**PROSPECTUS**

**Filed Pursuant to Rule 424(b)(4)**
**Registration No. 333-282324**

## 3,375,000 Shares
## Common Stock


# Apimeds Pharmaceuticals US, Inc.

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Apimeds Pharmaceuticals US, Inc. is offering 3,375,000 shares of its common stock, par value $0.01 per share, at an offering price of $4.00 per share. Prior to this offering, there has been no public market for our common stock.

Our common stock has been approved for listing on the NYSE American (the "NYSE American") under the symbol "APUS."

We are an "emerging growth company" under the federal securities laws and have elected to comply with certain reduced public company reporting requirements.

We are currently a "controlled company" under the corporate governance rules of the NYSE American. Inscobee Inc. (KRX: 006490) ("Inscobee"), a South Korean corporation, holds approximately 70.29% of our common stock, directly and through its wholly owned subsidiary Apimeds Inc. ("Apimeds Korea"). Upon completion of this offering Inscobee, directly and through Apimeds Korea, will hold 54.41% of our common stock, which will constitute a majority of the voting power of our stockholders. As a result, we will continue to be a "controlled company". However, we do not intend to rely upon the "controlled company" exemption. See the section titled "*Prospectus Summary — Controlled Company.*"

**Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 10.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

| | Per Share | Total |
|---|---|---|
| Initial public offering price | $ 4.00 | $ 13,500,000 |
| Underwriting discounts and commissions[(1)] | $ 0.28 | $ 945,000 |
| Proceeds to us, before expenses | $ 3.72 | $ 12,555,000 |

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(1) Underwriting discounts and commissions do not include a non-accountable expense allowance equal to 1.0% of the initial public offering price payable to the underwriters. We refer you to the section titled "Underwriting" beginning on page 115 for additional information regarding underwriters' compensation.

We have granted a 45-day option to the underwriters to purchase up to 506,250 additional shares of common stock solely to cover over-allotments, if any.

The underwriters are offering the shares for sale on a firm commitment basis. The underwriters expect to deliver the shares to purchasers on or about May 12, 2025.

*Sole Book-Running Manager*


The date of this prospectus is May 8, 2025

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You should rely only on the information contained in this prospectus. We and the underwriters have not authorized any other person to provide you with information different from or in addition to that contained in this prospectus, and we take no responsibility for any other information others may give you. If anyone provides you with different or inconsistent information, you should not rely on it. We and the underwriters are not making an offer to sell these securities in any jurisdiction where an offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of our common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus applicable to that jurisdiction.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision.*

*Unless the context otherwise indicates or requires, all references in this prospectus to "we," "us," "our," "our company" "the Company" and "Apimeds US" refer to Apimeds Pharmaceuticals US, Inc.*

*On January 6, 2022, we effected a 1-for-10,000 forward split of our common stock, and on February 25, 2025 we effected a 2.6-for-1 share reverse split of our common stock. All historical share amounts and share price information presented in this prospectus have been proportionally adjusted to reflect the impact of these stock splits.*

### Overview

We are a clinical stage biopharmaceutical company that is in the process of developing Apitox, an intradermally administered bee venom-based toxin which potentially exhibits diverse therapeutic effects. Apitox is currently marketed and sold by Apimeds Inc. ("Apimeds Korea") in the South Korea as "Apitoxin." Apimeds US is not associated with the market, sale and revenues generated from Apitoxin in South Korea, and Apitoxin has not been approved by the U.S. Food and Drug Administration (the "FDA") for any indication. Apimeds is currently developing Apitox as a potential osteoarthritis ("OA") treatment for patients with knee pain who failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics.

In 2003, after completing successful Phase I, II, and III trials, the Korean Ministry of Food and Drug Safety (the "MFDA") approved the use of Apitoxin to treat pain and mobility in patients with OA in South Korea. Apitoxin has been used in the South Korea to treat the reduction of pain associated with OA since 2003. Additionally, a post-marketing/approval safety study in South Korea followed 3,194 patients from 2003 through 2009, with no serious adverse events.

In 2013, the FDA authorized Apimeds Korea to conduct a preliminary Phase III to study the same indication approved in South Korea — the use of Apitoxin to treat pain and inflammation in patients with OA — which was completed in 2018 (the "Apimeds Korea Phase III OA Trial").

On August 2, 2021, we entered into an agreement with Apimeds Korea, a principal stockholder of Apimeds US (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, and to advance clinical research, develop, manufacture and commercialize and sell Apitox in the United States.

Based on the results from the Apimeds Korea Phase III OA Trial, which demonstrated therapeutic effect in the treatment group compared to the placebo group, but in combination with prior development by Apimeds 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 Apimeds 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 in knee OA. 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.

Apimeds Korea has also engaged in clinical trials to explore the therapeutic effect of Apitoxin in patients with multiple sclerosis ("MS"), including in 2014, submitting an Investigational New Drug Application ("IND") 122804 to run a Phase III clinical trial. Pursuant to the Business Agreement, Apimeds Korea transferred sponsorship of IND 122804 to Apimeds US in October 2020. Pursuant to the written correspondence from the FDA, as of the date of this prospectus, there are no clinical holds relating to the planned clinical trials.

However, we have made the strategic decision to focus our MS efforts on the early prosecution of appropriate patient populations through non-registered corporate sponsorship studies and will not be pursuing a Phase III trial for MS at this time.

Chronic diseases such as OA and MS cause considerable economic, personal, and societal burden. These diseases negatively impact quality of life and progress from the time of onset until death. We are dedicated to developing innovative therapies using Apitox that seek to restore the health and enhance the quality of life of patients suffering with these diseases.

To this date, Apimeds has generated no revenue from the sale and or distribution of Apitox in the United States. We have generated our clinical data and an opportunity to advance treatment opportunities with proceeds received from sales of our securities to prior investors and the work of our partners, Apimeds Korea and Inscobee Inc. ("Inscobee"). We do not currently hold any debt as prior investments in the form of convertible notes have since been converted to equity. We believe that naturalized bee venom can provide an additive treatment, that pending clinical demonstration of success and FDA approval, could provide value to OA patients in need and the physicians treating OA patients, and potentially MS. The advancement of Apitox as a candidate and Apimeds as a company, will be dictated by the clinical data and the regulatory agencies interpretation of such data in regard to effectiveness, safety and potential benefit beyond existing treatment options.

**Our Lead Candidate**

Apitox is a purified, pharmaceutical grade 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 as a therapeutic to treat pain for hundreds of years. Bee venom contains the peptides apamin and adolapin. Although these peptides act as toxins, they possess anti-inflammatory and pain-relieving properties.

While not FDA approved in a controlled, prescription based biologic environment for defined indications, the use of bee venom has been FDA approved as an "under the skin injection" to reduce the allergic reactions to bee stings. Apimeds 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 it sells 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 advanced knee OA and MS is speculative but based on direction provided by prior clinical data.

Apimeds Korea successfully completed Phase I, Phase II, and Phase III trials in South Korea in OA in 2003, at which point Apitoxin was approved by the MFDA to treat pain and mobility in patients with OA. Phase I trials 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 were authorized to enroll patients to study the use of Apitox for the same indication approved in South Korea in 2003. The first Phase III trial (the Apimeds Korea Phase III OA Trial) (330 patients) was completed in 2018, and displayed no serious adverse events. Based on the results from the Apimeds Korea Phase III OA Trial, which demonstrated therapeutic effect but did not meet the FDA's standards for approval, we will be pursuing a second Phase III trial to meet agreed upon FDA standards to best address our patient population, which we have defined as advanced knee OA patients, which is being designed to range from defined grade 2, 3 and 4 within this treatment group. We have selected this treatment group based on the results from the Apimeds Korea Phase III OA Trial and the need for treatments for higher grade knee OA patients.

Upon the successful completion of our Phase III trial demonstrating therapeutic effect and extended safety data for the use of Apitox to treat pain and mobility in patients with knee OA, we intend to submit a Biologics License Application ("BLA") for Apitox with the Centers for Biologics and Research, in consultation with the FDA. A BLA is a request to the FDA for permission to introduce, or deliver for introduction, a biologic product into interstate commerce. Issuance of a BLA is a determination that the product, the manufacturing process and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the product. 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.

We intend to outsource the manufacturing of Apitox to a third-party manufacturer and plan to rely on the same manufacturing process as used in prior trials. The manufacturing process of Apitox entails converting natural bee venom to a liquified biologic state. Once in this state, Apitox will have completed multiple rounds of process enhancement, development and stability. The process of converting natural bee venom to therapeutic biologic delivery has been previously patented in Korea (though now expired). We believe the regulatory protections that are available through a BLA filing, along with our trade secrets, will provide adequate protection for our manufacturing process.

**Our Market**

Apimeds US believes there is a significant market opportunity in the United States for Apitox to enhance treatment of the lack of mobility and pain management symptoms associated with of OA and MS. According to Precedence Research, the OA therapeutics market size in the United States accounted for $8.28 billion in 2022 and it is expected to hit around $20.24 billion by 2032, expanding at a compounded annual growth rate, or "CAGR", of 9.4% from 2023 to 2032. Although OA can damage any joint, the disorder most commonly affects joints in hands, knees, hips and spine. OA symptoms can usually be managed, although the damage to joints cannot be reversed. Apitox may have certain anti-inflammatory properties, which we believe could provide benefit in the treatment of symptoms related to certain chronic diseases that involve difficult to control pain and inflammation such as OA and MS.

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 initiate 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 OA, such as pain and lack of mobility. We also intend to continue the investigation of the use of Apitox to treat certain MS symptoms through non-registered corporate sponsorship studies.

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.

**Our Strategy**

Apimeds US aims is to impact high unmet medical needs of symptoms and quality of life issues surrounding knee OA and MS. Our primary business strategy is to become a leading biopharmaceutical company through the development of Apitox. Key elements of our business strategy are as follows:

- Initiate an additional Phase III trial in advanced knee OA, focusing on efficacy of a shorter-term treatment of patients who are eligible for knee replacement surgery. We intend the duration of the trial to be approximately eight weeks of treatment.
- Initiate multiple company sponsored trials in MS to determine the best path to clinical Phase III success. This includes evaluating varying forms of relapse MS, the frequency with which patients have relapse and the impact of Apitox on said relapse.
- Pursue potential collaboration arrangements and out-licensing opportunities.
- Seek non-dilutive funding and grant awards to support our clinical research and product candidate development.

Through the clinical development of Apitox we intend to engage organizations with strong needs and category leadership in Apimeds US's clinical areas of focus, specifically anti-inflammatory conditions. Numerous biotechnology and pharmaceutical companies have a presence in OA and MS, creating strong synergies for potential opportunities subsequent to demonstrated clinical success and FDA approval.

One of the principal purposes of this offering is to fund the execution of a Phase III trial in knee OA and the early prosecution of appropriate patient populations in MS. Proceeds will also fund manufacturing and expenses related to potential regulatory filings.

**The Science of Apitox**

Apitox is purified honeybee (*Apis mellifera*) venom manufactured as a lyophilized powder for reconstitution in 0.5% preservative-free lidocaine (lmg/mg) prior to intradermal dose injections. 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. There are several different types of prostaglandins, and they play several essential roles in regulating bodily processes, including healing and inflammation. 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 certain immune-inflammatory responses associated with MS. Such studies suggested that treatments with melittin prevent inflammatory cytokine expression and produces anti-inflammatory effects. As MS is a chronic inflammatory condition, we believe Apitox may be a potential treatment alternative for certain symptoms of MS.

**Intellectual Property**

Upon the successful completion of our Phase III trial demonstrating therapeutic effect and extended safety data for the use of Apitox to treat pain and mobility in patients with knee OA, Apimeds US will submit a BLA for Apitox with the Centers for Biologics and Research of the FDA. A BLA is used to request permission to introduce, or deliver a biologic product into interstate commerce. 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.

We intend to file a United States trademark application for "Apitox."

**Reverse Stock Split**

On February 25, 2025, we implemented 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 (the "Reverse Stock Split").

Unless otherwise indicated, and other than the consolidated financial statements and the related notes included elsewhere in this prospectus, the number of our shares of common stock presented in this prospectus is adjusted to reflect the Reverse Stock Split.

**Controlled Company**

Apimeds Korea's parent company, Inscobee Inc., has voting control over approximately 70.28% of our common stock, directly and through its wholly owned subsidiary Apimeds Korea, and therefore we currently meet the definition of a "controlled company" under the corporate governance standards for the NYSE American. Upon the closing of this offering, Inscobee Inc. directly and through Apimeds Korea, will hold 54.41% of the voting power of our outstanding voting stock.

As long as Inscobee Inc. owns at least 50% of the voting power of our Company, we will be a "controlled company" as defined under the NYSE American. Under that definition, we are permitted to rely on certain exemptions from corporate governance rules, including:

- an exemption from the rule that a majority of our Board must be independent directors;
- an exemption from the rule that the compensation of our chief executive officer must be determined or recommended solely by independent directors; and
- an exemption from the rule that our director nominees must be selected or recommended solely by independent directors.

Although we do not intend to rely on the "controlled company" exemption under the NYSE American listing rules following this offering, we could elect to rely on this exemption in the future. If we elect to rely on the "controlled company" exemption, a majority of the members of our board of directors might not be independent directors and our nominating and corporate governance and compensation committees might not consist entirely of independent directors.

As a result, if we elect to rely on this exemption in the future, you will not have the same protection afforded to shareholders of companies that are subject to these corporate governance requirements.

**Our Corporate Information**

Apimeds US was incorporated in Delaware on May 11, 2020. We are located at 2 East Broad Street, 2nd Floor, Hopewell, New Jersey 08525. Our telephone number is 808-209-7887. Our website address is *www.apimedsus.com*. Information contained on, or that can be accessed through, our website is not incorporated by reference in this prospectus.

**Risk Factors Summary**

Our business is subject to a number of risks of which you should be aware of before making an investment decision. You should consider all of the information set forth in this prospectus and, in particular, the specific factors set forth under "*Risk Factors*" in deciding whether to invest in our common stock. These risks include, without limitation, the following:

- Clinical development has inherent risk in its process and our product candidate. Apitox, will be evaluated in a clinical environment for an indication which it has limited patient exposure which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve or maintain profitability. Our stock is a highly speculative investment.
- Even after this offering, we may require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain parts of our development programs or other operations.
- The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.
- We have identified material weaknesses in our internal control over financial reporting, and the failure to remediate these material weaknesses may adversely affect our business, investor confidence in our company, our financial results and the market value of our common stock.

- Our business is substantially dependent on our relationships with Apimeds Korea. The loss of this relationship would have a material adverse effect on our business.
- We are dependent on the clinical success of Apitox in the treatment of symptoms of knee OA and MS in the United States.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidate we develop, our commercial opportunities will be negatively impacted. Our product candidate will, if approved, also compete with existing branded, generic and off-label products.
- Our business could be adversely affected by the effects of health epidemics in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations. Any future pandemic could materially affect our operations as well as the business or operations of our contract manufacturer organizations ("CMOs") or other third parties with whom we conduct business.
- Our product candidate may cause undesirable side effects or have other properties that could halt its clinical development, prevent its regulatory approval, limit its commercial potential or result in significant negative consequences. In addition, even if approved, our products may cause significant adverse events, toxicities or other undesirable side effects identified during post-marketing surveillance, which could result in regulatory action or negatively affect our ability to market the product.
- We rely on principally on trade secrets and other forms of non-patent intellectual property protection, which are difficult to protect.

**Market and Industry Data**

Unless otherwise indicated, information contained in this prospectus concerning our industry, competitive position and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and other third-party sources, as well as data from our internal research, and are based on assumptions we made upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, projections, assumptions and estimates of the future performance of the industry in which we operate and our future performance are necessarily subject to uncertainty and risk due to a variety of factors, including those described in "*Risk Factors*" and "*Special Note Regarding Forward-Looking Statements*." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

**Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- not being required to comply for a certain period of time with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act of 2002, as amended;
- exemption from the auditor attestation requirement in the assessment of critical audit matters in the auditor's report on the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a stockholder advisory vote on executive compensation and any golden parachute payments not previously approved.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the completion of this offering; (iii) the date on which we are deemed to be a "large accelerated filer," under the rules of the U.S. Securities and Exchange Commission, or the SEC, which means the market value of equity securities that is held by non-affiliates exceeds $700.0 million; and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the 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 we are no longer an emerging growth company, or we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

**THE OFFERING**

| | |
|---|---|
| Common stock offered by us | 3,375,000 shares |
| Over-allotment option | We have granted the underwriters an option for a period of 45 days from the date of this prospectus to purchase up to an additional 506,250 shares of common stock at the public offering price, less the underwriting discount. |
| Common stock to be outstanding immediately after this Offering | 11,571,497 shares (12,077,747 shares if the underwriters exercise their over-allotment option in full). |
| Use of proceeds | We estimate that the net proceeds from the sale of our common stock in this offering will be approximately $11.8 million, or approximately $13.7 million if the underwriters exercise their over-allotment option in full, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.<br><br>The principal purposes of this offering are to increase our capitalization and financial flexibility, create a public market for our common stock, facilitate future access to the public equity markets by us, our employees and our stockholders and increase our visibility in the marketplace. We intend to use the net proceeds we receive from this offering to fund our Phase III clinical trial in knee OA, to initiate at least one non-registered company sponsored trials in MS, manufacturing costs, to repay current debt liabilities, and any remaining amounts to fund working capital and general corporate purposes. See the section entitled "*Use of Proceeds*" for additional information. |
| Risk factors | An investment in our securities involves a high degree of risk and could result in a loss of your entire investment. Prior to making an investment decision, you should carefully consider all of the information in this prospectus and, in particular, you should evaluate the risk factors set forth under the caption. See the section entitled "*Risk Factors*" for additional information. |
| NYSE American symbol | "APUS" |
| Insider Participation | Inscobee has agreed to purchase 500,000 shares of common stock at the public offering price. |

The number of shares of common stock to be outstanding immediately after this offering is based on 8,196,497 shares of common stock outstanding on December 31, 2024, which includes approximately 292,647 shares of common stock issuable upon the conversion of outstanding convertible notes plus accrued interest thereon and excludes:

- 1,538,462 shares of our common stock that are available for future issuance under our Equity Incentive Plan;
- 213,692 shares of common stock issuable upon exercise of outstanding non-plan options; and
- 168,750 shares of our common stock issuable upon exercise of the representative's warrants to purchase up to 168,750 shares (or 194,063 shares if the over-allotment option is exercised in full) of

our common stock at an exercise price per share equal to 125% of the initial public offering price per share, that will be issued to the representative of the underwriters in connection with this offering (the "Representative's Warrants").

## SUMMARY FINANCIAL DATA

The following tables set forth our summary statements of operations data for the years ended December 31, 2024 and 2023. The statements of operations data for the years ended December 31, 2024 and 2023 have been derived from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. You should read the following summary financial data together with the sections entitled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

**Statement of Operations Data:**

| | Year Ended December 31, 2024 | Year Ended December 31, 2023 |
|---|---|---|
| Operating expenses | | |
| Research and development expenses | $ — | $ 98,544 |
| General and administrative expenses | 1,275,095 | 648,892 |
| Loss from operations | $ (1,275,095) | $ (747,436) |
| Interest income | $ 2,824 | $ 7,811 |
| Interest expense | $ (117,719) | $ (38,069) |
| Net loss | $ (1,389,990) | $ (777,694) |

**Selected Balance Sheet Data:**

| | December 31, 2024 | | |
|---|---|---|---|
| | Actual | Pro Forma[1] | Pro Forma As Adjusted[2] |
| **Balance Sheet Data:** | | | |
| Cash | $ 3,455 | $ 3,455 | $ 11,840,234 |
| Total assets | $ 13,057 | $ 13,057 | $ 11,849,836 |
| Note payable – related party | $ 250,000 | $ 250,000 | $ 250,000 |
| Convertible note, net of discounts – related party | $ 346,844 | $ — | $ — |
| Total liabilities | $ 1,371,178 | $ 923,452 | $ 923,452 |
| Total stockholders' deficit | $ (1,358,121) | $ (910,395) | $ 10,926,384 |

(1) On a pro forma basis to give effect to the conversion of an aggregate of $660,000 principal amount of convertible notes with an unamortized debt discount of $313,156, plus accrued and unpaid interest of approximately $100,882, into an aggregate of approximately 292,647 shares of our common stock.

(2) On a pro forma as adjusted basis to give effect to the pro forma adjustments, and the sale by us of 3,375,000 shares of our common stock in this offering at the initial public offering price of $4.00 per share, after deducting underwriting discounts and estimated offering expenses payable by us (assuming no exercise of the underwriter's over-allotment option).

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.*

### Risks Related to Our Financial Position and Capital Needs

***We are in the early stages of clinical development for our product candidate Apitox, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

To date, we have devoted substantially all of our resources to performing research and development, undertaking preclinical and clinical studies and enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology, performing business planning, establishing our intellectual property portfolio and raising capital to support and expand such activities. As an organization, we have not yet demonstrated an ability to conduct sales and marketing activities necessary for successful commercialization or arrange for a third party to conduct these activities on our behalf. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our current portfolio includes one product candidate, and we do not expect to generate revenue from our product candidate in the near future. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives, including with respect to our clinical candidate. We are transitioning from an early stage research and development company to late stage development company, with a focus on delivering Phase III clinical data establishing Apitox as a viable commercial candidate. We may not be successful in this transition.

***We have incurred significant net losses since inception and anticipate that we will continue to incur substantial net losses for the foreseeable future and may never achieve profitability.***

We are a clinical stage biopharmaceutical company that was formed on May 11, 2020. Investment in clinical stage companies is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidates will not gain regulatory approval or become commercially viable. We have not generated any revenue from product sales. As a result, we are not profitable and have incurred losses in each year since inception. Our net losses were $1,389,990 and $777,694 for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $4,391,294.

We expect to continue to spend significant resources to fund research and development of, and seek regulatory approvals for, our product candidate. We expect to incur substantial and increasing operating losses over the next several years. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. We may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

***Even after this offering, we will require substantial additional funding to finance our operations. If we are unable to raise additional capital when needed, we could be forced to delay, reduce or terminate certain of our development programs or other operations.***

As of December 31, 2024, we had cash of $3,455. We believe that the net proceeds from this offering, together with our existing cash as of the date of this prospectus, will fund our current operating plans through at least the next 12 months from the date of this offering. However, our operating plan may change as a result of many factors

currently unknown to us, and we may need to seek additional funds sooner than planned. We expect to finance our cash needs through public or private equity or debt financings, third-party (including government) funding and marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements or any combination of these approaches. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, including the trading price of common stock. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of research and development, testing, screening, manufacturing, preclinical development and clinical trials;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the U.S. Food and Drug Administration, or the FDA;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the identification and pursuit of additional clinical or regulatory opportunities;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights; and
- the costs of operating as a public company.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development of our product candidate or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the payment obligations or milestones under the agreements. We could be required to seek collaborators for our product candidate at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our products in markets where we otherwise would seek to pursue development ourselves.

***Raising additional capital may cause dilution to our stockholders, including investors in this offering, restrict our operations or require us to relinquish rights to one or more of our technologies.***

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, intellectual property, future revenue streams, research programs or current or future product candidates or grant licenses on terms unfavorable to us and our shareholders.

***The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.***

The report of our independent registered public accounting firm on our financial statements as of and for the years ended December 31, 2024 and 2023 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into licensing and collaboration arrangements or other contractual relationships with third parties and otherwise execute our development strategy.

***We have identified material weaknesses in our internal control over financial reporting, and the failure to remediate these material weaknesses may adversely affect our business, investor confidence in our company, our financial results and the market value of our common stock.***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on April 15, 2025 (the "Annual Report"), our management 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). Management identified a material weakness in our internal control over financial reporting. Specifically, the Company does not currently 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.

The material weakness did not result in any material misstatements to the Company's financial statements, and management has concluded that the Company's financial statements and other financial information included in its Annual Report fairly and accurately present the Company's financial condition, results of operations, and cash flows for the periods in accordance with GAAP.

We have begun exploring remedial efforts to address the underlying causes of the material weaknesses. There can be no assurance that any remedial efforts we take, if any, will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal controls over financial reporting or prevent future material weaknesses or control deficiencies from occurring.

If the Company fails to remediate the material weaknesses or any future deficiencies, or fails to otherwise maintain the adequacy of its internal controls, that could result in a restatement of the Company's financial statements for prior periods, a decline in the market value of the Company's common stock, one or more investigations or enforcement actions by state or federal regulatory agencies, stockholder lawsuits, or other adverse actions requiring the Company to incur defense costs or pay fines, settlements, or judgments.

**Risks Related to Our Business and Industry**

***Our business is substantially dependent on our relationships with our principal stockholder, Apimeds Korea. The loss of this relationship would have a material adverse effect on our business.***

We are dependent on a license from our principal shareholder, Apimeds Korea, to continue our clinical trials and development of Apitox. We have entered into a license agreement with Apimeds Korea to obtain exclusive rights in the United States to the principal trade secrets, know-how and data relating to Apitox. If we default or fail to perform any of our obligations under this agreement, Apimeds Korea may terminate the agreement, subject to advance notice to cure such default. Any termination of this license agreement would have a materially adverse impact on our business and prospects.

***There may be conflicts of interest amongst our directors and officers and Apimeds Korea.***

Conflicts may arise between our directors and officers and Apimeds Korea, as some of our directors and officers hold positions with both companies. Dr. Christopher Kim, our Chairman and Chief Medical Officer is the founder of Apimeds Korea and serves as a board member of Apimeds Korea. Mr. Jakap Koo, one of our directors, is the Chief Executive Officer of and President of Apimeds Korea and of Apimeds Korea's parent company, Inscobee Inc. These conflicts could discourage the parties from working collaboratively and our commercial success will be dependent, in part, upon the performance of our management. Although such officers and directors are aware of their duties and accountability to our Company and to applicable laws and policies relating to corporate opportunity and conflicts of interest, such conflicts of interest may include deciding how much time to devote to our affairs, as well as what business opportunities should be presented to us. Additionally, any dispute that may arise between us and Apimeds Korea may make it more difficult to favorably resolve such disputes.

***The Company is reliant on its key supplier.***

We contract directly with a United States company for the supply of dried bee venom and have exclusivity in the field of pharmaceutical use, which does not include using venom for immunology, cosmetic or any other non-pharmaceutical use, for a period of ten years from November 3, 2021. The exclusivity exception is for sales of bee venom to Apimeds Korea for use outside the United States. The agreement may be terminated upon mutual written consent of both parties. Termination of this agreement, variations in their terms or the failure of our key supplier to comply with its obligations under its agreement (including if our key supplier were to become insolvent) could have a material adverse effect on the Company's consolidated financial results and on your investment.

***As an organization, we have limited experience designing and implementing clinical trials, and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines.***

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or prevent initiation or completion of the trial, which can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. If we select an incorrect dose or dose administration schedule, that could negatively impact the results of the trial, including if we select doses that are too low to be effective or administer doses too infrequently based on the half-life of the active ingredient. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. See "— Risks Related to Reliance on Manufacturing and Third Parties." If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize Apitox or any future product candidates we develop, and our business could be materially harmed. Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for BLA submission and the FDA approval of Apitox or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop.

***If we are unable to successfully develop, receive regulatory approval for, and commercialize our product candidate or future product candidates, our business will be harmed.***

Our product candidate is still in preclinical and clinical development, and we are early in our development efforts. The FDA permitted our investigational new drug application for Apitox to proceed in 2014, and we began enrolling subjects. Our product candidate will require additional preclinical and/or clinical development, regulatory approval, obtaining manufacturing supply, capacity, and expertise, building a commercial organization

or successfully outsourcing commercialization, substantial investment, and significant marketing efforts, before we generate any revenue from product sales. We do not have any products that are approved for commercial sale, and we may never be able to develop or commercialize marketable products.

Our ability to generate revenue from our product candidate, which we do not expect will occur for several years, if ever, will depend heavily on the successful development, regulatory approval, and eventual commercialization of our product candidate. The success of our product candidate or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- timely and successful completion of preclinical studies and clinical trials;
- effective INDs submitted to the FDA that allow commencement of our planned clinical trials or future clinical trials for our product candidate;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful development of, or making arrangements with third-party manufacturers for, our commercial manufacturing processes for any of our product candidates that receive regulatory approval;
- making arrangements for the manufacturing of our product candidate for our clinical trials, and manufacturing our product candidate at an acceptable cost and on a timely basis;
- receipt of timely marketing approvals from the FDA;
- launching commercial sales of products, if approved;
- acceptance of the benefits and use of our products, if approved, by patients, the medical community, and third-party payors, for their approved indications;
- the prevalence and severity of adverse events or other safety issues experienced with our product candidate;
- the availability, perceived advantages, cost, safety, and efficacy of alternative therapies for any product candidate, and any indications for such product candidate, that we develop;
- our ability to produce any product candidates we develop on a commercial scale;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidate and otherwise protecting our rights in our intellectual property portfolio;
- maintaining compliance with regulatory requirements, including cGMP requirements;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by the FDA;
- maintaining a continued acceptable safety, tolerability and efficacy profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

If we do not succeed with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidate we develop, which would materially harm our business. If we do not receive marketing approvals for any product candidate we develop, we may not be able to continue our operations. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

***The FDA regulatory approval process is lengthy and time-consuming and may lead to significant delays in the clinical development and regulatory approval of our product candidate.***

The time required to obtain approval from the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of FDA. Any delay in obtaining FDA and/or other necessary regulatory approvals in the United States for any

investigational new drug and failure to receive such approvals would have an adverse effect on the investigational new drug's potential commercial success and on our business, prospects, financial condition, and results of operations.

We have not obtained regulatory approval for any product candidate. We have not previously submitted a BLA to the FDA. It is possible that none of our current or future product candidates will ever obtain regulatory approval from the FDA. The novel nature of our product candidate may create further challenges in obtaining regulatory approval. The regulatory approval pathway for our product candidate may be uncertain, complex, expensive, and lengthy, and approval may not be obtained. In addition, factors outside our control, such as government shutdowns, natural disasters, and public health emergencies, could disrupt business at the FDA, which could result in delays of reviews, approvals and communications with FDA related to our clinical trials and product candidates.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- The FDA may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of FDA that a product candidate is safe, pure, and potent for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- The FDA may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidate may not be sufficient to support the submission of a BLA to the FDA to obtain regulatory approval in the United States; and
- FDA may find deficiencies with or fail to approve our manufacturing processes or facility or the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies.

The lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would significantly harm our business, results of operations and prospects. FDA has substantial discretion in the approval process and in determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from current or future clinical trials of our product candidate are promising, such data may not be sufficient to support approval by FDA.

Even if we obtain approval, FDA may approve any of our product candidate for fewer or more limited indications, or a more limited patient population, than we request; may grant approval contingent on the performance of costly post-approval clinical trials or other post-marketing requirements; or may approve a product candidate with labeling that does not include the claims we believe are necessary or desirable for the successful commercialization of such product candidates. Moreover, if we modify Apitox, we may have to either file a supplemental BLA with FDA or receive FDA approval for a comparability protocol or obtain other regulatory approval. These requirements may be costly and time-consuming, and FDA ultimately may not approve of such changes.

FDA may also change its policies, promulgate additional regulations, revise existing regulations, or take other actions that may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

***We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect.***

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;

- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required institutional review board ("IRB"), approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites;
- developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- disruptions caused by any future pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials;
- delays in adding a sufficient number of trial sites;
- our ability to recruit suitable patients to participate in our clinical trials, which may be affected by, among other factors, patient eligibility and exclusion criteria defined in the protocol, the severity and difficulty of diagnosing the disease under investigation, the size of the patient population required for analysis of the trial's primary endpoints, the proximity of patients to study sites, and the design of the trial;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practice, or GCP, requirements or applicable regulatory guidelines in other jurisdictions;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner;
- patients dropping out of a study;
- occurrence of side effects associated with our product candidate that are viewed to outweigh their potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical trials being greater than we anticipate;
- clinical studies producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of drug for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes, we may be required to or we may elect to conduct additional studies to bridge our modified products to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our products and may harm our business and results of operations.

***Our programs for which we intend to seek approval as biologics may face competition sooner than anticipated.***

The Patient Protection and Affordable Act, as amended by the Healthcare and Education Reconciliation Act (the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or "biosimilar" product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

We believe that any of our programs approved as biologics under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our programs to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***Because Apitox represents a novel approach to the treatment of symptoms for knee OA and potentially MS, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and commercial potential of our product candidate.***

Because our candidate represents a novel approach to the treatment of the inflammation and pain management symptoms associated with knee OA and the potential treatment of MS, there are many uncertainties related to the development, marketing, reimbursement and the commercial potential for Apitox. There can be no assurance as to the length of the clinical trials, the number of patients the FDA will required to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of antibody products or that the design of or data generated in these trials will be acceptable to the FDA to support marketing approval.

In addition, the FDA may take longer than usual to come to a decision on any BLA that we submit and may ultimately determine that there is insufficient data, information or experience with our product candidates to support an approval decision. The FDA may also require that we conduct additional post-marketing studies or implement risk management programs, such as risk evaluation and mitigation strategies until more experience with our product candidate is obtained. Finally, after increased usage, we may find that our product candidate does not have the intended effect or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory approval and commercial prospects.

***Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.***

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical test and Phase I and Phase II clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will

be successful, nor does it predict final results. For example, we may be unable to identify suitable animal disease models for our product candidates, which could delay or frustrate our ability to progress clinical studies or obtain marketing approval. Our product candidates may fail to show the desired safety and efficacy in clinical development despite having progressed through preclinical and initial clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks, delays. and failures in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development.

***Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.***

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective. If the FDA or any regulatory authority limits the scope of our indication, or if we are unable to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. Further, we are only permitted to promote our products for those indications that the FDA specifically approves and are restricted from making communications regarding uses not approved and described in the product's labeling. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to advisory or enforcement action by these authorities. In addition, our failure to follow FDA requirements or guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of Apitox for the treatment of the inflammation and pain management symptoms associated with knee OA and MS. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications for these product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuation rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***If any potential future product candidate is approved and our CMO fails to produce the product in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate or be unable to meet market demand and may lose potential revenues.***

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Any termination or disruption of any current or future relationships relating to product development may materially harm our business and financial condition and frustrate any commercialization efforts for affected current or future product candidates.

Any current or future CMOs we engage must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its establishment inspection program. Despite the existence of CMO agreements and shared cGMP responsibilities our contract CMO may ignore these contractual provisions, or otherwise fail to meet the minimum standards set forth in the cGMP regulations, resulting in

manufacturing non-compliance. This may go unnoticed or uncorrected despite our best efforts to regulatory audit or confirm the CMOs regulatory responsibilities. Any failure to comply with applicable regulations may result in fines

and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recalls, re-stocking costs, damage to our reputation and potential for product liability claims.

If the CMOs upon which we rely to manufacture any current products, and any potential product candidates we may in-license or acquire, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification, or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, and jeopardize our ability to commence sales and generate revenue.

***Our preclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.***

To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of Apitox, we must demonstrate through lengthy, complex and expensive preclinical and clinical trials that Apitox is both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, a product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other data. A product candidate could be delayed in receiving, or fail to receive, regulatory approval for many reasons.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in us failing to obtain regulatory approval to market.

***The regulatory approval processes of the FDA and other regulatory authorities are inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize Apitox in the United States.***

If any current or future product candidates are associated with undesirable side effects, toxicities, or other negative characteristics, we may need to abandon such products' development or limit development to more narrow uses or subpopulations. Such side effects may affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims. Many compounds that show initial promise in early-stage testing are later found to cause side effects that prevent further development. If our clinical trials reveal severe or prevalent side effects, our trials could be suspended or terminated, we may be unable to recruit patients and enrolled patients may be unable to complete the trials, and the FDA or comparable foreign regulatory authorities could order issue a clinical hold or order us to cease further development or deny approval of the product candidate. Candidates may be harmed, which could significantly harm our business prospects.

***All of our current and future products are subject to and will remain subject to substantial regulatory scrutiny even after receiving regulatory approval.***

The preclinical and clinical development, testing, manufacture, safety, efficacy, labeling, storage, recordkeeping, and subsequent advertising, promotion, sale, marketing, and distribution, if approved, of our product candidate is subject to extensive regulation by the FDA and other regulatory authorities in the United States and elsewhere. These regulations also vary in important, meaningful ways from country to country. We are not permitted to market a potential drug in the United States until we receive approval of an NDA from the FDA for such drug. We have not received an NDA approval from the FDA for Apitox. There can be no guarantees with respect to our product candidate or future product candidates that clinical studies will adequately support an NDA, that the products will receive necessary regulatory approvals, or that they will prove to be commercially successful.

Further, any current or future product candidates we may license or acquire will be subject to ongoing regulatory and compliance requirements and oversight by the FDA and other regulatory authorities. These requirements include labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and other licensed medical professionals and recordkeeping of the drug.

The Food and Drug Administration Amendments Act of 2007 granted significant expanded authority to the FDA, much of which was aimed at improving the safety of drug products before and after approval. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling.

The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off-label marketing. While physicians and other healthcare providers may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the practice of medicine, including the clinical behavior of physicians and other healthcare providers in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use.

Violations of the Federal Food, Drug and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various

results, including:

- restrictions on such products, operations, manufacturers or manufacturing processes;

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- denial of permits to import or export our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

***Public concern regarding the safety of any of our current or future drug products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to incur additional costs.***

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products, and the establishment of risk management programs. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving any other potential future product candidate, our ability to obtain such product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of any potential future product candidate, the indications for which such product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize potential future product candidate may be otherwise adversely impacted.

***We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product we are commercializing or product candidates we develop, our commercial opportunities will be negatively impacted. Our product candidate will, if approved, also compete with existing branded, generic and off-label products.***

The development and commercialization of new drug products is highly competitive. Numerous companies are engaged in developing products for the treatment of MS symptoms, which we expect will compete with Apitox. We face competition with respect to our product candidate from many different sources, including major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide and existing treatments. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors also may obtain FDA approval or other regulatory authority approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

In addition, our ability to compete may be affected in many cases by insurers or other third-party payers, particularly Medicare, seeking to encourage the use of generic products. Generic products are currently being used for certain of the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years.

Many of the companies against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified sales, marketing scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***Even if we obtain regulatory approval of our products, the product may not gain market acceptance among regulators, advisory boards, physicians, patients, third-party payors and others in the medical community.***

Even if our product receives marketing approval, it may fail to receive recommendations for use by regulators or advisory boards that recommend products, or gain market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidate does not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any product, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the success of any potential clinic studies during the drug development process;
- physicians, hospitals, third-party payors and patients considering our products as safe and effective;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory and advisory bodies;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory and advisory bodies;
- the timing of market introduction of our products as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors, including government authorities;
- relative convenience and ease of administration, including as compared to competitive products and alternative treatments; and
- the effectiveness of our sales and marketing efforts.

Our ability to effectively promote and sell our products and any other current or future product candidates we may develop, license or acquire in the marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto formularies, as well as our ability to obtain sufficient third-party coverage or reimbursement. Since many insurance plans are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the marketplace will also depend on our ability to effectively promote any current or future product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected

or unexpected adverse side effects associated with our current or any future product candidates. If any current or future product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of any current or future product candidates may require significant resources and may never be successful.

Further, in both domestic and foreign markets, our any future product sales will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our current or future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

***Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.***

Adverse effects or other undesirable or unacceptable side effects caused by our product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidate. Such side effects could also affect trial recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. The data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. If serious adverse or unacceptable side effects are identified during the development of any of any current or future product candidates, we may need to abandon such products' development or limit development to more narrow uses or subpopulations. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. Adverse effects or other undesirable or unacceptable side effects caused by our product may cause us or the FDA to recall product or remove a product from the marketplace.

Any of these occurrences may harm our business, financial condition and prospects significantly.

***Upon completion of Phase III clinical programs, we plan to develop a sales organization, and there is no assurance our marketing and sales organization will be successful.***

If we are unable to successfully establish marketing and sales capabilities, we may not be able to generate product revenue. The development of an in-house marketing organization and sales force will require significant capital expenditures, management resources and time, and we will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. There can be no assurance that our in-house sales and distribution capabilities will be successful.

If we are unable or decide not to successfully establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products; however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our products ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our products.

***We are highly dependent on our key personnel, and if we are not able to retain these members of our management team or recruit and retain highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel. There is currently a significant strain on our managerial, operational and financial resources. The loss of the services of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct substantially all of our operations at our facilities in the New York Area. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

***Some of our key executives do not devote his full business time to our operations.***

Our Chairman and Chief Medical Officer, Dr. Christopher Kim, is involved in other businesses and does not devote all of his working time to our business.

Some of the other businesses engaged in by Dr. Kim could prove more successful than ours, Dr. Kim could choose to focus his attention on such businesses which could cause him to fail to devote sufficient attention to our business and our operations could suffer and our financial conditions and results of operations may be materially and adversely affected.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidate and will face an even greater risk if we commercialize any products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any products; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtain clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.***

The global credit and financial markets have experienced extreme volatility and disruptions in the past several years. Such volatility and disruptions have caused and may continue to cause severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

***Our business could be adversely affected by the effects of health epidemics, such as the COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations. Any future pandemic could materially affect our operations, including at our headquarters in the New York area.***

Health epidemics in regions where we have concentrations of potential clinical trial sites or other business operations could adversely affect our business, including by causing significant disruption in the operations of our CMO and other third parties upon whom we rely.

***We or the third parties upon whom we depend on may be adversely affected by natural disasters or acts of war, such as the conflicts in Ukraine and Israel, and our business continuity and disaster recovery plans may not adequately protect us from any such serious disaster.***

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to undergo clinical trials, fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidate or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event were to occur that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, governmental restrictions or as a result of labor disputes or unstable political environments. Supply chain issues, including those resulting from the COVID-19 pandemic and the ongoing military conflicts between Russian and Ukraine and Israel and surrounding areas and the attacks on marine vessels traversing the Red Sea, may affect our third-party vendors and cause delays. As of the date of this prospectus, our CMOs and third-party vendors have not experienced manufacturing difficulties or delays as a result of the military conflicts in Ukraine and Israel.

As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed and result in higher costs or adversely impact development of our product candidates.

***Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures, reckless and/or negligent conduct or unauthorized activities that violates (i) the laws and regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States, and (iv) laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation.

It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

**Risks Related to Our Reliance on Third Parties**

***We currently rely on third-party manufacturing and a single-source supplier to supply raw materials and components for, and manufacture, our product candidate. Our inability to have sufficient quantities of our product candidate manufactured, or our failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

Efficient and scalable manufacturing and supply is a vital component of our business strategy. We currently do not own or operate any manufacturing facilities. We have developed, in collaboration with third parties manufacturing processes that we believe can scale to address clinical and commercial supply. However, our assumptions as to our ability and our CMOs ability to produce our product candidate at the scale needed for

clinical development and commercial demand may prove to be wrong. If we encounter problems in our manufacturing processes or in our ability to scale to address commercial drug supply, our business would be materially adversely affected.

The manufacturing process for a drug is subject to FDA or comparable foreign regulatory authority review. Our suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as Current Good Manufacturing Practices, or cGMPs. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidate. Moreover, we do not control the manufacturing process at our CMOs and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all.

We purchase the bee venom necessary to produce Apitox for our clinical trials from a single third-party supplier. There are a limited number of suppliers for bee venom, and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of Apitox for our clinical trials and, if approved, ultimately for commercial sale. Any termination of our supply agreement or significant delay in the supply of bee venom for the manufacture of Apitox for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of our clinical trials, product testing and potential regulatory approval of Apitox.

Furthermore, if there is a disruption to our or our third-party suppliers' relevant operations, including as a result of the COVID-19 pandemic, we will have no other means of producing Apitox until they restore the affected facilities or we or they procure alternative facilities. Additionally, any damage to or destruction of our or our third party or suppliers' facilities or equipment may significantly impair our ability to manufacture Apitox on a timely basis.

If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture and market our product candidate in a timely and competitive manner, or at all. Identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines, which would impair our ability to meet our development objectives or generate revenues from the sale of Apitox, if approved.

***We rely and will continue to rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidate.***

We currently do not have the ability to independently conduct preclinical or clinical studies that comply with the regulatory requirements known as Good Laboratory Practice and Good Clinical Practice ("GCP"). The FDA and regulatory authorities in other jurisdictions require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical and clinical trials under agreements with us.

We will need to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol and legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our preclinical studies and clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our products. As a result, our financial results and the commercial prospects for our products would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites or any CRO that we may use in the future terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

***If we or our third-party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages.***

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business prospects, financial condition or results of operations.

***We rely on honeybee colonies to supply our active pharmaceutical ingredient, or API, for Apitox, and if these colonies are damaged from pests, disease organisms or other phenomena, it could result in a negative impact on our business.***

The mortality rate of honeybees has increased significantly over the last decade. Although the overall number of bee colonies in the United States. appears to be relatively stable, the increased mortality rate means beekeepers need to spend more time and money dividing their surviving colonies to create new ones to replace those lost. This could result in supply delays and cost increases for the bee venom we use to make Apitox. In addition, pests such as tracheal mites, Varroa mites and wax moths can either severely damage a bee colony or entirely wipe out a colony. American foulbrood is a lethal bacterial disease affecting bee larvae and pupae. Colonies may also be subject to "colony collapse disorder," a phenomenological happening wherein the worker bees from a specific beehive suddenly vanish causing the hive to die off. Although our supplier employs preventative measures, any of these risks may negatively impact the bee hives and our ability to obtain the bee venom to make Apitox, which would adversely affect our business and prospects.

***We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our discovery, development and commercialization efforts with respect to our products and any future products that we may seek to develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In

addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our products because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our products as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new strategic partnership agreements related to our products could delay the development and commercialization of our products in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

**Risks Related to Government Regulation**

***Our relationships with customers, physicians and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, health information privacy and security laws and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any products for which we have or obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. 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;

- the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which also impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, including health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf;
- the Federal Food Drug or Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which require tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We may also be subject to other laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibit, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

Even if resolved in our favor, litigation or other legal proceedings relating to healthcare laws and regulations may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be

negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development, manufacturing, sales,

marketing or distribution activities. Uncertainties resulting from the initiation and continuation of litigation or other proceedings relating to applicable healthcare laws and regulations could have an adverse effect on our ability to compete in the marketplace. In addition, if the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

***Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, their ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Of note, in response to the global COVID-19 pandemic, the FDA adopted a risk-based system for the conduct of inspections of manufacturing facilities and began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities inside and outside the United States may adopt similar restrictions or other policy measures in response to any future pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***We are subject to increasingly stringent and rapidly changing laws and regulations related to privacy and data security. The restrictions and costs imposed by these requirements, or our actual or perceived failure to comply with them, could harm our reputation, subject us to significant fines and liability, and adversely affect our business.***

We are subject to or affected by numerous evolving federal, state and foreign laws and regulations, as well as policies, contracts and other obligations governing the collection, use, disclosure, retention, and security of personal data. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This landscape may create uncertainty in our business, result in liability or impose additional costs on us. These laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised. The cost of compliance with these laws and regulations is high and is likely to increase in the future. Our failure or perceived failure to comply with these laws and regulations could result in negative publicity, diversion of management time and effort, an inability to process personal data or to operate in certain jurisdictions, restrictions on our operations and legal action against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

For example, HIPAA, as amended by HITECH, imposes requirements relating to the privacy and security of individually identifiable health information on health plans, healthcare clearinghouses and certain healthcare providers, and their respective contractors and their covered subcontractors that perform services for them involving individually identifiable health information. Additionally, certain states have adopted healthcare privacy and security laws and regulations comparable to HIPAA, some of which may be more stringent than HIPAA. In the event we fail to properly maintain the

privacy and security of individually identifiable health information governed by HIPAA or comparable state laws, and significant or we are responsible for an unauthorized disclosure or security breach of such information, we could be subject to enforcement action under HIPAA or comparable state laws, civil and criminal penalties, and fines.

Domestic privacy and data security laws beyond HIPAA and other healthcare privacy laws are also changing rapidly and becoming more complex. For example, California recently enacted the CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used, among others. The CCPA also requires covered businesses to provide detailed privacy notices to California residents and respond to requests from California residents to exercise their rights under the CCPA to access, delete and opt-out of certain sharing of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for clinical trial data, the CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the U.S. As of January 1, 2023, consumers have new rights in addition to those above, such as (i) the right to correct inaccurate personal information that a business has about them; and (ii) the right to limit the use and disclosure of sensitive personal information collected about them. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how it is interpreted.

***If our product candidates are approved for marketing and are found to have been improperly promoted for off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.***

If our approved product, or any of our product candidates that are approved, are found to have been improperly promoted for off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about approved prescription drug products. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of regulated products for off-label uses and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidate, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

***We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.***

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. By way of example, the ACA: increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology under which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; expanded

the eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established

a Center for Medicare and Medicaid Innovation ("CMMI") at the Centers for Medicare & Medicaid Services ("CMS"), to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. President Trump signed several Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been enacted. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, a process that is commonly referred to as the "individual mandate." In addition, the Further Consolidated Appropriations Act, 2020 permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, it also eliminated the health insurer tax. On December 14, 2018, the U.S. District Court for the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court reversed the Fifth Circuit's ruling, holding that the challengers lacked standing to sue and otherwise abstaining from reaching the merits of the case. There may be other efforts to challenge, repeal, or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

Former President Biden signed an Executive Order on Strengthening Medicaid and the Affordable Care Act, stating his administration's intentions to reverse the actions of his predecessor and strengthen the ACA. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are directed to review all existing regulations, orders, guidance documents, policies and agency actions to consider if they are consistent with ensuring coverage under the ACA and making high-quality healthcare affordable and accessible to Americans. We are unable to predict the likelihood of changes to the ACA or other healthcare laws which may negatively impact our profitability.

Former President Biden intended, as his predecessor did, to take action against drug prices which are considered "high." Such measures could be addressed in a legislative package later in 2021 or with the reauthorization of the Prescription Drug User Fee Act, or PDUFA, in 2022 as part of a package bill. Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government, and we expect to see legislation focusing on this in the coming year. The American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that eliminated the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the rebate cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030 with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through December 31, 2021, unless additional congressional action is taken. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, to review the relationship between pricing and manufacturer patient assistance programs, and to reform government program reimbursement methodologies for pharmaceutical products. The Prescription Drug Pricing Reduction Act, or PDPRA, which was introduced in Congress in 2019, and again in 2020, proposed to, among other things, penalize pharmaceutical manufacturers for raising prices on drugs covered by Medicare Parts B and D faster than the rate of inflation, cap out-of-pocket expenses for Medicare Part D beneficiaries, and proposes several changes to how drugs are reimbursed in Medicare Part B. A similar drug pricing bill, the Elijah E. Cummings Lower Drug Costs Now Act proposes to enable direct price negotiations by the federal government for certain drugs (with the maximum price paid by Medicare capped based

on an international index), requires manufacturers to offer these negotiated prices to other payors, and restricts manufacturers from raising prices on drugs covered by Medicare Parts B and D. This Act passed in the House of Representatives when it was introduced in 2019, and it has been introduced again in the 2021 term. We cannot predict whether any proposed legislation will become law and the effect of these possible changes on our business cannot be predicted at this time.

Further, the Centers for Medicare & Medicaid Services ("CMS") has significant regulatory authority to promulgate regulations and impose other compliance requirements that may increase our compliance costs and impact our ability to attain profitability and market our product candidate. CMS sets coverage and reimbursement rates for Medicare and oversees the implementation of Medicaid at the state level. CMS could modify or impose coverage restrictions or modify reimbursement rates on our product candidate in a manner that could adversely impact our business. For example, on January 8, 2021, CMS approved Tennessee's Medicaid section 1115 demonstration application, granting the state the unprecedented ability to implement a closed drug formulary without foregoing the state's entitlement to rebates under the Medicaid Drug Rebate Program. Implementation of a closed formulary could mean that our products could be excluded from coverage under Medicaid. It is unclear whether the Biden Administration will reverse or modify Tennessee's section 1115 demonstration approval.

Within CMS, CMMI, as established by the ACA, has broad authority to design, implement, and test new health care payment models that could potentially lower health care spending while maintaining quality or increase quality without increasing spending. CMMI has considered implementing models that could have a significant adverse effect on our business. For example, on November 27, 2020, CMMI finalized a mandatory Medicare Part B drug payment model that would have aligned payment for drugs with international reference prices, entitled the Most Favored Nation (MFN) Model. The MFN Model was enjoined by a Federal court on December 28, 2020 for failure to comply with rulemaking procedural requirements. It is unclear whether the Biden Administration will propose and implement the same or a similar model in future rulemaking, and we cannot predict how future regulatory actions by CMMI or any other component of CMS may impact our business.

These and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our current or future product candidates. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of any current or future product candidates, if any, may be. In addition, increased Congressional scrutiny of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

***Any product candidates for which we intend to seek approval as biologic products may face biosimilar competition sooner than anticipated.***

If we are successful in achieving regulatory approval to commercialize any biologic product candidate that we develop, it may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the data the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed by the FDA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intend to be implemented, BPCIA may be fully adopted by the FDA, any such processes could

have an adverse effect on the future commercial prospects for our biological products. There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. For example, in May 2021, the Biden administration expressed support for waiving intellectual property protections for COVID-19 vaccines amid concerns about vaccines access in foreign nations. Such waiver, if implemented, could extend to our product candidates. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

***Our business activities will be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.***

As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we intend to operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also required public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore may involve significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, of those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

**Risks Related to Our Intellectual Property**

***We rely principally on trade secrets and other forms of non-patent intellectual property protection, which are difficult to protect.***

Our API is a natural, non-synthetic compound that is not patentable, so we rely on trade secrets to protect our rights to Apitox, particularly the method and process of manufacturing Apitox. Trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors and other advisors may unintentionally or willfully disclose our information to competitors. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. We would expect any trade secret dispute to be governed by federal law, and in particular the Defend Trade Secrets Act ("DTSA") of 2016. However, in the event we are not able to utilize the DTSA, we would then be limited to resolving such dispute in state court. State trade secret laws in the United States vary, and state courts are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent

knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

***Our ability to compete depends in part on our ability to secure and maintain proprietary rights to our products.***

Apimeds Korea does not have any patent protection for Apitoxin. There could be several competitive products available in the marketplace possessing similar qualities.

Apimeds Korea's patents related to Apitoxin expired in early 2023. If Apimeds does decide to apply for patent protection, there can be no assurance that any patent issued Apimeds Korea, and licensed to us, will provide competitive advantages or will not be challenged by third parties. Furthermore, there can be no assurance that others will not independently develop similar products or design around Apimeds Korea's previous patents. Any of the foregoing activities could have a material adverse effect on the Company. Moreover, enforcement of any patent or license rights may require substantial litigation costs.

***Our success depends in part on not only our ability, but that of Apimeds Korea's to protect the intellectual property, including our trade secrets, which can be difficult and costly and is not assured.***

Our success depends in part on our ability, and that of Apimeds Korea, to obtain and maintain trade secret and trademark protection of our rights to Apitox, as well as successfully defending the intellectual property against third-party challenges. Our ability to stop unauthorized third parties from misusing our trade secrets by making or using Apitox is dependent upon the extent to which we have rights under trade secrets that cover these activities.

We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of these parties to use or disclose our confidential information, including our trade secrets. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. The intellectual property positions of biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. We cannot accurately predict future changes in the interpretation of intellectual property laws or changes to intellectual property laws which might be enacted into law. Those changes may materially affect our ability to protect our trade secrets.

Despite our efforts to protect our trade secrets, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Failure to protect our trade secrets, for any reason (or third-party claims against our trade secrets or proprietary rights, or our involvement in disputes over our trade secrets or proprietary rights, including involvement in litigation), could have a substantial negative effect on our results of operations and financial condition.

***We do not own the Apitox trademark, but may use the trademark pursuant to the terms of the Business Agreement with Apimeds Korea.***

We do not own the trademark that we use in our business and may be unable to protect this intellectual property against infringement from third parties. We are party to the Business Agreement with Apimeds Korea pursuant to

which Apimeds Korea granted us an exclusive, 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. 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. In the event that the Business Agreement is terminated, we will be required to, among other things, change the name of our product candidate. Any of these events could disrupt our recognition in the marketplace, damage any goodwill we may have generated, and otherwise have a material adverse effect on us. Furthermore, since we license the use of the name "Apitox" from Apimeds Korea, we are dependent on Apimeds Korea to defend against trademark infringement claims. Apimeds Korea's efforts to enforce or protect our rights related to the trademark "Apitox" may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

***If our future trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

We do not own any trademarks or tradenames, as we license the use of the name "Apitox" from Apimeds Korea pursuant to the Business Combination Agreement; however, in the future if we are to register and trademarks or tradenames, any registered trademarks or trade names may be challenged, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

***We may become involved in lawsuits to protect our intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. An adverse result in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our intellectual property rights are invalid or unenforceable. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

***Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business***.

We expect to rely on trademarks as one means to distinguish our products from those approved for marketing from the products of our competitors. We intend to file a United States trademark application for "Apitox" but have not yet begun the process of applying to register any trademarks for our current product candidate or any future products. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which

could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks. In addition, any proprietary name we propose to use with our current or any other product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Furthermore, 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, and to advance clinical research, develop, manufacture and commercialize and sell Apitox in the United States. The Company does not own international rights to the name "Apitox," and the Company has an exclusive license to use the name in the United States pursuant to the Business Agreement. The name "Apitox" may be used in different countries with respect to products that are not ours. We are aware of a Spanish company called PrismaNatural, offering an over-the-counter topical ointment product called "Apitox" that can be purchased in the United States. This may create confusion with respect to our product candidate and our business may be adversely affected.

As mentioned above, we are dependent on Apimeds Korea to defend against trademark infringement claims because we license the use of the name "Apitox" pursuant to the Business Agreement. Notwithstanding Apimeds Korea's efforts, there can be no assurance that its efforts to protect its trademarks will be successful, even if Apimeds Korea intends to maintain and keep current all of its trademark registrations and to pay all applicable renewal fees as they become due. The right of a trademark owner to use its trademarks is based on a number of factors, including their first use in commerce, and trademark owners can lose trademark rights despite trademark registration and payment of renewal fees. We therefore believe that these proprietary rights, licensed to us, have been and will continue to be important in enabling us to compete and if for any reason Apimeds Korea is unable to maintain its trademark that it licenses to us, our business could be materially and negatively affected. Nor can there be any assurance that third-parties will not assert claims against us for infringement of their intellectual proprietary rights. If an infringement claim is asserted, we may be required to obtain a license of such rights, pay royalties on a retrospective or prospective basis, or terminate our development, manufacturing and marketing of our infringing products. Litigation with respect to such matters could result in substantial costs and diversion of management and other resources and could have a material adverse effect on our business, financial condition, or operating results.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we expect to rely on third parties to manufacture Apitox and any future candidates, and we expect to collaborate with third parties on the development of our current and future therapeutics, we must, at times, share trade secrets with them. We also may conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Further, disputes may arise under these agreements regarding inventorship or ownership of proprietary information generated during research and development.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.***

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

**Risks Related to This Offering and Ownership of Our Common Stock**

***An active, liquid and orderly trading market may not develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock at or above the initial offering price, if at all.***

Prior to this offering there has been no public market for shares of our common stock. An active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***The price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment, progress or results of our planned or future preclinical studies or clinical trials of our products and those of our competitors;
- delays or terminations of clinical trials;
- regulatory or legal developments in the United States;
- announcements by our competitors of new product candidates or technologies, or the results of clinical trials or regulatory decisions;
- the recruitment or departure or key personnel;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;

- the level of expenses related to our products or preclinical and clinical development programs;
- the results of our efforts to develop additional products;
- unanticipated serious safety concerns related to the use of any product candidate;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations or reports by securities analysts;
- the level of expenses and capital investment related to manufacturing out products;
- our inability to obtain or delays in obtaining adequate supply for any approved products candidate;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies perceived to be similar to us;
- changes in the structure of healthcare payment systems, including coverage and adequate reimbursement for any approved medicines;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- Overall performance of the equity markets;
- general economic, political and market conditions and overall fluctuations in the financial markets in the United States; and
- investors' general perception of us and our business.

In addition, the stock market in general, the NYSE American and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, which has resulted in decreased stock prices for many companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

***Our financial condition and results of operations may fluctuate from quarter to quarter and year to year, which makes them difficult to predict.***

We expect our financial condition and results of operations to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock.

***We are controlled by our principal stockholders and management, which own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval, which will limit your ability to influence corporate matters.***

Prior to this offering, our executive officers, directors and 5% stockholders beneficially owned approximately 96.79% of our voting stock as of the date of this prospectus, and, upon the closing of this offering, that same group will continue to beneficially own approximately 69.08% of our outstanding voting stock (not including any shares that may be purchased by them in this offering). Moreover, Inscobee including through its wholly-owned subsidiary, Apimeds Korea, beneficially owns 70.29% of our outstanding common stock prior to this offering. Accordingly, even after this offering, these stockholders will have the ability to control us through this ownership position and significantly affect the outcome of all matters requiring stockholder approval. They effectively have the ability to determine all corporate actions requiring stockholder approval, including the election and removal of directors, any amendment to our certificate of incorporation, as amended and restated from time to time (the "Charter") or bylaws, or the approval of any merger or other significant corporate transaction, including a sale of substantially all of our assets. This could have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of the Company, which could cause the market price of our common stock to decline or prevent stockholders from realizing a premium over the market price for common stock. Their interests may conflict with our interests as a company or the interests of our other stockholders.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. The initial public offering price is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value of our tangible assets after subtracting our liabilities. Based on the initial public offering price of $4.00 per share, you will experience immediate dilution of $(3.06) per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the initial public offering price per share. See the section entitled "*Dilution*" for additional information.

***Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.***

Certain of our existing stockholders have agreed to purchase up to an aggregate of approximately $2 million of shares of our common stock in this offering at the initial public offering price (which represents approximately 14.82% of the shares sold in this offering). The underwriters will receive the same underwriting discounts and commissions on any shares of our common stock purchased by these entities as they will on any other shares of our common stock sold to the public in this offering. For more information regarding the potential impact on their ownership of shares of our common stock, see "*Principal Stockholders*."

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors, and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

***We are an emerging growth company and a smaller reporting company and intend to take advantage of reduced disclosure requirements applicable to emerging growth companies, which could make the common stock less attractive to investors.***

We are an "emerging growth company" ("EGC") as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an EGC until the earliest to occur of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the first sale of common stock pursuant to the registration statement; (iii) the date on which we have issued more

than $1.0 billion in non-convertible debt securities during the prior three-year period; or (iv) the date we qualify as a "large accelerated filer" under the rules of the SEC, which means the market value of the common stock held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter after we have been a reporting company in the United States for at least 12 months. For so long as we remain an EGC, we are permitted to and intend to rely upon exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act ("SOX").

We may take advantage of some, but not all, of the available exemptions available to EGCs. We cannot predict whether investors will find the common stock less attractive if we rely on these exemptions. If some investors find the common stock less attractive as a result, there may be a less active trading market for the common stock and the price of the common stock may be more volatile.

We are also a smaller reporting company, as defined in Rule 405 promulgated under the Securities Act ("SRC"). As an SRC, we intend to utilize certain reduced disclosure requirements, including publishing two years of audited financial statements instead of three years, as required for companies that do not qualify as an SRC. We will remain an SRC until the last day of the fiscal year in which we have (i) a public float that exceeded $250 million or (ii) annual revenues of more than $100 million and a public float that exceeded $700 million. To the extent we take advantage of such reduced disclosure obligations, it may make comparison of our financial statements to those of other public companies difficult or impossible.

After we cease to be an SRC, we are expected to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of SOX.

***As a public company, we will be subject to more stringent federal law requirements.***

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE American, and other applicable securities rules and regulations. Despite reforms made possible by the JOBS Act, compliance with these rules and regulations will nonetheless increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an emerging growth company. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results.

As a result of disclosure of information in this prospectus and in filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business, results of operations, financial condition and prospects could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our brand and reputation, business, results of operations, financial condition and prospects. We also expect that being a public company and the associated rules and regulations will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain adequate coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

***We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, investor relations and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and the NYSE American have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial

controls and corporate governance practices. Stockholder activism, the current political environment and the current high level of U.S. government intervention and regulatory reform may also lead to substantial new regulations and disclosure obligations, which may in turn lead to additional compliance costs and impact the manner in which we operate our business in ways we do not currently anticipate. Our management and other personnel will need to devote a substantial amount of time to comply with these requirements. Moreover, these requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements.

***We may not be able to satisfy listing requirements of the NYSE American or obtain or maintain a listing of our common stock on the NYSE American.***

Our common stock has been approved for listing on the NYSE American, and after the consummation of this offering, we must meet certain financial and liquidity criteria to maintain such listing. If we violate the NYSE American listing requirements, our common stock may be delisted. If we fail to meet any of the NYSE American's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from the NYSE American may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the Sarbanes-Oxley Act, the requirements of being a reporting company under the Exchange Act and any complex accounting rules in the future, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. To date, we have had limited financial and accounting personnel to fully execute our accounting processes and address our internal control over financial reporting. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our auditors, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

There can be no assurance that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by the NYSE American, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be

faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

***Our reported financial results may be adversely affected by changes in accounting principles generally accepted in the United States.***

Generally accepted accounting principles in the United States are subject to interpretation by the Financial Accounting Standards Board, the SEC and various bodies formed to promulgate and interpret appropriate accounting principles. A change in these principles or interpretations could have a significant effect on our reported financial results, may retroactively affect previously reported results, could cause unexpected financial reporting fluctuations and may require us to make costly changes to our operational processes and accounting systems.

***Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.***

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Based on shares of common stock outstanding as of the date of this prospectus, upon the closing of this offering we will have a total of 11,571,497 shares of common stock outstanding (12,077,747 shares if the underwriters exercise their over-allotment option in full). Of these shares, only the 3,375,000 shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. The underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

We expect that the lock-up agreements pertaining to this offering will expire 180 days after the date of this prospectus. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our Equity Incentive Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively***.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled "*Use of Proceeds*," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

***Certain provisions in our governing documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management***.

Certain provisions in our amended and restated bylaws ("Bylaws") and Charter may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could

limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- set limitations on convening special stockholder meetings, which could make it difficult for our stockholders to adopt desired governance changes;
- limit the manner in which stockholders can remove directors from the board;
- include a forum selection clause, which means certain litigation against us can only be brought in Delaware;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings; and
- authorize undesignated preferred stock, the terms of which may be established and shares of which may be issued without further action by our stockholders.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our Charter and Bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Bylaws provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our Bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors and executive officers. With certain exceptions, these agreements provide for indemnification for related expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in connection with any action, proceeding or investigation. We believe that these Charter and Bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

While we maintain directors' and officers' liability insurance, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may adversely impact our cash position.

***Our failure to maintain effective internal controls over financial reporting could have an adverse impact on us***.

We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely impact our public disclosures regarding our business, financial condition or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting, disclosure of management's assessment of our internal controls over financial reporting or disclosure of our public accounting firm's attestation to or report on management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our shares.

In addition, discovery and disclosure of a material weakness in the future or our inability to cure the material weakness we previously discovered and disclosed, by definition, could have a material adverse impact on our financial statements. Such an occurrence could negatively affect our business and affect how our stock trades. This could, in turn, negatively affect our ability to access public equity or debt markets for capital.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline***.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, including our statements regarding the benefits and timing of the roll-out of new technology, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would" or the negative of these words or other similar terms or expressions. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our use of the net proceeds from this offering;
- the timing of the initiation, progress and expected results of our preclinical studies, clinical trials and our research and development programs;
- our ability to advance our product candidate and successfully complete clinical trials;
- the commercialization of our product candidate, if approved;
- estimates of our total addressable market, future revenue, expenses, capital requirements and our needs for additional financing;
- our ability to compete effectively with existing competitors and new market entrants;
- our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement;
- our manufacturing capabilities and the scalable nature of our manufacturing process;
- potential effects of extensive government regulation;
- the pricing, coverage and reimbursement of our products, if approved;
- our ability to hire and retain key personnel;
- our ability to obtain additional financing in this or future offerings;
- the volatility of the trading price of our common stock; and
- our expectation regarding the time during which we will be an emerging growth company under the JOBS Act.

You should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section entitled "*Risk Factors*" and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this prospectus. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments.

## TRADEMARKS, SERVICE MARKS AND TRADE NAMES

We own or have rights to use a number of registered and common law trademarks, service marks and/or trade names in connection with our business in the United States and/or in certain foreign jurisdictions.

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensors to these trademarks, service marks and trade names. This prospectus contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. All trademarks, service marks and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies' trademarks, service marks, copyrights or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $11.8 million (or approximately $13.7 million if the underwriters exercise their option to purchase additional shares in full), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to fund our clinical trials, to increase our capitalization and financial flexibility, create a public market for our common stock, facilitate future access to the public equity markets by us, our employees and our stockholders and increase our visibility in the marketplace.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash, to fund our Phase III clinical trial in knee OA, to initiate at least one non-registered corporate sponsorship study in MS, manufacturing costs, and any remaining amounts to fund working capital and general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Further, due to the uncertainties inherent in developing Apitox, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. We cannot specify with certainty all of the particular uses for the remaining net proceeds to us from this offering. We may also use a portion of the net proceeds for acquisitions or strategic investments in complementary businesses, products, services or technologies. However, we do not have agreements or commitments to enter into any such acquisitions or investments at this time. We will have broad discretion over how to use the net proceeds to us from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The amounts and timing of our expenditures will depend upon numerous factors including the results of our research and development efforts, the timing and success of preclinical studies and any clinical trials we may commence in the future, the timing of regulatory submissions, and the amount of cash obtained through any future collaborations.

We estimate that the net proceeds from this offering, together with our current cash, will be sufficient for us to fund our operating expenses and capital expenditure requirements through at least the next 12 months. The expected net proceeds from this offering, together with our cash will allow us to fund a Phase III trial in knee OA, initiate at least one non-registered company sponsored trial in MS, fund our internal operations, and pay off our current debt liabilities as they come due. We believe the net proceeds from this offering will allow us to complete all of these activities within the next 24 months. We anticipate that approximately $9.3 million of the net proceeds will be used to fund the Phase III trial in knee OA, approximately $1.0 million will be used to initiate at least one non-registered corporate sponsorship study in MS, and approximately $1.0 will be used for manufacturing. In addition, approximately $0.1 and $0.2 and $0.2 million will be used for repayment of current debt liabilities comprised of three promissory notes with our majority stockholder, Inscobee, which accrue interest at 5% and mature May 19, 2025 and August 19, 2025 and December 31, 2026, respectively. All of the proceeds of such indebtedness is short-term borrowings used for working capital. The remaining net proceeds will be used for working capital and general corporate expenses. We have based these estimates on assumptions that may prove to be incorrect, and we could expend our available capital resources at a rate greater than we currently expect.

We intend to invest the net proceeds to us from this offering that are not used as described above in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## REVERSE STOCK SPLIT

On February 25, 2025, we implemented the 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 in connection with the Reverse Stock Split.

Unless otherwise indicated, and other than the consolidated financial statements and the related notes included elsewhere in this prospectus, the number of our shares of common stock presented in this prospectus is adjusted to reflect the Reverse Stock Split.

## DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, we may enter into agreements in the future that could contain restrictions on payments of cash dividends.

## CAPITALIZATION

The following unaudited table sets forth our cash, total capitalization and indebtedness as of December 31, 2024:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of an aggregate of $660,000 principal amount of convertible notes, plus accrued and unpaid interest of approximately $100,882 into an aggregate of approximately 292,647 shares of our common stock; and
- on a pro forma as adjusted basis to give effect to the pro forma adjustments, the Reverse Stock Split, and the sale by us of 3,375,000 shares of our common stock in this offering at an initial public offering price of $4.00 per share, after deducting underwriting discounts and estimated offering expenses payable by us (assuming no exercise of the underwriter's over-allotment option).

You should read this information together with our consolidated financial statements and related notes, as well as the information set forth under the headings "*Use of Proceeds*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" appearing elsewhere in this prospectus.

| | December 31, 2024 | | |
|---|---|---|---|
| | Actual[1] | Pro Forma | Pro Forma As Adjusted |
| Cash | $ 3,445 | $ 3,445 | $ 11,840,234 |
| | | | |
| Debt: | | | |
| Notes payable – related parties | $ 250,000 | $ 250,000 | $ 250,000 |
| Convertible notes, net of discount – related parties | $ 346,844 | $ — | $ — |
| Total debt | $ 596,844 | $ 250,000 | $ 250,000 |
| | | | |
| Shareholders' equity | | | |
| Common stock, par value $0.01; 100,000,000 shares authorized; 7,903,850, 8,196,497, and 11,571,497 issued and outstanding as of actual, pro forma and pro forma as adjusted[1] | $ 79,039 | $ 81,965 | $ 115,715 |
| Additional paid-in capital | $ 2,954,764 | $ 3,712,720 | $ 15,515,749 |
| Accumulated deficit | $ (4,319,924) | $ (4,705,080) | $ (4,705,080) |
| Total shareholders' equity | $ (1,358,121) | $ (910,395) | $ 10,926,384 |
| Total capitalization | $ (761,277) | $ (660,395) | $ 11,176,384 |

The table above excludes:

- 1,538,462 shares of our common stock that are available for future issuance under our Equity Incentive Plan;
- 213,692 shares of common stock issuable upon exercise of outstanding non-plan options; and
- 168,750 shares of our common stock issuable upon exercise of the Representative's Warrants to purchase up to 168,750 shares (or 194,063 shares if the over-allotment option is exercised in full) of our common stock at an exercise price per share equal to 125% of the initial public offering price per share, that will be issued to the representative of the underwriters in connection with this offering.

## DILUTION

If you purchase shares of our common stock offered in this prospectus, your ownership interest will be diluted to the extent of the difference between the initial public offering price in this offering of $4.00 per share, and the adjusted net tangible book value per share of our common stock upon consummation of this offering. As of December 31, 2024, we had a historical net tangible book value (deficit) of $(1,358,121) or $(0.17) per share of common stock. Our historical net tangible book value per share represents the book value of our total tangible assets less the book value of our total liabilities divided by the number of shares of common stock then issued and outstanding.

Our pro forma net tangible book value, as of December 31, 2024, was $(910,395) or $(0.11) per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the conversion of the convertible notes into 292,647 shares of common stock. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding, as of December 31, 2024, after giving effect to the pro forma adjustments described above.

After giving further effect to our sale of 3,375,000 shares of common stock in this offering at the initial public offering price of $4.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma, as adjusted net tangible book value as of December 31, 2024, would have been $10,926,384 or $0.94 per share (assuming no exercise of the underwriters' option to purchase additional shares of our common stock). This represents an immediate and substantial dilution of $(3.06) per share to new investors purchasing common stock in this offering. The following table illustrates this dilution per share:

| | | |
|---|---|---|
| Initial public offering price per share | $ | 4.00 |
| Historical net tangible book value (deficit) per share as of December 31, 2024 | $ | (0.17) |
| Increase in net tangible book value per share attributable to conversion of convertible notes principal and accrued interest | $ | 0.06 |
| Pro forma net tangible book value per share as of December 31, 2024 | $ | (0.11) |
| Increase in pro forma, as adjusted net tangible book value per share attributable to investors purchasing shares of common stock in this offering | $ | 1.05 |
| Pro forma, as adjusted net tangible book value per share after giving effect to this offering | $ | 0.94 |
| Dilution in as adjusted net tangible book value (deficit) per share in this offering | $ | (3.06) |

If the underwriters exercise their over-allotment option in full to purchase additional shares of common stock, the pro forma, as adjusted net tangible book value per share after the offering would be $1.06 per share, representing an immediate increase to existing stockholders of $1.23 per share, and immediate dilution to new investors in this offering of $(2.94) per share.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2024, the total number of shares of common stock owned by existing stockholders and to be owned by new investors, the total consideration paid, and the average price per share paid by our existing stockholders and to be paid by new investors in this offering, calculated before deduction of estimated underwriting discounts and commissions:

| | Shares Purchased | | Total Consideration | | Average Price Per Share |
|---|---|---|---|---|---|
| | Number | Percent | Amount | Percent | |
| Existing stockholders | 8,196,497 | 71% | $ 2,815,882 | 17% | $ 0.34 |
| New investors participating in this offering | 3,375,000 | 29% | $ 13,500,000 | 83% | $ 4.00 |
| Total | 11,571,497 | 100% | $ 16,315,882 | 100% | $ 1.41 |

If the underwriters exercise their option to purchase additional shares in full, the number of shares of common stock held by existing stockholders will be reduced to 68% of the total number of shares of common stock to be

outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to 32% of the total number of shares of common stock to be outstanding after this offering.

## 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 prospectus. 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 prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. 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 "*Certain Relationships and Related Person 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.

**Material Weakness**

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on April 15, 2025 (the "Annual Report"), our management 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). Management identified a material weakness in our internal control over financial reporting. Specifically, the Company does not currently 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.

The material weakness did not result in any material misstatements to the Company's financial statements, and management has concluded that the Company's financial statements and other financial information included in its Annual Report fairly and accurately present the Company's financial condition, results of operations, and cash flows for the periods in accordance with GAAP.

We have begun exploring remedial efforts to address the underlying causes of the material weaknesses. There can be no assurance that any remedial efforts we take, if any, will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal controls over financial reporting or prevent future material weaknesses or control deficiencies from occurring. If the Company fails to remediate the material weaknesses or any future deficiencies, or fails to otherwise maintain the adequacy of its internal controls, that could result in a restatement of the Company's financial statements for prior periods, a decline in the market value of the Company's common stock, one or more investigations or enforcement actions by state or federal regulatory agencies, stockholder lawsuits, or other adverse actions requiring the Company to incur defense costs or pay fines, settlements, or judgments.

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**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 $1,2750,95 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, | | |
|---|---|---|---|
| | 2024 | 2023 | Change |
| Interest income | $ 2,824 | $ 7,811 | $ (4,987) |
| Interest expense | (117,719) | (38,069) | (79,650) |
| | $ (114,895) | $ (30,258) | $ (84,637) |

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**

***Sources of Liquidity***

We are a development stage company as we have not generated any product revenues to date and do not expect to have significant revenues until we are able to sell a product candidate after obtaining applicable regulatory approvals or we establish collaborations that provide funding, such as licensing fees, milestone payments, royalties, research funding or otherwise. To date, operations have been funded through capital contribution from shareholders, convertible note and promissory notes.

Our objectives, when managing capital, are to ensure there are sufficient funds available to carry out our research, development and eventual commercialization programs. We do not hold any asset-backed commercial paper, and our cash is not subject to any external restrictions. We manage liquidity risk by frequently monitoring actual and projected cash flows. The majority of our accounts payable and accrued liabilities have maturities of less than six months. We are dependent on our ability to generate revenues from our future products or secure additional financing to continue our research and development activities and meet our ongoing obligations.

The Company's management acknowledges that the current cash position does not reflect the necessary runway for a period longer than 12 months from financial statement issuance, that would allow the Company to continue operations without securing additional financing. As such, we believe that these conditions raise substantial doubt as to the Company's ability to continue as a going concern within 12 months of the date the Financial Statements are issued. Additional funding will be necessary to fund our research and development efforts to advance product candidates. We will seek additional funding through public and private financings, debt financings, collaboration agreements, strategic alliances and licensing agreements. There is no assurance of success in obtaining such additional financing on terms acceptable to us, if at all, and there is no assurance that we will be able to enter into collaborations or other arrangements. If we are unable to obtain funding, it could force us to delay, reduce or eliminate research and development programs and product portfolio expansion. These potential delays, reductions and eliminations could adversely affect future business prospects, and the ability to continue operations.

**Funding Requirements**

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidate. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. The timing and amount of our operating expenditures will depend largely on our ability to:

- advance development of our Apitox clinical programs;
- acquire additional product candidates;

- manufacture, or have manufactured on our behalf, our preclinical and clinical drug material and develop processes for late clinical stage manufacturing;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- hire additional clinical, quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts and our operations as a public company; and
- obtain, maintain, expand and protect our intellectual property portfolio.

As of December 31, 2024, we had cash of $3,455. We believe that the anticipated net proceeds from this offering, together with our existing cash, will enable us to fund our operating expenses and capital expenditure requirements for the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We anticipate that we will require additional capital as we advance our programs, seek regulatory approval of our product candidate, and pursue in-licenses or acquisitions of other product candidate.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs, timing and ability to manufacture our product candidates to supply our preclinical development efforts and our clinical trials;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch, should any of our product candidates receive marketing approval;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, expanding and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations.

If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research and product development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

**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 | $ (407,026) | $ 404,310 | $ (811,336) |

*Operating activities*

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.

# BUSINESS

## Overview

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 Apimeds Inc. ("Apimeds Korea") in South Korea as "Apitoxin" for the treatment of OA. Apimeds 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. Apimeds 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.

Apimeds 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 2023 — treatment of pain and lack of mobility in patients with OA (the "Apimeds Korea Phase III OA Trial"). The Apimeds Korea Phase III OA Trial (330 patients) was completed in 2018, and displayed no serious adverse events.

Based on the results from the Apimeds 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 Apimeds 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 Apimeds 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 Apimeds 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.

We intend to use a portion of the proceeds of this offering to facilitate the early prosecution of appropriate MS patient populations through non-registered corporate sponsorship studies.

**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 cannot 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-κB), 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 (lmg/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).

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**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 Apitox 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 Apitox 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 Apitox 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 $8^{th}$ 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 6$^{th}$ 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 8$^{th}$ 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 8$^{th}$ 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 6$^{th}$ week (48.70%), while 42.95% (67/156) of the Nabumetone group showed lower improvement rate than during the 6$^{th}$ 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 Apimeds 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, Apimeds

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 Apimeds 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 Apimeds 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 Apimeds Korea with respect to Apitoxin:

| | Phase 1 | 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 Apimeds Korea | Hauser et al 2001 Altern Compl Ther. | Guju Pharma Apimeds Korea | Guju Pharma Apimeds Korea | Wesselius et al 2005 Neurology | Apimeds Korea | Apimeds 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<br><br>No Serious Adverse Events | Approved | No Serious Adverse Events<br><br>No negative safety signals | Mean Improvement in MS Functional Composite symptoms<br><br>No Serious Adverse Events | No Serious Adverse Event<br><br>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).

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**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 "Wesselius 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 ApitoxAdd-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.

*Wesselius Phase II Trial*

The Wesselius 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 Wesselius 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.

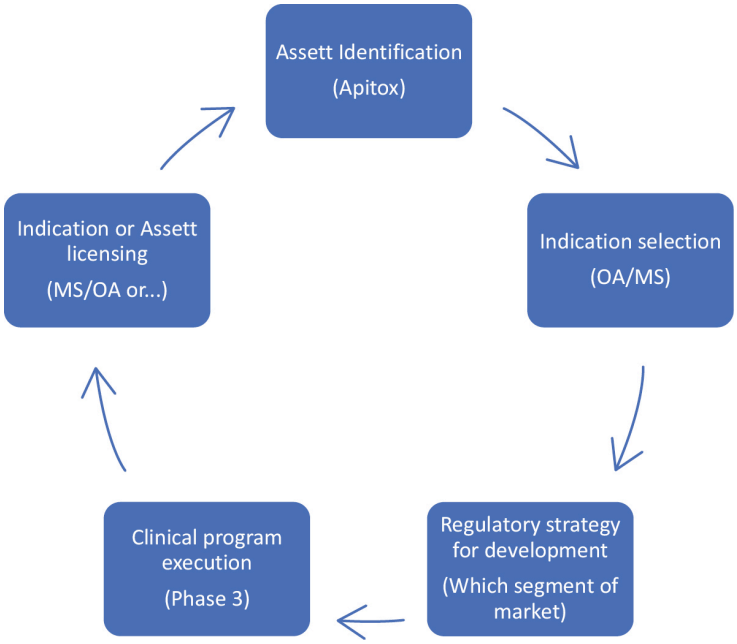
From June 2014 to June 2018, Apimeds Korea corresponded with the FDA and there were no clinical holds at that time. Sponsorship of IND 122804 was transferred from Apimeds Korea to us in October 2020. On September 21, 2021, we responded to customary non-clinical hold comments from the FDA. In November 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 Apimeds Korea. Apimeds 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 Apimeds 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 Mellifea 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 prospectus, 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.

**Legal Proceedings**

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

**Facilities**

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.

# MANAGEMENT

## Executive Officers and Directors

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 of directors.

### *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 of directors.

***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 of directors.

**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 of directors.

***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 of directors.

***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 of directors.

***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 of directors.

**Number and Terms of Office of Officers and Directors**

Our board of directors consists of seven members. The term of office of the directors will expire at our first annual meeting of stockholders.

In accordance with the NYSE American corporate governance requirements, we are not required to hold an annual meeting until one year after our first fiscal year end following our listing on the NYSE American. Subject to any other special rights applicable to the stockholders, any vacancies on our board of directors may be filled by the affirmative vote of a majority of the remaining members of the board of directors, although less than a quorum, or by a sole remaining director.

Our officers are appointed by the board of directors and serve at the discretion of the board of directors, rather than for specific terms of office. Our board of directors is authorized to appoint people to the offices set forth in our Bylaws as it deems appropriate.

**Family Relationships**

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

**Involvement in Certain Legal Proceedings**

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

**Director Independence**

Our independent directors are as follows:

| Name | Position |
|---|---|
| Dr. Bennet Weintraub PhD | Director |
| Dr. Hankil Yoon PhD | Director |
| Carol O'Donnell | Director |
| Elona Kogan | Director |

The NYSE American listing standards require that a majority of our board of directors be independent. An "independent director" is defined generally as a person other than an officer or employee of the company or its subsidiaries or any other individual having a relationship which in the opinion of the Company's board of directors, would interfere with the director's exercise of independent judgment in carrying out the responsibilities of a director. Our audit committee is entirely composed of independent directors meeting the NYSE American's additional requirements applicable to members of the audit committee. Our independent directors will have quarterly scheduled meetings at which only independent directors are present.

**Executive Officer and Director Compensation**

After the completion of the offering decisions regarding the compensation to be paid to the members of our board of directors, if any, will be determined and/or ratified by the board of directors with recommendations given by the compensation committee. It is anticipated that directors' fees will consist of (i) an annual board cash retainer of $10,000 for all non-employee directors, (ii) an annual cash retainer of $3,000 for service as a chairperson on a committee, and (iii) an annual equity award of $10,000 in stock options issued pursuant to the Equity Incentive Plan. The directors who also serve as an employee of the Company do not receive additional compensation for their service as a director. We are not party to any agreements with our executive officers and directors that provide for benefits upon termination of employment.

**Committees of the Board of Directors**

Our board of directors has three standing committees: an audit committee, a compensation committee and the nominating and corporate governance committee. Subject to phase-in rules and a limited exception, the NYSE American rules and Rule 10A-3 of the Exchange Act require that the audit committee of a listed company be comprised solely of independent directors, and the NYSE American rules require that the compensation committee of a listed company be comprised solely of independent directors.

**Audit Committee**

Our board of directors has established an audit committee. Under the NYSE American listing standards and applicable SEC rules, we are required to have at least three members of the audit committee, all of whom must be independent. Our audit committee is chaired by Carol O'Donnell and its other members are Elona Kogan and Dr. Bennet Weintraub. Our board of directors has confirmed that audit committee members are independent under the NYSE American listing standards and applicable SEC rules.

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 and meets the financial sophistication requirements of the NYSE rules. In making this determination, our board considered Ms. O'Donnell's previous and current experience in actively supervising individuals in financial and accounting roles. We have adopted an audit committee charter, which details the purpose and principal functions of the audit committee, including:

- assisting board oversight of (1) the integrity of our financial statements, (2) our compliance with legal and regulatory requirements, (3) our independent auditor's qualifications and independence, and (4) the performance of our internal audit function and independent auditors.
- reviewing the appointment, compensation, retention, replacement, and oversight of the work of the independent auditors and any other independent registered public accounting firm engaged by us.
- pre-approving all audit and non-audit services to be provided by the independent auditors or any other registered public accounting firm engaged by us, and establishing pre-approval policies and procedures.
- reviewing and discussing with the independent auditors all relationships the auditors have with us in order to evaluate their continued independence;
- setting clear hiring policies for employees or former employees of the independent auditors;
- setting clear policies for audit partner rotation in compliance with applicable laws and regulations;
- obtaining and reviewing a report, at least annually, from the independent auditors describing (1) the independent auditor's internal quality-control procedures and (2) any material issues raised by the most recent internal quality-control review, or peer review, of the audit firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years respecting one or more independent audits carried out by the firm and any steps taken to deal with such issues;
- meeting to review and discuss our annual audited financial statements and quarterly financial statements with management and the independent auditor, including reviewing our specific disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations";
- reviewing and approving any related party transaction required to be disclosed pursuant to Item 404 of Regulation S-K promulgated by the SEC prior to us entering into such transaction; and
- reviewing with management, the independent auditors, and our legal advisors, as appropriate, any legal, regulatory or compliance matters, including any correspondence with regulators or government agencies and any employee complaints or published reports that raise material issues regarding our financial statements or accounting policies and any significant changes in accounting standards or rules promulgated by the Financial Accounting Standards Board, the SEC or other regulatory authorities.

**Compensation Committee**

Our board of directors has established a compensation committee. Under the NYSE American listing standards and applicable SEC rules, we are required to have at least two members of the compensation committee, all of whom must be independent. The Chair of our compensation committee is Carol O'Donnell and, the other member is Hankil Yoon. Our board of directors has confirmed that all of our compensation committee members are independent under the NYSE American listing standards and applicable SEC rules.

We have adopted a compensation committee charter, which details the purpose and responsibility of the compensation committee, including:

- reviewing and approving on an annual basis the corporate goals and objectives relevant to our Chief Executive Officer's compensation, evaluating our Chief Executive Officer's performance in light of such goals and objectives and determining and approving the remuneration (if any) of our Chief Executive Officer based on such evaluation;
- reviewing and making recommendations to our board of directors with respect to (or approving, if such authority is so delegated by our board of directors) the compensation, and any incentive-compensation and equity-based plans that are subject to board approval of all of our other officers;
- reviewing our executive compensation policies and plans;
- implementing and administering our incentive compensation equity-based remuneration plans;
- assisting management in complying with our proxy statement and annual report disclosure requirements;
- approving all special perquisites, special cash payments and other special compensation and benefit arrangements for our officers and employees;
- producing a report on executive compensation to be included in our annual proxy statement; and
- reviewing, evaluating and recommending changes, if appropriate, to the remuneration for directors.

The charter also provides that the compensation committee may, in its sole discretion, retain or obtain the advice of a compensation consultant, independent legal counsel or other adviser and will be directly responsible for the appointment, compensation and oversight of the work of any such adviser.

However, before engaging or receiving advice from a compensation consultant, external legal counsel or any other adviser, the compensation committee will consider the independence of each such adviser, including the factors required by the NYSE American and the SEC.

**Nominating and Governance Committee**

Our board of directors has established a nominating and corporate governance committee, which consists of two members. The chair of our nominating and corporate governance committee is Elona Kogan, and the other member is Carol O'Donnell. Our board of directors has confirmed that each member of the nominating and corporate governance committee is independent under the listing standards of the NYSE American.

We have adopted a nominating and corporate governance committee charter, which details the purpose and responsibility of the nominating and corporate governance committee, including:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors.

We have not formally established any specific, minimum qualifications that must be met or skills that are necessary for directors to possess. In general, in identifying and evaluating nominees for director, the committee considers educational background, diversity of professional experience, knowledge of our business, integrity, professional reputation, independence, wisdom, and the ability to represent the best interests of our stockholders.

**Code of Business Conduct and Ethics**

We have adopted a code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. Upon the closing of this offering, our code of business conduct and ethics will be available under the Corporate Governance section of our website at *www.apimedsus.com*. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of the NYSE American concerning any amendments to, or waivers from, any provision of the code. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this prospectus.

# EXECUTIVE COMPENSATION

## Overview

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. 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 only 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 | 2024 | 300,000 | — | — | — | — | 300,000 |
| *Chief Executive Officer* | 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 principal 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 of directors 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 of directors.

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 of directors' 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.

**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.

1,538,462 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 prospectus, 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 Company board may impose such other clawback, recovery or recoupment provisions in a stock award agreement as the Company 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 prospectus.

**Director Compensation Table**

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

## CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Other than compensation arrangements for our directors and executive officers, which are described elsewhere in this prospectus, below we describe transactions since January 1, 2023, and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets as of December 31, 2023 and 2024; and
- any of our directors, executive officers or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

### 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 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 fist 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 my 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 this 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 this 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 this 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 this 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 pursuant to a promissory note (the "March 2025 Note") agreement with Apimeds, Inc., one of its shareholders. The March 2025 Note bears interest at 5% per annum and mature on the earlier of (a) December 31, 2026 or (b) consummation of a Qualified Offering.

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.

On January 27, 2025, the Company received an additional $17,000 from Erik Emerson, the Company's Chief Executive Officer, as advance payable to the related party to cover certain expenses of the Company.

**Policies and Procedures for Transaction with Related Persons**

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 the Related Party Transaction Policy.

**Indemnification Agreements**

In connection with this offering, we intend to enter into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our capital stock as of the date of this prospectus, by:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose.

The beneficial ownership prior to the offering is based on the number of shares of our capital stock issued and outstanding as of the date of this prospectus. Applicable percentage ownership after the offering is based on 11,571,497 shares of common stock outstanding immediately after the closing of this offering and 213,692 shares of common stock issuable upon exercise of outstanding non-plan options, assuming no exercise by the underwriters of their option to purchase additional shares and does not include any shares which may be purchased by any person or entity named in the table in this offering. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to conversion from convertible preferred stock upon the completion of the offering and options held by the person that are currently exercisable, or exercisable within 60 days of the date of this prospectus. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable. Unless otherwise noted, the business address of each of the following entities or individuals is 65-1277 Ki Rd., Kamuela, Hawaii 96743.

| | Number of Shares Beneficially Owned | Percentage of Common Shares Beneficially Owned | |
|---|---|---|---|
| Name of Beneficial Owner | Prior to Offering | Before Offering | After Offering |
| **Directors and Named Executive Officers:** | | | |
| Christopher Kim, MD[(1)] | 213,692 | 2.54% | 1.81% |
| Erik Emerson | — | — | — |
| Bennett Weintraub, PhD | — | — | — |
| Hankil Yoon | — | — | — |
| Carol O'Donnell | — | — | — |
| Jakap Koo | 615,385 | 7.32% | 5.22% |
| All directors and officers as a group (7 individuals) | 829,077 | 9.86% | 7.03% |
| **5% or Greater Stockholders:** | | | |
| Inscobee Inc.[(2)] | 5,911,882 | 70.29% | 54.41% |
| Dominus IB, Inc.[(3)] | 800,000 | 9.51% | 6.79% |
| Seed 1 ho[(4)] | 600,000 | 7.13% | 5.09% |

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

(2) Represents 1,597,979 shares or 19.00% held directly by Inscobee Inc. and 4,313,903 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. The percentage of shares of

common stock beneficially owned before the offering reflects the conversion of an aggregate of $660,000 principal amount of convertible notes with an unamortized debt discount of $313,156, plus accrued and unpaid interest of approximately $100,882, into an aggregate of approximately 292,647 shares of our common stock (the "Conversion"). The percentage of shares of common stock beneficially owned after the offering reflects the Conversion and the purchase of 500,000 shares of common stock purchased in the offering.

(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.

# DESCRIPTION OF CAPITAL STOCK

## 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 11,571,497 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 120$^{th}$ day prior to such annual meeting and not later than the 90$^{th}$ day prior to such annual meeting or, the 10$^{th}$ 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 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**

Our common stock has been approved for listing on the NYSE American under the symbol "APUS."

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Although our common stock has been approved for listing on the NYSE American, we cannot assure you that there will be an active public market for our common stock.

Following the closing of this offering, based on the number of shares of our common stock outstanding as of the date of this prospectus and assuming (i) the issuance of 3,375,000 shares of common stock in this offering, and (ii) no exercise of the underwriters' option to purchase additional shares, we will have an aggregate of approximately 11,571,497 shares of common stock outstanding.

Of these shares, all shares of common stock sold in this offering (except for any shares which may be purchased by our officers, directors, principal stockholders and their affiliates) will be freely tradable without restriction or further registration under the Securities Act, except for any shares of common stock purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of common stock outstanding after this offering (including any shares which may be purchased by our officers, directors, principal stockholders and their affiliates) will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, each of which is summarized below. We expect that all of these shares will be subject to a 180 day lock-up period under the lock-up and market stand-off agreements described below.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may also be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition, investment or other transaction.

In addition, shares of common stock that are either subject to outstanding options or warrants or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

### Lock-Up Agreements

We, along with our directors, executive officers and all of our other securityholders, have agreed with the underwriters that for a period of 180 days after the date of this prospectus, subject to specified exceptions as detailed further in the section entitled "*Underwriting*," we or they will not, except with the prior written consent of the representative offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sale of, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, request or demand that we file a registration statement related to our common stock or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. All of our security holders are subject to a market stand-off agreement with us which imposes similar restrictions.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

### Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible

stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed

to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described above.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described above. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 115,715 shares immediately after this offering; or
- the average weekly trading volume in our common stock on the NYSE American during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

**Rule 701**

Rule 701 generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described above.

**Form S-8 Registration Statement**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to issuance under the Equity Incentive Plan. We expect to file the registration statement covering shares offered pursuant to the Equity Incentive Plan shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with applicable lock-up agreements described above, and the resale provisions of Rule 144.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS

The following summary describes the material U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common stock acquired in this offering by non-U.S. Holders (as defined below). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, and does not deal with foreign, state and local consequences that may be relevant to non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences (such as gift and estate taxes) other than income taxes. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Internal Revenue Code of 1986, as amended, or the Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, "controlled foreign corporations," "passive foreign investment companies," corporations that accumulate earnings to avoid U.S. federal income tax, corporations organized outside of the United States, any state thereof or the District of Columbia that are nonetheless treated as U.S. taxpayers for U.S. federal income tax purposes, persons that hold our common stock as part of a "straddle," "hedge," "conversion transaction," "synthetic security" or integrated investment or other risk reduction strategy, persons who acquire our common stock through the exercise of an option or otherwise as compensation, persons subject to the alternative minimum tax or federal Medicare contribution tax on net investment income, persons subject to special tax accounting rules under Section 451(b) of the Code, "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds, partnerships and other pass-through entities or arrangements, and investors in such passthrough entities or arrangements. Such non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and Treasury Regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked, or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the non-U.S. Holder holds our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment).

This discussion is for informational purposes only and is not tax advice. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income, estate, and other tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local or foreign tax consequences.

For the purposes of this discussion, a "non-U.S. Holder" is, for U.S. federal income tax purposes, a beneficial owner of common stock that is neither a U.S. Holder, nor a partnership (or other entity treated as a partnership for U.S. federal income tax purposes regardless of its place of organization or formation). A "U.S. Holder" means a beneficial owner of our common stock that is for U.S. federal income tax purposes any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity treated as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the U.S., any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (i) is subject to the primary supervision of a court within the U.S. and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

As described in the section entitled "Dividend Policy," we have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Distributions, if any, made on our common stock to a Non-U.S. Holder to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, subject to the discussions below regarding effectively connected income, backup withholding, and foreign accounts. To obtain a reduced rate of withholding under a treaty, a non-U.S. Holder generally will be required to

provide us with a properly executed IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. This certification must be provided to us or our paying agent prior to the payment of dividends and must be updated periodically. In the case of a non-U.S. Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty and you do not timely file the required certification, you may be able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular rates applicable to U.S. residents. A corporate non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce the Non-U.S. Holder's adjusted basis in our common stock, but not below zero, and then will be treated as gain to the extent of any excess amount distributed, and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

**Gain on Disposition of Our Common Stock**

Subject to the discussions below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (i) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such holder maintains in the United States), (ii) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (iii) we are or have been a "United States real property holding corporation" within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period. In general, we would be a United States real property holding corporation if our interests in U.S. real estate comprise (by fair market value) at least half of our business assets. We believe that we have not been, and we are not, and do not anticipate becoming, a United States real property holding corporation. Even if we are treated as a United States real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, or indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (A) the five-year period preceding the disposition or (B) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market. If any gain on your disposition is taxable because we are a United States real property holding corporation and your ownership of our common stock exceeds 5%, you will be taxed on such disposition generally in the manner as gain that is effectively connected with the conduct of a U.S. trade or business (subject to the provisions under an applicable income tax treaty), except that the branch profits tax generally will not apply.

If you are a non-U.S. Holder described in (i) above, you will be required to pay tax on the net gain derived from the sale at regular U.S. federal income tax rates, and corporate non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable

income tax treaty. Gain described in (ii) above will be subject to U.S. federal income tax at a flat 30% rate or such lower rate as may be specified by an applicable income tax treaty, which gain may be offset by certain U.S.-source capital losses (even though you are not considered a resident of the United States), provided that the non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

**Information Reporting Requirements and Backup Withholding**

Generally, we must report information to the IRS with respect to any dividends we pay on our common stock (even if the payments are exempt from withholding), including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a non-U.S. Holder who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-ECI, or otherwise establishes an exemption. Notwithstanding the foregoing, backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E or otherwise meets documentary evidence requirements for establishing non-U.S. person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be credited against the tax liability of persons subject to backup withholding, provided that the required information is timely furnished to the IRS.

**Foreign Accounts**

Sections 1471 through 1474 of the Code (commonly referred to as FATCA) impose a U.S. federal withholding tax of 30% on certain payments, including dividends paid on, and the gross proceeds of a disposition of, our common stock paid to a foreign financial institution (as specifically defined by applicable rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities identifying information regarding certain U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). FATCA also generally imposes a federal withholding tax of 30% on certain payments, including dividends paid on, and the gross proceeds of a disposition of, our common stock to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. An intergovernmental agreement between the United States and an applicable foreign country may modify those requirements. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules.

Holders are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

**EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT OR PROPOSED CHANGE IN APPLICABLE LAW.**

## UNDERWRITING

D. Boral Capital LLC is acting as the representative of the underwriters of this offering (sometimes referred to herein as the "representative"). On May 8, 2025, we entered into an underwriting agreement with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below, and each underwriter named below has severally agreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

| Underwriter | Number of Shares |
|---|---|
| D. Boral Capital LLC | 3,375,000 |
| Total | 3,375,000 |

The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to various conditions and representations and warranties, including the approval of certain legal matters by their counsel and other conditions specified in the underwriting agreement. The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer to the public and to reject orders in whole or in part. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares of common stock are taken, other than those shares of common stock covered by the over-allotment option described below.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

### Over-Allotment Option

We have granted a 45-day option to the representative of the underwriters to purchase up to 506,250 additional shares of our common stock at an initial public offering price of $4.00 per share, solely to cover over-allotments, if any. If any of these additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

### Discounts and Commissions

The underwriters propose initially to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to dealers at those prices less a concession not in excess of $0.14 per share of common stock. If all of the shares of common stock offered by us are not sold at the public offering price, the underwriters may change the offering price and other selling terms by means of a supplement to this prospectus.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise of the over-allotment option we granted to the representative of the underwriters.

| | Per Share | Total Without Over-Allotment Option | Total With Full Over-Allotment Option |
|---|---|---|---|
| Initial public offering price | $ 4.00 | $ 13,500,000 | $ 15,525,000 |
| Underwriting discount (7.0%) | $ 0.28 | $ 945,000 | $ 1,086,750 |
| Proceeds, before expenses, to us | $ 3.72 | $ 12,555,000 | $ 14,438,250 |

We have agreed to pay a non-accountable expense allowance to the underwriters equal to 1.0% of the gross proceeds received in this offering.

We will be responsible for and will pay all expenses relating to the offering, including, without limitation, (a) all filing fees and expenses relating to the registration of the shares of common stock with the SEC; (b) all fees and expenses relating to the listing of the common stock on a national exchange; (c) all fees, expenses and

disbursements relating to the registration or qualification of the shares under the "blue sky" securities laws of such states and other jurisdictions as the representative may reasonably designate (including, without limitation, all filing and

registration fees, and the reasonable fees and disbursements of our "blue sky" counsel), if applicable; (d) all fees, expenses and disbursements relating to the registration, qualification or exemption of the shares of common stock under the securities laws of such foreign jurisdictions as the representative may reasonably designate; (e) the costs of all mailing and printing of the offering documents; (f) transfer and/or stamp taxes, if any, payable upon the transfer of shares from the Company to the underwriters; (g) all filing fees and communication expenses associated with the review of the offering by FINRA; (h) up to $30,000 of the representative's actual accountable road show expenses and due diligence expenses for the offering; (i) the $29,500 cost associated with the Ipreo's book building, prospectus tracking and compliance software for the offering; (j) the costs associated with bound volumes of the offering materials as well as commemorative mementos and lucite tombstones in an aggregate amount not to exceed $5,000; (k) the fees and expenses of legal counsels to the underwriters in an amount not to exceed $175,000; and (l) up to $10,000 for background checks of our directors and officers; provided, however, that the total costs and expenses relating to this offering for which we will reimburse the underwriter shall not exceed $222,500.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discount and non-accountable expense allowance, will be approximately $358,000.

**Representative's Warrants**

Upon closing of this offering, we have agreed to issue to the representative or its designees warrants to purchase up to a total of 168,750 shares (or 194,063 shares if the over-allotment option is exercised in full) of our common stock (5.0% of the aggregate number of shares of common stock sold in this offering), or the Representative's Warrants. The Representative's Warrants will be exercisable at a per share exercise price equal to 125% of the public offering price per share of the shares of common stock sold in this offering. The Representative's Warrants are exercisable at any time, from time to time, in whole or in part, during the four- and one-half year period commencing 180 days from the commencement of sales of the securities in this offering.

The Representative's Warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(e)(1) of FINRA. The representative (or permitted assignees under Rule 5110(e)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the effective date of the registration statement of which this prospectus is a part. In addition, the warrants provide for registration rights upon request, in certain cases. The Representative's Warrants will provide for adjustment in the number and price of the Representative's Warrants and the shares underlying the Representative's Warrants in the event of recapitalization, merger, stock split, or other structural transaction, or a future financing undertaken by us, consistent with FINRA Rule 5110, and further, the number of shares underlying the Representative's Warrants shall be reduced if necessary to comply with FINRA rules and regulations. The sole demand registration right provided will not be greater than five years from the effective date of the registration statement in compliance with FINRA Rule 5110(g)(8)(C). The piggyback registration rights provided will not be greater than seven years from the effective date of the registration statement in compliance with FINRA Rule 5110(g)(8)(D). We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

**Right of First Refusal**

The underwriting agreement provides that for a period of twelve months from the closing of the offering, we will grant the representative an irrevocable right of first refusal to act as sole investment banker, sole book-runner, sole financial advisor, sole underwriter and/or sole placement agent, at the representative's sole discretion, for each and every future public and private equity and debt offering, including all equity linked financings, during such Twelve-month period for us, or any successor to or any subsidiary of us, on terms customary to the representative. The representative has the sole right to determine whether or not any other broker dealer shall have the right to participate in any such offering and the economic terms of any such participation.

**Tail Financing Payments**

We have also agreed to pay the representative a tail fee equal to 8% of the total gross proceeds received by us from any investor who was contacted by the underwriter during the term of its engagement, if such investor provides us with capital in any public or private offering or other financing or capital raising transaction within twelve months after final closing of this offering.

**Advisory Services**

We have also engaged the representative to provide advisory services from time to time. As part of the advisory services, the representative may introduce us to third parties which may be interested in financing or entering into an M&A transaction. We have agreed that if during the twelve months following the final closing of this offering we or any party the representative to whom we were introduced, directly or indirectly, by the representative, or which was contacted by the representative on our behalf in connection with the advisory services proposes a financing or M&A transaction, we shall pay the representative an agreed upon fee, payable upon closing of such transaction.

**Lock-Up Agreements**

Pursuant to "lock-up" agreements, we, our executive officers and directors, and stockholders, have agreed, without the prior written consent of the representative not to directly or indirectly, offer to sell, sell, pledge or otherwise transfer or dispose of any of shares of (or enter into any transaction or device that is designed to, or could be expected to, result in the transfer or disposition by any person at any time in the future of) our common stock, enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of shares of our common stock, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for common stock or any other securities of ours or publicly disclose the intention to do any of the foregoing, subject to customary exceptions, for a period of 180 days after the date of this prospectus in the case of our officers and directors and six months after the date of this prospectus in the case of, the Company and any successor of the Company and other securityholders.

**Termination Agreement**

On June 19, 2024, we entered into a termination agreement (the "TE Termination Agreement") with ThinkEquity LLC, acting as financial advisor and underwriter in connection with this offering. Pursuant to the TE Termination Agreement, ThinkEquity LLC retained $50,000 of the advance we paid to it, which it used as a reimbursement for actual out-of-pocket expenses, including payment of its legal expenses. We agreed to pay ThinkEquity the amount of $26,493 for payment of additional legal expenses, upon the closing of this offering.

**Discretionary Accounts**

The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

**NYSE American Listing**

Our common stock has been approved for listing on the NYSE American under the symbol "APUS."

**Determination of Offering Price**

The public offering price of the securities we are offering was negotiated between us and the underwriters. Factors considered in determining the public offering price of the shares include the history and prospects of the Company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

**Other**

From time to time, certain of the underwriters and/or their affiliates may in the future provide, various investment banking and other financial services for us for which they may receive customary fees. In the course of their businesses, the underwriters and their affiliates may actively trade our securities or loans for their own account or for the accounts of customers, and, accordingly, the underwriters and their affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering, no underwriter has provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus.

**Indemnification**

We have agreed to indemnify the underwriters against liabilities relating to this offering arising under the Securities Act and the Exchange Act, liabilities arising from breaches of some or all of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriters may be required to make for these liabilities.

**Price Stabilization, Short Positions, and Penalty Bids**

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares than are set forth on the cover page of this prospectus. This creates a short position in our common stock for its own account. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares of common stock over-allotted by the underwriters is not greater than the number of shares of common stock that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares common stock in the over-allotment option. To close out a short position, the underwriters may elect to exercise all or part of the over-allotment option. The underwriters may also elect to stabilize the price of our common stock or reduce any short position by bidding for, and purchasing, common stock in the open market.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter or dealer repays selling concessions allowed to it for distributing shares of common stock in this offering because the underwriter repurchases the shares of common stock in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, shares of our common stock in market making transactions, including “passive” market making transactions as described below.

These activities may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities and may discontinue any of these activities at any time without notice. These transactions may be effected on the national securities exchange on which our shares of common stock are traded, in the over-the-counter market, or otherwise.

**Electronic Distribution**

This prospectus in electronic format may be made available on websites or through other online services maintained by one or more of the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on any underwriter’s website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

**Selling Restrictions**

No action has been taken in any jurisdiction (except in the United States) that would permit a public offering of our common stock, or the possession, circulation or distribution of this prospectus or any other material relating to us or our common stock in any jurisdiction where action for that purpose is required. Accordingly, our common stock may

not be offered or sold, directly or indirectly, and this prospectus or any other offering material or advertisements in connection with our common stock may be distributed or published, in or from any country or jurisdiction, except in compliance with any applicable rules and regulations of any such country or jurisdiction.

**Australia**

This prospectus is not a disclosure document under Chapter 6D of the Australian Corporations Act, has not been lodged with the Australian Securities and Investments Commission and does not purport to include the information required of a disclosure document under Chapter 6D of the Australian Corporations Act. Accordingly, (i) the offer of the securities under this prospectus is only made to persons to whom it is lawful to offer the securities without disclosure under Chapter 6D of the Australian Corporations Act under one or more exemptions set out in section 708 of the Australian Corporations Act, (ii) this prospectus is made available in Australia only to those persons as set forth in clause (i) above, and (iii) the offeree must be sent a notice stating in substance that by accepting this offer, the offeree represents that the offeree is such a person as set forth in clause (i) above, and, unless permitted under the Australian Corporations Act, agrees not to sell or offer for sale within Australia any of the securities sold to the offeree within 12 months after its transfer to the offeree under this prospectus.

**China**

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

**European Economic Area — Belgium, Germany, Luxembourg and Netherlands**

The information in this document has been prepared on the basis that all offers of securities will be made pursuant to an exemption under the Directive 2003/71/EC ("Prospectus Directive"), as implemented in Member States of the European Economic Area (each, a "Relevant Member State"), from the requirement to produce a prospectus for offers of securities.

An offer to the public of securities has not been made, and may not be made, in a Relevant Member State except pursuant to one of the following exemptions under the Prospectus Directive as implemented in that Relevant Member State:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during its last fiscal year; (ii) a total balance sheet of more than €43,000,000 (as shown on its last annual unconsolidated or consolidated financial statements) and (iii) an annual net turnover of more than €50,000,000 (as shown on its last annual unconsolidated or consolidated financial statements);
- to fewer than 100 natural or legal persons (other than qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive) subject to obtaining the prior consent of the Company or any underwriter for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of securities shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive.

**France**

This document is not being distributed in the context of a public offering of financial securities (offre au public de titres financiers) in France within the meaning of Article L.411-1 of the French Monetary and Financial Code (Code Monétaire et Financier) and Articles 211-1 et seq. of the General Regulation of the French Autorité des marchés financiers ("AMF"). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France.

This document and any other offering material relating to the securities have not been, and will not be, submitted to the AMF for approval in France and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in France.

Such offers, sales and distributions have been and shall only be made in France to (i) qualified investors (investisseurs qualifiés) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-1 to D.411-3, D.744-1, D.754-1; and D.764-1 of the French Monetary and Financial Code and any implementing regulation and/or (ii) a restricted number of non-qualified investors (cercle restreint d'investisseurs) acting for their own account, as defined in and in accordance with Articles L.411-2-II-2° and D.411-4, D.744-1, D.754-1; and D.764-1 of the French Monetary and Financial Code and any implementing regulation.

Pursuant to Article 211-3 of the General Regulation of the AMF, investors in France are informed that the securities cannot be distributed (directly or indirectly) to the public by the investors otherwise than in accordance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 to L.621-8-3 of the French Monetary and Financial Code.

**Ireland**

The information in this document does not constitute a prospectus under any Irish laws or regulations and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005 (the "Prospectus Regulations"). The securities have not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(l) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

**Israel**

The securities offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority (the ISA), or ISA, nor have such securities been registered for sale in Israel. The shares may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the securities being offered. Any resale in Israel, directly or indirectly, to the public of the securities offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

**Italy**

The offering of the securities in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa, "CONSOB" pursuant to the Italian securities legislation and, accordingly, no offering material relating to the securities may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998 ("Decree No. 58"), other than:

- to Italian qualified investors, as defined in Article 100 of Decree no.58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999 ("Regulation no. 1197l") as amended ("Qualified Investors"); and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the securities or distribution of any offer document relating to the securities in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and

- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the securities in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such securities being declared null and void and in the liability of the entity transferring the securities for any damages suffered by the investors.

**Japan**

The securities have not been and will not be registered under Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948), as amended (the "FIEL") pursuant to an exemption from the registration requirements applicable to a private placement of securities to Qualified Institutional Investors (as defined in and in accordance with Article 2, paragraph 3 of the FIEL and the regulations promulgated thereunder). Accordingly, the securities may not be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan other than Qualified Institutional Investors. Any Qualified Institutional Investor who acquires securities may not resell them to any person in Japan that is not a Qualified Institutional Investor, and acquisition by any such person of securities is conditional upon the execution of an agreement to that effect.

**Portugal**

This document is not being distributed in the context of a public offer of financial securities (oferta pública de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the securities have not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissào do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of securities in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

**Sweden**

This document has not been, and will not be, registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this document may not be made available, nor may the securities be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of securities in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

**Switzerland**

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

**United Arab Emirates**

Neither this document nor the securities have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor has the Company received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the securities within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the securities, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by the Company.

No offer or invitation to subscribe for securities is valid or permitted in the Dubai International Financial Centre.

**United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended ("FSMA") has been published or is intended to be published in respect of the securities. This document is issued on a confidential basis to "qualified investors" (within the meaning of section 86(7) of FSMA) in the United Kingdom, and the securities may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances which do not require the publication of a prospectus pursuant to section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) received in connection with the issue or sale of the securities has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of FSMA does not apply to the Company.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 ("FPO"), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (together "relevant persons"). The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

**Canada**

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws. Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor. Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI33-105 regarding underwriter conflicts of interest in connection with this offering.

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Nelson Mullins Riley & Scarborough LLP, Raleigh, North Carolina. Certain legal matters in connection with this offering will be passed upon for the underwriters by Blank Rome LLP, New York, New York.

## EXPERTS

The financial statements of Apimeds Pharmaceuticals US, Inc. as of and for the fiscal years ended December 31, 2024, and 2023, included in this prospectus, have been audited by Kreit & Chiu CPA LLP, an independent registered public accounting firm, as set forth in their report thereon, which includes an explanatory paragraph as to Apimeds Pharmaceuticals US, Inc.'s ability to continue as a going concern, appearing elsewhere in this prospectus, and are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus is a part of the registration statement and does not contain all of the information set forth in the registration statement and its exhibits, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information about us and our common stock, you should refer to the registration statement and its exhibits. Statements contained in this prospectus regarding the contents of any contract or other document referred to in those documents are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement or other document. Each of these statements is qualified in all respects by this reference.

Following the completion of this offering, we will become subject to the informational reporting requirements of the Exchange Act and, in accordance with the Exchange Act, we will file annual, quarterly and current reports, proxy statements and other information with the SEC. Our filings with the SEC will be available to the public on the SEC's website at *http://www.sec.gov*. Those filings will also be available to the public on, or accessible through, our website *www.apimedsus.com* under the heading "Investors." The information we file with the SEC or contained on or accessible through our corporate website or any other website that we may maintain is not part of this prospectus or the registration statement of which this prospectus is a part.

## 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, except for Note 2 Segment Information, which is dated May 1, 2025

**Apimeds Pharmaceuticals US, Inc.**
**Balance Sheets**

| | December 31, 2024 | December 31, 2023 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash | $ 3,455 | $ 410,481 |
| Prepaid expenses and other current assets | 9,602 | 11,595 |
| Total current assets | 13,057 | 422,076 |
| **Total assets** | **$ 13,057** | **$ 422,076** |
| | | |
| 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 | 1,024,334 | 123,316 |
| Convertible note – related party | 346,844 | 266,891 |
| Total liabilities | 1,371,178 | 390,207 |
| | | |
| 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 $0.01, 100,000,000 shares authorized; 7,903,850 issued and outstanding as of December 31, 2024 and December 31, 2023 | 79,039 | 79,039 |
| Additional paid-in capital | 2,954,764 | 2,954,764 |
| Accumulated deficit | (4,391,924) | (3,001,934) |
| Total shareholders' equity (deficit) | (1,358,121) | 31,869 |
| **Total liabilities and shareholders' equity (deficit)** | **$ 13,057** | **$ 422,076** |

*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 | (1,275,095) | (747,436) |
| | | |
| Other (expenses) income | | |
| Interest income | 2,824 | 7,811 |
| Interest expense | (117,719) | (38,069) |
| Total other expense | (114,895) | (30,258) |
| | | |
| **Net loss** | **$ (1,389,990)** | **$ (777,694)** |
| **Weighted average shares outstanding** | **7,903,850** | **4,598,265** |
| **Basic and diluted loss per share** | **$ (0.18)** | **$ (0.17)** |

*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").

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**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**

The Company operates as a single operating and reportable segment, which aligns with the way the Chief Executive Officer, designated as the Chief Operating Decision Maker (CODM), evaluates performance and allocates resources. The Company is a clinical-stage entity focused on the development of a proprietary intradermally administered

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (cont.)

bee venom-based therapeutic. As of December 31, 2024, and 2023, the Company has not generated any revenue and does not have any long-lived assets. The CODM assesses the Company's performance primarily through the analysis of operating expenses, specifically within key categories such as research and development and general and administrative expenses. Given the Company is in a pre-revenue stage, these expense categories serve as the primary financial drivers.

Financial information provided to and utilized by the CODM is consistent with the Company's GAAP financial statements, including the Statements of Operations, which reflect the loss. A single management team reports directly to the CODM and oversees the entire business comprehensively. Resource allocation, performance evaluation, incentive setting, and forecasting activities are conducted at the corporate level using the financial statements and a unified budget. Accordingly, the Company does not evaluate performance by geographic area or product line, as it has not yet commenced commercial operations and has limited activity due to current liquidity and funding constraints. All operations are based in the United States of America, and all assets and operating expenses — including those related to research and development and general and administrative functions — are attributed to the Company's single reportable 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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (cont.)

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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (cont.)

**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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (cont.)

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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**2. BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES** (cont.)

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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**4. DEBT** (cont.)

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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

## 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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

**7. SHAREHOLDERS' DEFICIT** (cont.)

*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 6, 2023, the Company issued 2,134,616 shares of common stock of the Company to related parties for cash consideration in aggregate of $550,000.

**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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

## 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.

**Apimeds Pharmaceuticals US, Inc.**
**Notes to Financial Statements**

## 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 patty.

*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.

# 3,375,000 Shares of Common Stock

# Apimeds Pharmaceuticals US, Inc.

**PROSPECTUS**

May 8, 2025

Through and including June 2, 2025 (the 25th day after the date of this offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.