition to (and not in lieu of) any right of repayment, forfeiture or off-set against any Covered Person that may be available under applicable law or otherwise (whether implemented prior to or after adoption of this Policy). The Board may, in its sole discretion and in the exercise of its business judgment, determine whether and to what extent additional action is appropriate to address the circumstances surrounding any Restatement to minimize the likelihood of any recurrence and to impose such other discipline as it deems appropriate.

2. Administration of Policy. The Board shall have full authority to administer, amend or terminate this Policy. The Board shall, subject to the provisions of this Policy, make such determinations and interpretations and take such actions in connection with this Policy as it deems necessary, appropriate or advisable. All determinations and interpretations made by the Board shall be final, binding and conclusive. The Board may delegate any of its powers under this Policy to the Compensation Committee of the Board or any subcommittee or delegate thereof.

3. Acknowledgement by Executive Officers. The Board shall provide notice to and seek written acknowledgement of this Policy from each Executive Officer; provided that the failure to provide such notice or obtain such acknowledgement shall have no impact on the applicability or enforceability of this Policy.

4. No Indemnification. Notwithstanding the terms of any of the Company’s organizational documents, any corporate policy or any contract, no Covered Person shall be indemnified against the loss of any Recoverable Compensation.

5. Disclosures. The Company shall make all disclosures and filings with respect to this Policy and maintain all documents and records that are required by the applicable rules and forms of the U.S. Securities and Exchange Commission (the “SEC”) (including, without limitation, Rule 10D-1 promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”)) and any applicable Exchange listing standard.

6. Definitions. In addition to terms otherwise defined in this Policy, the following terms, when used in this Policy, shall have the following meanings:

“Applicable Period” means the three completed fiscal years preceding the earlier to occur of: (i) the date that the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement; or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare a Restatement. “Applicable Period” also includes, in addition to the three fiscal year period described in the preceding sentence, any transition period (that results from a change in the Company’s fiscal year) within or immediately following that completed three fiscal year period; *provided, further*, a transition period between the last day of the Company’s previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months would be deemed a completed fiscal year.

“Covered Person” means any person who receives Recoverable Compensation.

“Exchange” means any national securities exchange or national securities association upon which the Company has a class of securities listed.

“Executive Officer” includes the Company’s president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person (including any executive officer of the Company’s subsidiaries or affiliates) who performs similar policy-making functions for the Company. At a minimum, the term “Executive Officer” shall include all executive officers identified in SEC filings pursuant to Item 401(b) of Regulation S-K, 17 C.F.R. §229.401(b).

“Financial Reporting Measure” means a measure that is determined and presented in accordance with the accounting principles used in preparing the Company’s financial statements, and any measure that is derived wholly or in part (including “non-GAAP” financial measures, such as those appearing in earnings releases) from such measures; provided, however, that any such measure need not be presented within the Company’s financial statements or included in a filing made with the SEC. Examples of Financial Reporting Measures include measures based on: revenues, net income, operating income, financial ratios, EBITDA, liquidity measures (such as free cash flow), return measures (such as return on assets or return on invested capital), profitability of one or more segments, and cost per employee. Stock price and total shareholder return (“TSR”) also are Financial Reporting Measures.

“Impracticable” means, after exercising a normal due process review of all the relevant facts and circumstances and taking all steps required by Exchange Act Rule 10D-1 and any applicable Exchange listing standard, the Compensation Committee determines that recovery of the Recoverable Compensation is impracticable because: (i) it has determined that the direct expense that the Company would pay to a third party to assist in enforcing this Policy and recovering the otherwise Recoverable Compensation would exceed the amount to be recovered; (ii) it has concluded that the recovery of the Recoverable Compensation would violate home country law adopted prior to November 28, 2022; or (iii) it has determined that the recovery of the Recoverable Compensation would cause a tax-qualified retirement plan, under which benefits are broadly available to the Company’s employees, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder. The Company must: (i) in the case of clause (i) of the preceding sentence, prior to making that determination, make a reasonable attempt to recover any Recoverable Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange; and (ii) in the case of clause (ii) of the preceding sentence, obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and provide that opinion to the Exchange.

“Incentive-Based Compensation” means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure; however it does not include: (i) base salaries; (ii) discretionary cash bonuses; (iii) awards (either cash or equity) that are based upon subjective, strategic or operational standards; and (iv) equity awards that vest solely on the passage of time.

“Received” – Incentive-Based Compensation is deemed “Received” in any Company fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period.

“Recoverable Compensation” means all Incentive-Based Compensation (calculated on a pre-tax basis) Received after October 2, 2023 by a Covered Person: (i) after beginning service as an Executive Officer; (ii) who served as an Executive Officer at any time during the performance period for that Incentive-Based Compensation; (iii) while the Company had a class of securities listed on an Exchange; and (iv) during the Applicable Period, that exceeded the amount of Incentive-Based Compensation that otherwise would have been Received had the amount been determined based on the Financial Reporting Measures, as reflected in the Restatement. With respect to Incentive-Based Compensation based on stock price or TSR, when the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement: (i) the amount must be based on a reasonable estimate of the effect of the Restatement on the stock price or TSR upon which the Incentive-Based Compensation Received by the Covered Person originally was based; and (ii) the Company must maintain documentation of the determination of the reasonable estimate and provide such documentation to the Exchange.

“Restatement” means an accounting restatement of any of the Company’s financial statements due to the Company’s material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements (often referred to as a “Big R” restatement), or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (often referred to as a “little r” restatement). A Restatement does not include situations in which financial statement changes did not result from material non-compliance with financial reporting requirements, such as, but not limited to retrospective: (i) application of a change in accounting principles; (ii) revision to reportable segment information due to a change in the structure of the Company’s internal organization; (iii) reclassification due to a discontinued operation; (iv) application of a change in reporting entity, such as from a reorganization of entities under common control; (v) adjustment to provision amounts in connection with a prior business combination; and (vi) revision for stock splits, stock dividends, reverse stock splits or other changes in capital structure.

Adopted by the Board of Directors on February 7, 2025.